EUROPEAN COMMISSION
Research & Innovation

COOPERATION

Regional Biotechnology

Establishing a methodology and performance indicators for assessing bioclusters and bioregions relevant to the Knowledge-based Bio-economy in Europe

03 February, 2011

Disclaimer

This document represents the **Final Report** prepared based on the results of all analysed bioclusters and the outcomes of the final workshop (10 December, 2010; Brussels). This Final Report on **"Regional Biotechnology"** focused on establishing both a methodology and performance indicators for assessing bioclusters and bioregions relevant to the knowledge-based bioeconomy. The study was conducted by PwC Luxembourg in collaboration with some other member firms of the PwC network, namely PwC Netherlands, PwC Belgium, PwC Canada, and in consultation with the external experts; Prof Aard Groen from the Netherlands, Dr. David Brown from UK, Prof Patrick Kenis from Belgium, and Prof. Rolf Sternberg from Germany. It was prepared for the use of the European Commission, Directorate-General for Research and innovation (DG Research and Innovation). The content of the report reflects the opinions of the authors and does not necessarily represent the official position of the European Commission.

EUROPEAN COMMISSION
Directorate-General for Research

Office SDME 08,
B-1049 Brussels, Belgium

EC Contacts

Bernhard Zechendorf
DG Research and Innovation, Directorate E, Scientific Officer
Tel :(+32-2) 295 79 10
E-mail: bernhard.zechendorf@ec.europa.eu

John Claxton
DG Research and Innovation, Directorate E, Deputy HoU Biotechnologies
Tel: (+32-2) 298 43 75
E-mail: john.claxton@ec.europa.eu

For further information on this report, please contact:

Laurent Probst
Partner, Pharmaceuticals and Life Sciences, PwC LU
Industry Leader, LU
Tel: (+352) 49 48 48 2564
E-mail: laurent.probst@lu.pwc.com

Erica Monfardini, Ph.D.
Director, Pharmaceuticals and Life Sciences, Advisory, PwC LU
Tel: (+352) 49 48 48 6194
E-mail: erica.monfardini@lu.pwc.com

Nuray Unlu-Bohn, Ph.D.
Expert, Pharmaceuticals and Life Sciences, Advisory, PwC LU
Tel: (+352) 49 48 48 4113
E-mail: nuray.unlu.bohn@lu.pwc.com

PricewaterhouseCoopers S.à r.l.
400, route d'Esch
B.P. 1443 L-1014 Luxembourg
http://www.pwc.com/lu

Additional contacts:

Wouter Jansen, Ph.D.
Senior Advisor, Advisory, PwC NL
Tel: 070 3426140
E-mail: wouter.jansen@nl.pwc.com

Kristina Dervojeda, Drs
Advisor, Advisory, PwC NL
Tel: +31 (0)88-792 3228
E-mail: kristina.dervojeda@nl.pwc.com

Ingrid Maes
Director, Performance Improvement Consulting, PwC BE
Tel: +32 3 2593305
E-mail: ingrid.maes@pwc.be

Table of Contents

EXECUTIVE SUMMARY 1

ACTIVITY OVERVIEW 9

INTRODUCTION 14

Rationale of the Study 20
Study Design 21
Theoretical part 21
Methodological section 21
Policy-Oriented section 22

THEORY 24

Definitions and Concepts 24
Life Sciences and Biotechnology 24
Reasons for Biotech Clustering 31
Impact of virtual clustering 31
Genesis of clusters: Regional potential necessary to spur clustering 31
Cluster typologies 33
Biocluster Lifecycle 34
Performance Indicators for Clusters 36

METHODOLOGY 41

Main steps of the Methodology Section 41
Selection of Model Bioclusters 42
Data Collection 46
Validation and Assessment of Critical Success Factors and Economic Performance Indicators 48
Validation of Critical Success Factors 49
Assessment of Critical Success Factors 55
Validation of Economic Performance Indicators 57
Assessment of Economic Performance Indicators 59

RESULTS, DISCUSSION AND RECOMMENDATIONS 64

Results and discussion on the importance and availability of the CSFs 64
Results and Discussion on the Economic Performance Indicators 76
Comparison between the main findings of the first and the second sets 76
Results and Discussion on the 5 Major Driving Forces 78

POLICY RECOMMENDATIONS 103

Approach to Policy Recommendations 103
Policy Recommendations 111
Policy Theme 1: KBBE 111
Policy Theme 2: FUNDING 116
Policy Theme 3: INCUBATORS 119
Policy Theme 4: CLUSTER ORGANISATIONS 121
Policy Theme 5: TECHNOLOGY TRANSFER 124
Policy Theme 6: ENTREPRENEURIAL CULTURE 128
Roadmap to Cluster Excellence 131

CONCLUSIONS 136

Policy Recommendations **136**
Proposing a roadmap to cluster excellence.. **137**
REFERENCES **142**

ANNEXES*

1. List of major biotech “Science Parks” in Europe focusing on KBBE
2. List of “Model Bioclusters” including those not chosen
3. List of major “Bioclusters” in Europe and all around the world
4. Detailed information on three “Bioregions” studied
5. Survey Responses obtained during the cluster analysis
6. Graphical presentations of the importance and availability of CSFs for 16 model bioclusters together with cluster summaries
7. List of Economic Performance Indicators, including both, those initially chosen and those finally applied
8. Individual cluster reports for 16 model bioclusters
9. Meeting Minutes (not available for the public)
10. List of interviewed stakeholders (not available for the public)

*All Annexes will be provided via CD-ROM. This report together with its annexes can also be accessed through:
http://cordis.europa.eu/fp7/kbbe/library_en.html
http://circa.europa.eu/Public/irc/rtd/biocluster/library

List of Figures

Figure 1: Study design 22
Figure 2: Model of the agglomeration of association activities 30
Figure 3: The forces behind cluster expansion 33
Figure 4: Presentation of Cluster Lifecycle 35
Figure 5: Distinction between two types of indicators 37
Figure 6: Key driving forces of a biotech cluster 38
Figure 7: Main steps of the Methodology Section 42
Figure 8: Approach towards data collection 47
Figure 9: Two-stage validation of performance indicators 49
Figure 10: Policy Steps 107
Figure 11: Total Value Chain 108
Figure 12: Roadmap to Cluster Excellence 131
Figure 13: Stages of Cluster Emergence and Development 137
Figure 14: Relationship between CSFs, EPIs and Policy Recommendations 138
Figure 15: Approach for driving biocluster development to the next level of maturity 140

List of Tables

Table 1 - List of bioclusters analysed during the first and second set of cluster analyses. 9

Table 2 - The list of meetings as well as dates and their brief contents contractually agreed with the European Commission. 12

Table 3 - Economic Performance Indicators for biotechnology clusters 33

Table 4 - List of 8 bioclusters analysed during the first set 44

Table 5 - List of 8 bioclusters analysed during the second set 45

Table 6 - Employed data collection types 47

Table 7 - Operationalisation of critical success factors for biotechnology clusters 50

Table 8 - Questions used to determine availability of CSFs 56

Table 9 - Operationalisation of economic performance indicators for biotechnology clusters............. 58

Table 10 - Overview of the data source 62

Table 11 - Importance of Critical Success Factors 64

Table 12 - Overall availability and importance of Critical Success Factors. CSFs considered important but not available have been marked in bold. 65

Table 13 - Importance and availability of Critical Success Factors according to the stakeholder groups. CSFs considered important but not available have been marked in bold. 67

Table 14 - Importance and availability of Critical Success Factors for Emerging clusters (n=2). CSFs considered important but not available have been marked in bold. 68

Table 15 - Importance and availability of Critical Success Factors for Developing clusters (n=5). CSFs considered important but not available have been marked in bold. 69

Table 16 - Importance and availability of Critical Success Factors for Mature clusters (n=9). CSFs considered important but not available have been marked in bold. 70

Table 17 - Economic Performance Indicators for clusters – Cluster Dynamics 72

Table 18 - Economic Performance Indicators for clusters – Cluster Enablers 73

Table 19 - Economic Performance Indicators for clusters – Cluster Outputs 74

Table 20 - Comparison of Critical Success Factors between the 1st and the 2nd set. CSFs considered important but for which data is not available have been marked in bold. 77

Table 21 - Types of collaborations the stakeholders engaged in (in the context of the biocluster)........ 80

Table 22 - Problem statement and strategic objectives for the 6 Policy Themes 109

Table 23 - Policy Actions to be undertaken for KBBE 113

Table 24 - Policy Actions to be undertaken for Funding 117

Table 25 - Policy Actions to be undertaken for Incubators 119

Table 26 - Policy Actions to be undertaken for Cluster Organisations 120

Table 27 - Policy Actions to be undertaken for Technology Transfer 126

Table 28 - Policy Actions to be undertaken for Entrepreneurial Culture 130

Table 29 - Prioritisation of Policy Actions and expected timeframe for impact outcome 136

List of Abbreviations

ABCEurope: Advanced Biotech Cluster Platforms for Europe
ARWU: Academic Ranking of World Universities
BE: Belgium
BIO: Biotechnology Industry Organisation
BDC: The Biotechnology Development Centre
BERD: Business Enterprise R&D
BMBF: Bundesministerium für Bildung und Forschung – (Federal Ministry of Education and Research)
BMELV: Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz – (Federal Ministry of Food, Agriculture and Consumer Protection)
BMU: Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit – (the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety)
BMZ: Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung – (The Federal Ministry for Economic Cooperation and Development)
CEBR: Council of European Bioregions
CH: Switzerland
CI: Cluster Initiative
CIP: Competitiveness and Innovation Framework Programme
CO: Cluster Organisation
CoR: Committee of the Regions
CSFs: Critical Success Factors
CSR: Corporate Social Responsibility
DE: Deutschland
DF: Driving Forces
DG: Directorate General
DK: Denmark
EAFRD: European Agricultural Fund for Rural Development
EC: European Commission
ECA: European Cluster Alliance
ECEI: European Cluster Excellence Initiative
ECPG: The European Cluster Policy Group
EIB: European Investment Bank
EIF: European Investment Fund
EPIs: Economic Performance Indicators
ERA: European Research Area
ETP: European Technology Platforms
EU: European Union
EUR: Euro
FR : France
FAO: Food and Agriculture Organisation
FCPR: Fond Commun Placement à Risques
FEDER: Fonds Européen de Développement Régional
FDI: Foreign Direct Investment
FP7: 7^{th} Framework Programme
GCRC: General Clinical Research Centre
GLP: Good Laboratory Practice
GMP: Good Manufacturing Practice
HR: Human Resources
HTEC: High-tech industry and knowledge-intensive service
IASP: International Association of Science Parks
ICT: Information and Communication Technologies
IAR: Industries & Agro-Resources, France
IP: Intellectual Property

IPR: Intellectual Property Rights
IRDA: The Institut de Recherche et Développement en Agroenvironnement
IRE: Innovating Regions in Europe
IZB: Innovations- und Gründerzentrum Biotechnologie (IZB) – (The Innovation and Start-up Centre for Biotechnology)
KBBE: Knowledge-Based Bio-Economy
KPI: Key Performance Indicator
LMI: Lead Market Initiative
LRD: Leuven Research & Development
M&A: Merger & Acquisition
MLP: Mutual Learning Platform
NMR: Nuclear Magnetic Resonance
OECD: Organisation for Economic Cooperation and Development
PHARE: The Poland and Hungary: Assistance for Restructuring their Economies (PHARE)
R&D: Research & Development
RDI: Research, Development and Innovation
RI: Research Institute
ROI: Return on Investment
PwC: PricewaterhouseCoopers
SCAR: Standing Committee on Agricultural Research
SE: Sweden
SMEs: Small and Medium-sized Enterprises
TACTICS: Transnational Alliance of Clusters Towards Improved Cooperation Support
TiE: The Industry Entrepreneurs
TTO: Technology Transfer Office
UKSPA: United Kingdom Science Parks Association
UAFC: Upper Austrian Food Cluster
UK: United Kingdom
USA: United States of America
VC: Venture Capital
WCC: World Class Cluster

Executive Summary

Executive Summary

Biotechnology has evolved from a single set of technologies in the mid seventies into the full grown economic activity that it is today. Modern biotechnology is becoming the driving force of dramatic changes in innovation processes in many sectors (e.g. pharmaceutical, agriculture, food, chemical, environment, energy etc). Due to its pervasive nature, stimulating developments in modern biotechnology is considered to be highly important, as is the competitiveness of the European Industry.

Bio-economy can be defined as the sustainable production and conversion of biomass for food, health, fibre and industrial products, and for energy. Renewable biomass encompasses any biological material that is to be used as a raw material. **Knowledge-based Bio-economy (KBBE)** plays an important role in creating economic growth and in formulating effective responses to pressing global challenges. Over the last few decades, the major economic driving forces behind the KBBE in Europe includes the increasing demand for a sustainable supply of food, raw materials and fuels, as well as recent scientific progress.

The European Commission (Directorate General Research) has developed the concept of the KBBE in 2005 with the aim of reaching excellence in science, technology and industry to deliver innovation. In parallel, an EU cluster policy, including bioclusters, to support KBBE has been developed by the DG Enterprise and Industry. DG Research and Innovation has set the terms for the agro-food, bioenergy, bioprocessing, marine biotech etc. sectors as follows: "The KBBE within FP7 focuses on the agro-food, bioenergy, bioprocessing, marine biotech etc. sectors and typically excludes health applications of biotechnology[1]. However, health applications are heavily represented in bioclusters". Therefore, in the context of this report, the KBBE has included health applications, and where these are excluded we used the term "non-medical KBBE". Bioclusters are currently categorised under different colour codes such as "**red biotech**" focusing on healthcare applications (e.g. development of new diagnostics and therapeutics) boosted by advances in genomics and proteomics; "**green biotech**" with a focus on agro-food biotech including renewable energy from agricultural resources stimulated by plant genome research; "**white biotech**" focusing on industrial biotech applications using bioprocessing and bioproduction for the production of biochemicals, biopharmaceuticals, food ingredients, etc., to help industry to be more resource efficient and environmentally friendly; and "**blue biotech**" used to describe the marine and aquatic applications of biotechnology including land based marine aquaculture.

Biotechnology is often interdisciplinary and consequently many applications can be classified in more than one colour category. On several occasions these extensive biotechnologies have been combined to produce even better results in specific cases. For instance, the production of biofuels from the food crops can be considered both as white and green biotech while from the marine, algae can be classed as white and blue biotech. Thus, as observed in this study, mixed clusters are becoming increasingly common in comparison to those focused solely in one sector to create synergy between different sectors. This pattern has been observed in our study for several bioclusters which originated as red, and have subsequently developed a "green" arm. Moreover, the recent advances in computer science support the advances in biotechnology that rely on rapid microprocessors, massive databases, and clever algorithms for the analysis and interpretation of large amounts of information. **Bioinformatics** (referred as gold biotech) is an interdisciplinary field which addresses biological problems using computational techniques, known as computational biology. It plays a key role in

[1] John Claxton, Deputy Head of Unit E2 "Biotechnologies", Directorate General for Research and Innovation, European Commission-Personal Communication.

various areas, such as functional genomics, structural genomics, and proteomics, and forms a key component in the biotechnology and pharmaceutical sector.

In 2008, the European Commission (DG Enterprise and Industry) recognised the important role of bioclusters in stimulating innovation and improving competitiveness, and undertook efforts to improve their coordination and sustainability "through improved science-industry linkages, world-class innovation clusters and the development of regional clusters and networks". Clusters are thus considered important elements within the new global economic growth environment, in which the European 2020 strategy has to succeed. Likewise, DG Enterprise and Industry intends to support Member States and regions in their efforts to improve their cluster policies, notably by providing objective information on clusters, cluster organisations and cluster policies, in addition to improving facilitation of policy learning across Europe. In 2008, **The European Cluster Policy Group (ECPG)** was formed by the Commission to strengthen the quality of cluster programmes across Europe, and a Commission Decision was published (2008/824/EC)[2]. This independent expert group was tasked to improve policy responses in support of cluster excellence, and make recommendations on how to better design cluster policies in the Community. The work of the group was structured around four key themes:

- Better support to international cluster cooperation;
- The role of clusters in support of emerging industries;
- Raising the excellence of clusters and cluster organisations;
- Creating better synergies between community instruments with a cluster dimension.

The ECPG presented their final recommendations for Policy Action on 30 September, 2010 at the first European Cluster Conference under three principles and eight action proposals addressed to the EU institutions and Members States for them to take on board[3]. These recommendations call for an improved coordination between the different EU initiatives in support of clusters and proposes that the "focus of cluster programmes needs to be shifted from capacity building and compensation for poor performance towards a clear orientation on excellence, focusing on clusters with the ability and willingness to upgrade in the face of global competition, ensuring the consistent provision of public knowledge infrastructure to support them".

Bioclusters are heterogeneous entities, varying widely in structure, evolution and goals that represent a local complex system where different types of organisations interact for research, innovation and economic growth. Existing literature suggests that the clusters offer key competitive advantages with respect to three key variables: employment, innovation, and productivity. Productivity is enhanced by lowering transaction costs with untraded interdependencies. Innovation is dependent on the interactive knowledge exchange between varieties of knowledge actors, especially because of the proximity necessary for tacit knowledge exchange. Employment comes as a result of new business formations and is massively assisted by mentoring, role-model provision, learning, communication, and commercialisation gains that arise from operating in a cluster setting. These key competitive advantages are enabled by complex and interrelated critical success factors. Understanding the nature of these **Critical Success Factors (CSFs)** and their link to the Economic Performance of the Cluster is crucial for policy makers.

Seemingly it has been indicated in the White Paper on the emergence of European World-Class Clusters[4] and also been stated by the ECPG, that there is an urgent need in Europe for implementing a commonly agreed assessment indicators through all States in Europe. This would allow for the economic performance assessment of the clusters to meet the challenges appearing on a global scale.

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:288:0007:0011:en:PDF

[3] http://www.proinno-europe.eu/ecpg

[4] http://intercluster.eu/index.php?option=com_content&view=article&id=169%3Athe-white-paper-on-the-emerging-of-european-world-class-clusters-&catid=2&Itemid=59&lang=en

The main problem in Europe is the fragmentation and differentiation of its 27 Member States and their regional or local level cluster policies. DG Research and Innovation pursued its double goal by launching this study:

1) Establishing a methodology and performance indicators for assessing bioclusters;
2) Analysing especially the till now neglected non-medical bioclusters in KBBE-relevant fields.

Within the scope of this study, the following objectives were set out:

- To **identify the CSFs** behind the successful economic performance of the bioclusters by analysing 16 model-bioclusters in and out of Europe;
- To determine the **importance and availability of identified CSFs;**
- To **suggest measurable Economic Performance Indicators (EPIs)** relevant to the performance of the bioclusters for their evaluation and allocation for future financial support;
- To **generate policy recommendations** based on the gap analysis of the highly important but scarcely available CSFs together with the evaluation of interviews, cluster reports and expert opinions. These are based on the EPIs (to be implemented) that aim to stimulate the development of bioeconomy in Europe.

In order to achieve the objectives of this study, 16 model-bioclusters located in and out of Europe have been chosen based on the criteria of their maturity level, sector (mostly those involved in healthcare, but also several in the agro-food, agro-environment, bioenergy and bioindustry sectors), geographical location, and transnationality. Selected bioclusters were then analysed in detail during two separate rounds of cluster analysis via online surveys and phone/face-to-face interviews. A total of **275** online survey responses have been collected while **169** interviews were conducted. The availability and importance of CSFs and EPIs were determined and assessed by our external experts' opinions and by the survey responses. Phone/face-to-face interviews were conducted to get a more in-depth feedback and to discuss survey responses. We were then able to verify our hypotheses that were supported by desk research.

Identified CSFs that were valid for all biotech industry sectors were grouped and discussed under five main **Driving Forces (DFs)** such as:

- Scientific DFs (e.g. existence of renowned universities and research institutions with renowned researchers);
- Industrial DFs (e.g. existence of large companies, SMEs start-ups/spin-offs, their survival and influence on the cluster development together with skill base supported by specialised training and attractiveness factors);
- Financial DFs(e.g. availability, sustainability, and type of funds available, barriers to access);
- Supporting DFs (e.g. presence of effective cluster organisations, strong infrastructure such as incubators and technology transfer organisations, regulatory and policy framework);
- Cultural DFs (e.g. presence of entrepreneurial and networking cultures).

Our analyses on the determination of EPIs were carried out on different levels:

- Review of existing EPIs already collected in the official statistical databases;
- Review of meaningful EPIs available at cluster organisational and member levels;
- Integration of interview, survey results, and the comments of the EC.

The suggested EPIs are categorised under three dimensions: cluster dynamics, enablers, and outputs;

- **Cluster Dynamics**
  - Number of jobs created;
  - Number of companies established (including growth and survival rates within the last three years).

- **Cluster Enablers**
  - Public funds raised;
  - Private funds raised;
  - Framework conditions;
  - Cluster organisations (cluster management/facilitator).

- **Cluster Outputs**
  - Revenues from marketed biotech products/technologies;
  - Revenues from licensing activities on biotechnology products/technologies;
  - Newly developed & marketed biotechnology products/technologies.

The analysis of data collected during the first and the second sets of clusters confirmed the difficulty in gathering high quality data and highlighted the absence of a common methodology for measuring and collecting EPIs. Data collection for EPIs represents an important challenge for European, national and regional authorities. Incentive built and enforcement mechanisms are suggested to be put in-place for regular data collection at the EU level in order to build a common assessment framework.

Our policy recommendations were based on the gap analysis (rated of high importance and low availability) performed on CSFs together with the assessment of all insights we gathered through phone interviews, individual cluster reports, our external experts and desk research. Following this methodological approach, policy suggestions have been categorised under six themes: KBBE aspects, funding, incubators, technology transfer, cluster organisations, and entrepreneurial culture. The main points under each policy recommendation highlighted are listed below;

1. **KBBE Aspects**: For supporting the further development of bioeconomy in Europe, it is recommended to:

   - Develop policy actions consisting in incentives and regulations supporting all **KBBE** sectors (e.g. tax credits, tax breaks, tax exemptions etc);
   - Develop standards, regulations, labelling, certification (e.g. Environmental Technology Verification-ETV), and testing standards for newly developed products/technologies developed under KBBE (particularly important for industrial biotechnology);
   - Encourage “Green Public Procurement”;
   - Allocate more funding under FP8 towards non-medical KBBE sectors to balance the gap between medical and non-medical KBBE applications and more towards production and commercialisation;
   - Increase the funding share for SMEs (>25%) in collaborative projects;
   - Increase public support and acceptance through trainings, workshops, conferences etc, towards the benefits of bioeconomy to increase awareness for public as well as policy makers and investors;
   - Ease cross-border mobility of key personnel between EU and non-EU countries;
   - Create more translational research centres in specific KBBE domains to boost industrial applications.

2. **Funding:** In order to cover the major funding gap existing in all KBBE sectors, it is first suggested to make existing funding on the market more accessible. Then, it is crucial to create new funding resources and attractive funding mechanisms for the entrepreneurs and investors. For this reason it is suggested to:

- Provide competitive funding to the clusters tailored according to their maturity level;
- Increase the efficiency of risk-sharing mechanisms (e.g. offered by EIB);
- Stimulate strong deal flow and investment size in EU to strengthen the link between EU funding resources (e.g. EIB) and trans-regional innovation banks;
- Increase the awareness and in turn, the efficient use of Innovation Vouchers;
- Ease application and maintenance procedures to obtain funding (e.g. FP7);
- Create incentives to attract investors particularly VC to invest into KBBE sectors.

3. **Incubators:** In order to increase the efficiency and the awareness of the importance of incubators, it is suggested to create new added value on incubators through:

- Encouraging the creation of new bio-incubators at cluster or regional level where there is none and to strengthen the structure of the existing ones;
- Defining funding and governance structure;
- Setting up incentives (e.g. tax incentives and credits) for the companies launching at the incubators and to offer fair running and service costs to its tenants;
- Defining the expected services from bio-incubators to meet the specific needs of each KBBE sector (e.g. to offer business, scientific, legal, funding advice as well as providing well-equipped and sophisticated Good Laboratory Practice (GLP) certified labs allowing also biosafety work (level three), animal labs, and Good Manufacturing Practice (GMP) certified pilot plants, green houses for agricultural trials etc);
- Providing "soft-landing practices" to allow the launch of international companies to benefit from the incentives of that country and so to increase international collaboration and visibility.

4. **Technology Transfer:** To stimulate the innovation, the technology transfer process should be revised and eased. For this reason it is suggested to:

- Increase the link and collaboration between technology transfer organisations that is currently quite fragmented. This should be carried out at institutional level;
- Define the services and structure of ideal TTO by determining the highest performing TTOs in Europe;
- Encourage regions and states for the creation of European TTO where all individual offices are connected to this central organisation;
- Ease the filing procedures, lower the fees and time required for patent filing
- Allocate and continuously train the personnel of TTOs;
- Support open innovation;
- Create patent families rather than individual applications;
- Offer by TTOs training sessions to the scientists/researchers/industry on the importance of disclosing their invention, creating a company and advice on how to proceed;
- Develop criteria to clarify the IPR management on public-private partnerships.

5. **Cluster Organisations**: In order to bring cluster organisations to the excellence level, it is suggested to:

- Define the expected services, funding and governance structure of the cluster organisations to increase their efficiency and importance;
- Create EU level competitions on each KBBE sector to reward successful clusters according to their maturity;
- Create rewards that can be granted by the time less mature clusters meet the requirements of higher level maturity;
- Develop reward systems for role model cluster managers/teams;
- Develop special trainings for cluster organisations to increase the quality and threshold of their services;
- Set up a study programme at Universities for "Cluster Management";
- Further support the development and activities of "European Cluster Excellence Initiative" and encourage the cluster organisations to take an active participation in those platforms;
- Educate and train the cluster organisations about the challenges of bioeconomy so that they can convince the potential stakeholders and investors of the benefits of new technologies and products;
- Develop a certification scheme for cluster organisations at a national and/or EU level by the time they meet the defined services and criteria;
- Enforce and support the cluster organisations to collect EPIs on their own cluster regularly.

6. **Entrepreneurial Culture:** In order to stimulate the entrepreneurship and revert the risk-averse culture dominating the EU, it is suggested to:

- Create clear regulations and attractive incentives especially for the newly developing non-medical KBBE sectors;
- Create reward system for role model entrepreneurs;
- Offer business trainings, especially to the researchers, and create platforms for sharing success stories;
- Stimulate the establishment of communication platforms between public and private parties;
- Stimulate the establishment of innovation platforms within the public entities;
- Create special grants for financing the entrepreneurship programmes and skilled workforce from abroad;
- Create finance mechanism for risk sharing (e.g. guarantees, insurances). To remove barriers for collaborative education and for workforce administrative burdens.

Over the last five years, the Commission continued to promote and stimulate the development of the KBBE sector in various ways. The understanding of the factors behind the success of the **regions** (namely bioregions) and the role of bioclusters in the success of bioregions has been indicated as a major point of interest, and so that has been tackled and investigated in this study.

In the rapidly developing biotechnology sector, not only the EU and Member State initiatives play an important role in providing an adequate environment, but also, below the national level, with the local and regional bodies playing a key role. At the sub-national level, biotechnology is developing under several forms such as **biotech parks, bioclusters** and **bioregions.** The main factors which have been identified to be essential in our study for the growth of bioclusters and for the successful development of bioregions are the following: the awareness at regional level of the importance of the local economic development, the consequent allocation of the necessary resources and means for this purpose, and the willingness of the regional policy makers and politicians to bring this subject into the agenda at national and EU level. Moreover, the regions with strong political commitment and local cluster policies in-place are found to have strong bioclusters, a factor that plays a pivotal role in boosting the region's economic growth and job creation.

Activity Overview

Activity Overview

Kick-off Meeting: 14 October 2009

The project was officially launched on 14 October 2009 with the first "Kick-off Meeting" taking place in Brussels at the DG Research and Innovation offices. DG Research and Innovation and PwC agreed on the project objectives, timelines, governance, and communication rules. The main objective of this "Regional Biotechnology" study was to examine the key success factors of bioclusters mostly involved in KBBE, and to suggest key performance indicators enabling the measurement of the cluster impact on the macroeconomic development of the region, indirectly addressing the link with innovation processes. The key objective of the study was to generate practical recommendations for the analysis of cluster impact, policy making, and cluster support. This kick-off meeting was followed by the "Inception Report" shortly after.

Second Meeting: 25 November 2009

During this meeting, following the presentation of the final pool of recommended model bioclusters to be analysed, the set of bioclusters to be analysed during the first and second sets have been mutually agreed. In total, 16 bioclusters were invited to take part in the study, all of whom accepted participation. The list of the selected bioclusters is given in Table 1. These clusters were selected based on a complex set of criteria including their key activities, maturity, geographical location, success, and transnationality.

Table 1 - List of bioclusters analysed during the first and second set of cluster analyses.

N°	Cluster	Country
1	BioValley Cluster	France Germany Switzerland
2	Paris Biocluster (Genopole)	France
3	Cambridge Cluster	UK
4	Munich Cluster (Biotech Region Munich)	Germany
5	Umea Cluster (Biotech Umea)	Sweden
6	Barcelona Cluster (Biocat)	Spain
7	Oslo Cluster (Teknopol)	Norway
8	Medicon Valley	Denmark Sweden

N°	Cluster	Country
9	Industries & Agro-Resources (Association industries et agro-resources, IAR)	France
10	Upper Austrian Food Cluster	Austria
11	Hokkaido BIO Industrial Cluster Forum	Japan
12	Quebec Cluster (Saint-Hyacinthe Technopole)	Canada
13	San Diego Biocluster	U S A
14	Bioval – Valencian Biotechnology	Spain
15	Food Valley Wageningen	Netherlands
16	Ghent Biocluster (Ghent Bio-Energy Valley)	Belgium

As agreed during the "Second Meeting", PwC provided a draft questionnaire to the EC for conducting the clusters surveys on 18 December 2009, which was then approved and launched during January 2010. In addition to the online questionnaire, it was agreed to conduct approximately ten interviews per cluster, with the main stakeholders representing cluster organisations, universities, research institutions, start-ups, SMEs, large companies, investors, technology transfer offices, incubators and policy makers.

Once the first set of eight bioclusters was agreed with the EC, each cluster organisation was contacted individually to verify their willingness to take part in the study. These first bioclusters mainly focused on the red biotech (health related bioclusters). Following confirmation of the cluster organisations, major stakeholders belonging to each cluster were prepared in collaboration with the cluster organisations. Each stakeholder that was identified received an invitation letter to take part in the study by the cluster organisation, followed by an official invitation sent by PwC. Shortly afterwards, phone interviews were set up and personal access codes for the online-survey were sent out to the participants that had been identified to take part in the study. After the completion of the first set of surveys and interviews, preliminary critical success factors and performance indicators were determined. These were supposed to be verified and validated on a second step, during the second set of interviews. The results based on the first set of cluster analyses are provided in the "First Short Report".

Third Meeting: 20 April 2010

The individual cluster report template was discussed and exemplified by two separate sample reports produced by PwC for the Umea and Munich bioclusters. It was decided to examine major driving forces under five categories (scientific, industrial, financial, supporting and cultural driving forces). More precisely, as a result of discussions held during the third meeting, the category of "Cultural Driving Forces" was added as the fifth driving force, that was originally proposed in the two sample reports. Additionally, it was agreed to modify the existing questionnaire before the second set of cluster analysis, based on experience of both the importance and the availability (easy to obtain or not) of data obtained during the first set. As suggested:

- A total of ten stakeholder groups were defined on the questionnaire, instead of four, and the questions were rearranged according to the new stakeholder groups;
- Some questions were reorganised by placing the most general ones at the beginning (e.g. on cluster objectives) and placing the specific ones within the relevant sections;
- Some previously unclear terminologies were re-defined;
- Overly specific questions, which did not make generalisations to the whole cluster were removed;
- New questions were added, particularly to validate some hypotheses (e.g. performance indicators and success factors);
- A new set of key questions was developed for use in the second set of interviews.

The modified questionnaire was re-launched before beginning the survey of the second set of clusters. The same methodological procedure was followed for the second set, which brought in an additional eight clusters covering a wider sector of KBBE areas, by including agro-food, agro-environment, bio-energy, and clean technology as well as biomedical/pharmaceutical.

During the third meeting, the content and the main agenda items for the final workshop, aiming to present and validate the participants were also agreed.

Fourth Meeting: 22 September 2010

The study findings from the second set of cluster analyses were presented. These were based on five main driving forces, including a general comparison of the results from the two sets. The identified critical success factors and key performance indicators based on all cluster analyses were also presented. It was agreed that key EPIs will be provided under three categories such as Cluster Dynamics, Enablers and Output. EC suggested categorising those CSFs and EPIs under "Framework Conditions", "Excellence of Cluster Organisations", and "Excellence of Clusters". It was decided to identify relevant indicators for assessing the effectiveness and performance of the cluster organizations and management in addition to the performance of the cluster itself.

The fourth meeting was followed by the "Second Short Report", in which the results relating to the second set of cluster analysis were given, followed in turn by the "Intermediate Report" which provided the methodology of data collection and analysis in detail, consolidated results and discussion on CSFs, key EPIs and major driving forces with a short introduction to "Policy Outlook".

Fifth Meeting: 18 October 2010

The "Policy Outlook" was discussed and agreed during this meeting, as well as the structure of the Final Draft Report and the 10 December, 2010 workshop presentations and preparations. It was agreed that policy recommendations at the EU, National and Regional levels will be provided in detail in the "Final Draft Report", based on the gap analysis on the importance and availability of critical success factors. For the significantly important critical success factors, when the availability was evaluated to be low, it was agreed that an action plan would be suggested. The importance and the availability of CSFs would be shown in spider graphs for the 16 clusters analysed. Policy recommendations are provided under six themes (e.g. KBBE specific aspects; funding; entrepreneurship; technology transfer; incubators; cluster organisations) correlated with the best practices.

The contents of the meetings are summarized in Table 2 with their brief summary. All 16 of the preselected clusters (13 in Europe, 1 in USA, 1 in Canada and 1 in Japan) showed an interest and gave support to us to conduct the study. In total, 275 survey responses were collected in addition to the 169 phone/face-to-face interviews conducted. All of those inputs combined with desk research allowed us to generate in-depth cluster analyses for each individual cluster for each of the 16 clusters examined. Individual cluster reports are provided under **Annex 8**.

Based on each cluster analysis, critical success factors have been identified and their availability and importance assessed based on experts' opinion, survey responses, cluster reports and phone interviews. Based on the gap analysis (high importance vs. low availability), the themes for the final draft report have been identified and presented under six, instead of seven, themes as it had been decided that the two KBBE themes would have been merged. The final list of themes will be: KBBE specific aspects, funding, entrepreneurship, technology transfer, incubators, cluster organisations on which we have generated policy recommendations at EU, National and Regional levels.

In collaboration with the EC, a workshop was organised on 10 December, 2010 in Brussels, with key participants presenting and validating study results as well as policy recommendations. The conclusions of the workshop have been incorporated in the "Final Report".

Table 2 - The list of meetings as well as dates and their brief contents contractually agreed with the European Commission.

Meetings/Status	Purpose
Kick-off Meeting* After the first month of the study Date: **14 October 2009, Brussels**	• Discussion on the priority topics for the Study • Discussion on the outstanding issues of interest to the Commission • Agreement on the definitions needed within the framework of the study • Preliminary overview of the bioclusters to be included in the project • Outline of the performance indicators to be measured for the clusters
Second Meeting* Preparatory meeting before the cluster analysis Date: **25 November 09, Brussels**	• Selection of model bioclusters (first and the second sets) for further analysis • Evaluation of potential performance indicators • Discussion of Cluster-Network-Monitoring approach by applying Social Network Analysis • Discussion of the data gathering approach
Third Meeting* After the completion of first set of cluster analysis Date: **20 April 2010, Brussels**	• Provision of an overview and update on the cluster analysis study • Discussion of the individual cluster report template • Discussion of two sample reports • Discussion of the first short report template (first insights) • Review and approval of the updated questionnaire for the 2nd set
Fourth Meeting* After the completion of second set of cluster analysis Date: **22 September 2010, Brussels**	• Presentation of the results obtained during the second set of cluster analysis • Comparison of the results between the first and second set • Presentation of the identified CSFs and key EPIs • First Approach to policy recommendations • 10 December, 2010 workshop preparation
Fifth Meeting* Last meeting before the workshop Date: **18 October 2010, Brussels**	• Discussion on the Policy Outlook Template based on the gap analysis results highlighting the discrepancy between the importance and the availability of CSFs, and agreement on the seven proposed themes (e.g. funding, technology transfer, incubators, cluster organisations, entrepreneurship and KBBE aspects for legislative matters and KBBE for non-legislative matters) • Discussion on the structure and the content of the Final Draft Report and its Appendices • December 10th Workshop preparation • Follow-up of the study performed by PwC, following the workshop, and consisting in the implementation of the results contained in the Final Report
Workshop meeting before the final report to discuss and validate the study results and policy recommendations with key study participants Date: **10 December 2010, Brussels**	Aiming at discussing and validating the study results and policy recommendations with: Cluster Organisation Representatives, Scientists, Researchers, Investors, Technology Transfer Organisations, Incubator Representatives, KBBE specialists, and Policy Makers. This discussion aimed to enrich the policy recommendations, and results have been integrated into the Final Report

*: All meeting minutes are provided under Annex 9

Introduction

Introduction

In 2005, through its first conference, the European Commission (DG Research and Innovation) launched the concept of the **Knowledge-based Bio-economy (KBBE)**[5] with the aim of reaching excellence in science, technology and industry to deliver innovation, world leadership in food technologies and products, animal breeding technologies, whilst developing a strong chemical and manufacturing industry base.

KBBE is a broad concept which can be defined in a number of ways. In essence, the vision is of a Europe in which fossil fuel feedstocks have been replaced by renewable plant raw materials, where chemical processes have been replaced by biological ones and waste is virtually eliminated by working in closed-loop systems. Above all, it will build on a strong European knowledge base enabling science and technology and will generate sustainable employment for European citizens[6]. According to the definition in the Cologne paper (May 2007), KBBE can be concisely defined as "transforming life sciences knowledge into new, sustainable, eco-efficient and competitive products"[7]. In effect, KBBE can be defined as the sustainable management, production and use of renewable biological resources through life sciences and biotechnology. The final aim would be the conversion of biomass, for a range of food, health, fibre and industrial products. Renewable biomass encompasses any biological material to be used as raw material. The KBBE within FP7 typically excludes healthcare applications (red biotech) of biotechnology. The KBBE clusters known as "bioclusters" are categorised under different colour codes such as "**red biotech**" focusing on healthcare applications (e.g. development of new diagnostics and therapeutics) boosted by the advances in genomics and proteomics; "**green biotech**" with a focus on agro-food biotech including renewable energy from agricultural resources stimulated by plant genome research; "**white biotech**" focusing on industrial biotech applications using bioprocessing and bioproduction for the production of biochemicals, biopharmaceuticals, food ingredients, etc., to help industry to be more resource efficient and environmentally friendly; and "**blue biotech**" used to describe the marine and aquatic applications of biotechnology including land based marine aquaculture. Bioclusters are heterogeneous entities, varying widely in structure, evolution and goals. Bioclusters are created to fulfil the political expectations of creating jobs, fostering innovation and improving competitiveness. This study aimed at providing some key messages to the policy-makers on how to support and promote bioclusters to help them meet their expected roles based on the best and worst practices identified by our cluster analysis. So far, only a few "green/white/blue biotech" bioclusters have reached to the maturity level in Europe. This study also aimed at determining the key barriers for the newly developing sectors in Europe for accelerating their growth.

KBBE plays an important role in creating economic growth and in formulating effective responses to the pressing global challenges. The major economic driving forces behind the KBBE in Europe refer to the increasing demand for a sustainable supply of food, raw materials and fuels, as well as recent scientific progresses. The European non-medical KBBE has been growing continuously in its main sectors of agriculture, forestry, fisheries, food, energy and chemicals with an estimated market size of the European bio-economy currently accounting for more than 2 trillion EUR with approximately 21.5 million employees. This trend is not only favourable from an economic point of view, but also leads to improved public well-being in general, and implies a smarter, more sustainable and inclusive economy.

---

[5] http://www.kbbe2010.be/en/kbbe2010/about-kbbe/kbbe-europe

[6] KBBE Conference Report 2010: http://sectie.ewi-vlaanderen.be/sites/default/files/documents/KBBE_Report_Chall_to_Oppo_LR_final.pdf

[7] http://www.kbbe2010.be/en/kbbe2010/about-kbbe/defining-kbbe

The **Europe 2020 strategy** calls for an innovative and resource efficient Europe, and highlights the building of a bio-economy by 2020 as one of the deliverables under the **Innovation Union Flagship Initiative**. The importance of creating a strong European bio-economy reflects the concerns of European society to globalisation and economic crisis; guaranteeing food security while adapting to a changing climate; reducing the environmental impact of agriculture and industry; maintaining an affordable, safe, healthy and nutritious food supply[8].

Over the last five years, the Commission continued to promote and stimulate the development of the KBBE sector in various ways. Such examples are that, , nine KBBE-specific (e.g. Plants for the Future[9], Food for Life[10], Sustainable Chemistry[11], Sustainable Farm Animal Breeding and Reproduction[12], Forest-based Sector[13], Biofuels[14], Agricultural Engineering[15], Aquaculture Technology and Innovation[16], and Global Animal Health[17]) **European Technology Platforms** (ETPs) have been set up. Furthermore, numerous research projects in the area of KBBE have been financed through the Commission's FP6 (2002-2006) and FP7 (2007-2013) Framework Programmes (for post 2013, the following programme is under preparation) and several Member State initiatives. Research in the KBBE area has also been strengthened by the implementation of several **ERA-Nets** (e.g. Plant Genomics, Systems Biology, Industrial Biotechnology, Food Safety Research Programming, Marine Fisheries Science and Fisheries Management, etc). In addition, several expert groups have been established including the Advisory Group on Food, Agriculture and Biotechnologies, the **KBBE-Net**, the KBBE National Contact Point, and the EU Standing Committee for Agriculture Research (**SCAR**)[18].

In 2009, the Commission published an action plan for the **Key Enabling Technologies** (KET)[19] which includes industrial biotechnology. The key objective of this plan is to remove the obstacles hindering the further development of biotechnology in Europe and to fully exploit the research results. Another recent initiative refers to the SusChem's European Innovation project BIOCHEM[20] funded under the INNOVA scheme. The objective of the project is to define and promote bio-based product opportunities in the chemical sector, and to facilitate new bio-based business ideas to proof-of-concept.

In order to stimulate converting the science-based findings into commercially viable products by reducing barriers, the European Commission has also launched the "**Lead Market Initiative**" (LMI)[21] following the EU's 2006 Broad Based Innovation Strategy whereby public authorities facilitate industry-led innovation by creating the conditions for a successful market uptake of innovative products and services in the identified lead market areas. These areas include e-Health, Recyling, Bio-based Products, Renewable Energies, Sustainable Construction and Protective Textiles. EC works

---

8 International Innovation, 2010 : http://www.research-europe.com/index.php/2010/08/maive-rute-director-of-the-biotechnologies-agriculture-and-food-directorate-dg-research-european-commission/

9 http://www.plantetp.org

10 http://www.etp.ciaa.eu

11 http://www.suschem.org

12 http://www.fabretp.org

13 http://www.forestplatform.org

14 http://www.biofuelstp.eu

15 http://www.manufuture.org

16 http://www.eatip.eu

17 http://www.ifahsec.org

18 The Knowledge Based Bio-Economy (KBBE) in Europe: Achievements and Challenges (2010). http://sectie.ewi-vlaanderen.be/sites/default/files/documents/KBBE_A4_1_Full%20report_final.pdf

19 Preparing for our future: Developing a common strategy for key enabling technologies in the EU, COM(2009) 512

20 http://www.biochem-project.eu/

21 EC, DG Enterprise and Industry, Lead Market initiative for Europe: http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/index_en.htm

together with the Member States and the Industry to carry out the action plans for the lead markets. Concerning the bio-based products, a series of specific recommendations and actions have been developed, ranging from improving the implementation of the present targets for bio-based products to standardisation, labelling and certification, in order to ensure the quality and consumer information on the new products[22],[23]. Additionally, in 2008 the Commission set up an expert group for bio-based products composed of representatives from national governments, industry and academia, called the **Ad-hoc Advisory Group for Biobased Products**. Since the bio-based products are largely affected by legal acts and public policies at the EU, National or even local levels, the Advisory Group has analysed the current market conditions and how the existing legislative and policy framework conditions affecting the introduction of products made from renewable raw materials and have generated a report[24] covering measures relating to legislation, policies, standards, labels, certification and public procurement.

However, in the rapidly developing biotechnology sector, not only do the EU and Member State initiatives play an important role in providing an adequate environment, but also, below the national level, local and regional bodies play a crucial role. On the sub-national level, biotechnology is developing in several forms such as biotech parks, bioclusters and bioregions. In fact, regional concentrations of life science activities and networks have been observed to have a major impact on the national performance of the bio-economy. Under the **Innovation Policy of EC**, regions and cities are considered to be the primary spatial units whereby knowledge is transferred, innovations systems are built and competition to attract investments and talents takes place. Many regional governments are known to have important competencies and budgets in the field of innovation. Their geographical proximity facilitates the acquisition, accumulation and use of knowledge. EU innovation policy has placed a strong emphasis on networks which link the business to the surrounding environment (other firms, universities, research institutes, etc.) and are active mostly at regional level, e.g. in the field of cluster initiatives.

The main factors which have been identified to be essential in our study for the growth of bioclusters and for the successful development of bioregions are the following: an increased awareness at the regional level of the importance of the local economic development, the consequent allocation of the necessary resources and means for this purpose, and the willingness of the regional policy makers and politicians to bring this subject into the agenda at national and EU level. Moreover, the regions with strong political commitment and local cluster policies in-place are found to have strong bioclusters: these play a pivotal role in boosting the region's economic growth and job creation.

For instance in Germany, biotech innovation is found to have a strong regional focus since some state governments (e.g. Bavaria, Baden-Württemberg, and North Rhine-Westphalia) had programmes fostering network structures between science and industry since 1980s, long before the Federal Government started in the mid-1990s[25]. When biotech patent applications were examined in Germany between 1995-2005, Bavaria was positioned second after North Rhine-Westphalia. When figures for the individual regions are broken down, Munich took the top position with around one tenth of the biotech patents originated from this area. This is attributed to the influence of the "**BioRegio**" competition organized by the Federal Ministry of Education and Research **(**BMBF**)** in 1996 since two

[22] The Knowledge Based Bio-Economy (KBBE) in Europe: Achievements and Challenges (2010).

[23] EC, DG Enterprise and Industry, Bio-based Products: http://ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/biobased-products/index_en.htm

[24] Measures to promote the market introduction of innovative bio-based products, 2009: http://ec.europa.eu/enterprise/sectors/biotechnology/files/docs/bio_based_from_promise_to_market_en.pdf

[25] Cluster Policy in Europe: A brief summary of cluster policies in 31 European countries, 2008: http://ekstranett.innovasjonnorge.no/Arena_fs/Synthesis_report_cluster_mapping%20-%20final.pdf

of the four largest biotech clusters are located in the winning regions of Munich and Rhineland[26]. During the examination of "Munich Biotech Cluster", the main objectives of the biocluster are found to be in line with the regional objectives of the Bavaria. Ongoing support provided by the Bavarian State Government to the life sciences industry brought the community to a high level both in Germany and Europe. The Bavarian Government is committed to long term investments and encourages the innovation and establishment/expansion of businesses in biotechnology via its business promotion agency, "*Invest-in-Bavaria*", at national and international levels; supports overall development of science and business through its cluster initiative "*Bayern Innovative Alliance*" and "*Bavarian Research Alliance*"; offers different biotech specific research funding specially for SMEs (e.g. Gene and Biotech); combines scientists from different universities in Bavaria to focus on functional genome research in collaboration with industry with "*Bavarian Genome Research Network*"; fosters transition of immunotherapeutic approaches into clinical application via "*BaylmmuNet*" network; provides high risk capital to young biotech and medtech companies via "*Bayern Kapital*".

According to the results indicated in the Europe INNOVA study on Cluster Policy in Europe, in all the countries investigated, the importance of cluster policy at a regional level is highly correlated to cluster policy at the national level. Exceptions are however represented by Austria, Spain and Denmark, countries which rely on a greater endorsement to cluster policy at regional than national level. This operating model in the policy setting could be attributed to the strong role played by regions, especially in terms of innovation and regional economic development in these countries. The number of regional cluster programmes is found to be particularly high in Spain. In general, the regional programmes consist of providing finance, knowledge/network or both.

Regional concentrations of life science activities and networks are indicated to have a major impact on the national performance of the bio-economy. Likewise, the bioclusters involving a science/technology park in it were found to be more efficient than those that had none. The existence of incubators with efficient technology transfer services and shared technology platforms have been found to be important success factors (e.g. Saint-Hyacinthe Technopole, CA; Oslo Technopole, NO; Paris Genopole, FR).

The **Innovating Regions in Europe (IRE) Network**[27] was set up by the Commission in the 90's and is open to all European regions that are committed to developing their regional innovation systems[28]. Their aim is to facilitate the exchange of experience and good practice among European regions that are enhancing their capacity to support innovation and competitiveness among regional firms through the development and implementation of regional innovation strategies and schemes. Around 235 member regions are gathered in the IRE network and three working groups have been created for the period 2006-2008 focusing on effective regional innovation systems; effective knowledge transfer between universities and enterprises; and innovative clusters. The **Mutual Learning Platform (MLP)**[29] for research and innovation within EU regions was established to encourage regional policy makers to share their experiences and enable regions to participate fully in the knowledge-based society. The platform is a joint initiative of the Commission's Enterprise and Industry, Research, Regional Policy and Information Society DGs, with the active involvement of the Committee of the Regions (CoR). It pulls together a number of existing Community initiatives providing greater coherence, such as regional foresight activities, the European Innovation TrendChart and Scoreboard, and the Regions of Knowledge pilot actions. The MLP aims to support

---

[26] http://www.biotechnologie.de/

[27] Innovating Regions in Europe (IRE) Network: http://ec.europa.eu/enterprise/ire/Innovating-regions/www.innovating-regions.org/network/presentation/index.html

[28] EC, DG Enterprise and Industry, Regional Innovation Policy: http://ec.europa.eu/enterprise/policies/innovation/policy/regional-innovation/index_en.htm

[29] Mutual Learning Platform: http://ec.europa.eu/enterprise/ire/Innovating-regions/www.innovating-regions.org/mlp/index.html

regions in developing their research strategies, taking into account their individual situation and specific needs. Its activities concentrate on three core topic areas within the field of research and innovation: regional foresight, regional benchmarking and regional profiles.

For supporting the bioregions, European Council of Bioregions (CEBR)[30] was launched in 2006 through an FP6 funded project with the intention of providing a network between biotechnology clusters across Europe to bring support to professionals through direct services including networking, incubation, partnering and cluster promotion for the development of local biocommunities.

In March 2008, the European Council has recognised the important role of clusters in stimulating innovation and improving competitiveness, and strived to improve coordinated efforts to sustain them "through improved science-industry linkages and world-class innovation clusters and the development of regional clusters and networks"[31]. Furthermore, the Commission intends to "support Member States and regions in their efforts to improve their cluster policies, notably by providing objective information on clusters, cluster organisations and cluster policies, as well as by facilitating policy learning across Europe"[32]. With the existence of around 2000 clusters, the EU does not lack clusters, but needs more world-class excellence. That's why existing efforts and initiatives at the EU, National and Regional levels should be harmonised to elevate the standards of bioclusters to a world-class cluster level.

In launching the European Cluster Memorandum in January 2008, the EU Heads of State, or applicable Government underlined the need to better coordinate the framework conditions for innovation through improved science-industry linkages, world-class innovation clusters, and the development of regional clusters and networks. The Commission's communications have emphasised that "European countries already have a lot of clustering activities, but still suffer from persistent weaknesses like market fragmentation, weak industry linkage and insufficient cooperation within the EU. If major improvements are not made to address those specific problems, the EU won't have the necessary critical mass and innovation capacity to sustainably face global competition and to be world-class"[33].

The main directions have already been defined, thus, the actions that have to be promoted on the European stage, and that have to be undertaken at the national level, include:

- Improving cluster policies;
- Fostering trans-national cluster cooperation;
- Promoting excellence of cluster organisations;
- Improving the integration of innovative SMEs into the clusters [34].

Regarding the topics outlined above, some initiatives at EU level have already been set up. For instance, **PRO INNO Europe®** is created as an initiative of DG Enterprise and Industry, which aims at becoming the main **focal point for innovation policy analysis and policy cooperation in Europe**, with the view of learning from the best and contributing to the development of new and better innovation policies in Europe[35]. This initiative gave rise to the European Cluster Policy Group (**ECPG**)[36] in October 2008, with a mandate to advise the Commission and Member States on how to better support the development of more world-class clusters in the EU. Under the same PRO INNO

---

30 European Council of Bioregions (CEBR):http://www.cebr.net/

31 Reinhard Büscher: "The way forward for European bioclusters"; in: Results of NetBioCluE, INNOVA, 2008, p.10

32 COM (2008) 652: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0652:REV1:en:PDF

33 Towards world-class clusters in the European Union: Implementing the broad-based innovation strategy, COM(2008) 652

34 Towards world-class clusters in the European Union: Implementing the broad-based innovation strategy, COM(2008) 652.

35 http://proinno.intrasoft.be/index.cfm?fuseaction=page.display&topicID=87&parentID=0

36 http://proinno.intrasoft.be/index.cfm?fuseaction=page.display&topicID=512&parentID=511

initiative, the European Cluster Alliance (**ECA**)[37] was also founded in September 2006 as an important European initiative to foster cluster cooperation. It was conceived as an open platform, established to maintain a permanent policy dialogue at the EU level among national and regional public authorities, responsible for developing cluster policies and managing cluster programmes in their countries. The ECA is much more than just another cluster networking project. Since January 2008 the ECA has been open to external public cluster-relevant organisations in Europe willing to share experiences, and to develop joint activities with the other partners of the Alliance. Pro INNO also initiated a project named Transnational Alliance of Clusters Towards Improved Cooperation Support (**TACTICS**)[38] to support and further expand the ECA, and to contribute to the development of better cluster policies and practical tools in Europe. Striving for excellent clusters is aimed to be achieved by fostering international cluster cooperation, evaluating cluster excellence, and supporting cluster marketing and branding. Making better use of excellent clusters will be attained by using excellent clusters to address emerging industries, and by channelling RDI funding through them.

To improve the excellence of clusters and cluster organisations, The European Commission has also launched the European Cluster Excellence Initiative (**ECEI**)[39], which was started in September 2009. Cluster-Excellence.eu puts together the most experienced people and organisations in Europe, to identify and set up a meaningful set of quality indicators, and peer-assessment procedures for cluster management. The intention is to develop training materials and set up an approach for a higher quality labelling of cluster management. This will ultimately assist cluster managers in achieving higher levels of excellence in their duties, and to succeed in the peer-assessments. The peer review system for the labelling will allow a rapid scaling of qualified reviewers. Training materials will be licensed to all organisations or academic institutions wanting to engage in cluster management training.

The European Cluster Managers' Club and the **European Cluster Collaboration Platform** are modules in the framework of Cluster-Excellence.eu to promote excellence in cluster management. The European Cluster Collaboration Platform[40] was launched during the "European Cluster Conference 2010" on the 29th of September in Brussels, with the aim of providing information and services that enables an improved and more specifically targeted interaction between cluster organisations and their members. The objective is to improve their performance and increase their competitiveness through the stimulation of European and international cluster collaboration. The ECMC was launched parallel to this, on the same day to create an interactive forum for cluster managers, allowing them to gain inspiration and new ideas for their activities.

Advanced Biotech Cluster platforms for Europe (**ABCEurope**)[41] was established to reinforce the international dimensions of EU Biocluster cooperation inside- and outside the EU, to create a more efficient innovation support service for biotech companies (linking research, entrepreneurship and finance), and to strengthen the partnerships between EU bio-communities and the support for "result-oriented transnational cooperation". This same project then launched the European Biotechnology Cluster Managers Group.

In addition to the above mentioned initiatives financed under European Programme, the **Europa Intercluster**[42] association has been established as an independent initiative to promote synergies around high-value-added products and services, and thereby contributing to the emergence of several

37 http://www.proinno-europe.eu/eca

38 http://www.proinno-europe.eu/page/project-overview-4

39 http://www.cluster-excellence.eu

40 http://www.cluster-collaboration.eu

41 http://www.europe-innova.eu/web/guest/cluster-cooperation/cluster-innovation-platform/abceurope/about

42 http://www.intercluster.eu

European industrial projects. Cooperation between clusters can take place in the form of cooperation as the sharing of information, coordination and integration.

Our study was conceived with the aim of complementing and enlarging the European Cluster Excellence Initiative, and its related platforms by analysing CSFs and EPIs with a broader scope, including other important dimensions of biocluster success, such as industrial, scientific, financial, cultural, and supporting forces. The policy recommendations which are contained in this study would provide meaningful directions to policy makers for harmonising current actions of networks and platforms on a more consolidated approach, and to put in place strategic objectives and actions addressing the development of the CSFs, and of the economic development parameters to be collected for the reporting of the EPIs.

Rationale of the Study

Despite their major economic effects, the bioclusters' and bioregions' structure, creation, development, functioning and interconnectedness, as well as the various economic and political impacts affecting them, are not well understood as of yet. So far, several studies have been carried out on regarding some, or all, of these aspects of clusters in general, but only a few studies looked specifically at life sciences. Of these few, to our knowledge, none of them, however, have taken a fundamental approach by laying out the basic lines of a theory of regional biotechnology; and hardly any of them have aimed at analysing the phenomenon of regional biotechnology within a political context.

There is a clear need for policy-makers to have a greater understanding of regional biotechnology processes in order to be able to make the right political choices on how, and to what extent, these activities should be supported. The Commission has given a clear warning that indiscriminate proliferation of clusters in Europe will not have the desired outcome. Rather, policy should strive for excellence on all levels while fostering the life sciences sector to reach to the world class level[43].

In addition, scientists who may be called in for advice on this matter are lacking the tools and methods they would need to use. Therefore, policy-makers and their advisors need precise tools for biocluster assessment that they could apply to concrete cases. Although a broad range of tools do exist, their usefulness is still debatable in the absence of any generally agreed upon theoretical basis. Consequently, two advancements are needed: first, a useful theoretical basis of the concept; and second, a methodology from which tools can be derived to measure the performance of regional biotechnology entities.

Biocluster studies have, so far, almost exclusively focused on medical biotechnology clusters (or so called red biotech). Such a one-sided approach can be explained by the atypical nature of the non-medical biotech clusters, or by the scarcity of mature alternatives to this type of biocluster. As a result of what stated so far, the analysis of established clusters in the agro-food, energy, environment, marine biotechnology and industrial bio-processing areas in an adequate way is now pivotal. The contribution of biotechnology in the areas of food production, renewable materials, waste prevention and bioremediation to sustainable development has been discussed earlier [44] and the the rationale behind launching this study has been articulated by Zechendorf[45] earlier. These other types of biotech clusters are essential to support the activities crucial to the KBBE concept, and should indeed play a

[43] Towards world-class clusters in the European Union: implementing the broad-based innovation strategy, COM (2008) 652
[44] Zechendorf, B.(1999). Trends in Biotechnology: Vol 17, 219-225. Sustainable development: how can biotechnology contribute?
[45] Zechendorf, B. (2008) Regional Biotechnology: Establishing performance indicators for bioclusters and bioregions relevant to the KBBE area. The Concept. DG Research E – Biotechnologies, Agriculture, Food. Research Directorate General, European Commission.

key role in the realisation of the KBBE. The current study aims to provide an important contribution in this respect.

Given a number of objectives, the study consists of the following distinctive sections:

- Theory section;
- Methodology section;
- Policy-oriented section.

Study Design

Theoretical part

Within the theoretical part, the study focuses on cluster concepts and definitions that include:

- The concept of bioclusters;
- The concept of bioregions;
- The clarification of the definitions;
- The typology of bioclusters;
- The underlying reasons for clustering;
- The regional potential which is necessary to spur clustering;
- The impacts on clustering of the various scientific, economic and political factors;
- The networking phenomenon in both aspects, internal and external;
- The virtualisation of cluster development (virtual clusters);
- The three-level approach to regional biotechnology (biotech parks – bioclusters – bioregions).

The study builds upon existing renowned research with practical and useful outcomes in both the theoretical and methodology part. The employed theoretical models have been adjusted based on the observations and analysis performed in the project to better reflect the phenomena of the non-health clusters.

Methodological section

The methodological section of the study focuses on the identification and development of performance indicators for bioclusters by proceeding in several steps. The objective of this section is to develop a minimal set of relevant indicators from a selected set of bioclusters (called "model bioclusters"). The usefulness of these indicators is then demonstrated by applying them to a series of further model bioclusters used as test cases.

Life sciences cover a large range of fields dealing with many features of the biosphere (e.g. food, agriculture, environment, energy, materials, biological processes, molecular engineering, medicine, therapeutics). For that reason, establishing performance indicators applicable to all kinds of bioclusters implies that the selection of examples and test cases has to take into consideration a good balance between the different types of bioclusters. These clusters include those orientated towards agro-food, industrial biotechnology, marine, health and environmental activities, as well as industrial bio-processing and bioengineering. However, a strictly proportional representation was not enforced.

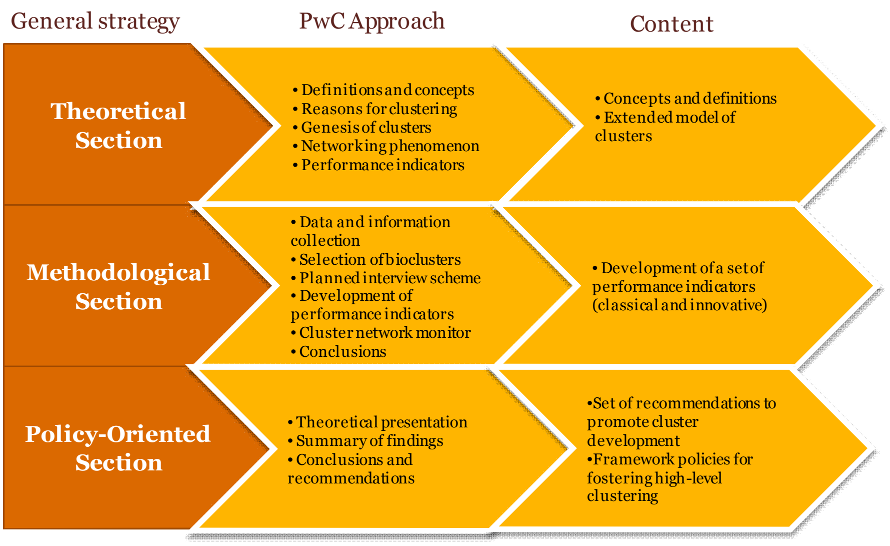
Policy-Oriented section

The policy-orientated section focuses on:

- Stating the identified problems of the bioclusters (based on the ones analysed);
- Establishing a set of evidence-based policy recommendations based on the gap analysis between the availability and importance of critical success factors;
- Suggested actions to be taken.

Figure 1 presents three main components of the study: Theoretical, Methodological and Policy-Oriented Sections.

Figure 1: Study design



The study employs *utilization-focused methodology*[46] that is oriented towards extracting rigorous evidence-based results. The utilization-focused methodology, first of all, implies the identification of the target population (stakeholders) of the study. This means locating the particular individuals who have a genuine interest in the study, and are willing to take the time and effort to cooperate with the research team. The task was to find people who are willing to share information relevant to the answers that the study needs to provide. Secondly, we engaged some of these stakeholders in different project stages rather than only in data collection stage. Stakeholders can often provide crucial insights and feedback that, when taken on board, results in significantly higher response rates and more rigorous data. For example, the stakeholder feedback was particularly important when designing a survey or an interview scheme. Furthermore, it was important for questions to be empirical, that is, answers should be based on data rather than values or judgments of individual respondents. After the data have been collected, a similar step takes place, in which stakeholders participate in interpreting the findings. The final steps in the methodology are for the research team to facilitate the intended use of the study results by the users, and to disseminate the findings to a larger group of potential secondary users. We are convinced that this approach is likely to result in a considerable added value for the Commission and for the bioclusters in Europe.

---

[46] Patton, Michael Quinn. 1986. Utilization-focused Evaluation. London: Sage; Patton, Michael Quinn. 1990. Qualitative Evaluation and Research Methods. London: Sage.

Theory

Theory

Definitions and Concepts

Life Sciences and Biotechnology

Life Sciences

Of great importance for this study are the definitions related to biotechnological activities and structures. It is vital to start with the definitions of *Life Sciences* and *Biotechnology* which are at the core of all other phenomena to be analysed.

There are many basic definitions of "Life Sciences" used by different investigators. They include the following**:**

- Any of several branches of science, such as biology, chemistry, medicine, anthropology, or ecology, that deal with living organisms and their organisation, life processes, and relationships with each other and their environment. It is also called *biosciences*.[47];
- Any of the sciences concerned with the structure and behaviour of living organisms such as biology, botany, or zoology.[48].

We will define Life Sciences as "the activities related to the study of living organisms, such as plants, animals and human beings, as well as the conditions and milieu of their life".

Biotechnology

In order to ensure the comparability of the results of this study with other research conducted internationally we will use the OECD definition of biotechnology.

Biotechnology is defined as "the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services".[49]

In certain contexts it may be useful to subdivide the formal definition of biotechnology according to specific activities. In this case a list-based definition of biotechnology will be applied. The list includes four general categories for nucleic acid, protein, metabolite, and cell related technologies, plus a fifth category for supporting tools. Some of these tools include a number of technologies. We are aware that due to a technological "convergence"[50] a strict separation may be somewhat artificial; however for the purpose of clarity we will observe a strict categorisation.

Many commercial entities analysed in this study can be described as biotech enterprises. We will use the following definition when referring to such entities:

---

[47] The American Heritage Dictionary of the English Language, Fourth Edition. (2003) Houghton Mifflin Company.

[48] Collins Essential English Dictionary, 2nd Edition. (2006) HarperCollins Publishers.

[49] OECD (2005) Biotechnology Statistical Framework. Paris.

[50] RAND (2006) The Global Technology Revolution 2020, In-Depth Analyses. Bio/Nano/Materials/Information Trends, Drivers, Barriers, and Social Implications. Silberglitt R., Anton P.S., Howell D.R., Wong A. (eds.) Santa Monica CA, accessed atwww.rand.org.

Biotech enterprises are "the organisations involved both in the research in the fields of Life Sciences and in the exploitation of the research results".

Biotechnology has evolved from a single set of technologies in the mid seventies (e.g. recombinant DNA technology) into the full grown economic activity of today. At first, new biotechnologies were applied for the development of pharmaceuticals, to enable the production of 'humanised' proteins contained in cells (as an alternative for the derivation of these proteins from animal tissue or plasma). These developments were led by several dedicated biotechnology firms that were much better equipped than traditional pharmaceutical firms to take up this challenge. Since the beginning of the 1990's, modern biotechnologies have been applied in the food sector, e.g. in the cheese making and agriculture. Currently, modern biotechnology has become the driving force of dramatic changes in innovation processes in many sectors (e.g. pharmaceutical, agriculture, food, animal healthcare, environment, renewable energy, industrial processes). Due to its pervasive nature, stimulating developments in modern biotechnology is considered to be highly important, as is the competitiveness of the European industry[51].

"Modern Biotechnology" can be defined as a collection of technologies, for instance genomics, proteomics, combinatorial biology and chemistry, and high-throughput screening, which cause a rapid advance in all the traditional life sciences, particularly in the pharmaceutical R&D process[52].

Biotech and Life Science Parks

There are a number of types of science parks in Europe and over the world. There is also not only one definition for science parks since each country has a different history of science parks and has its own terms. There is a range of existing definitions used by science parks to describe themselves, as well as political definitions used to describe science parks. We will restrict ourselves to use the definition of the International Association of Science Parks (IASP):

"A Science Park is an organisation managed by specialised professionals, whose main aim is to increase the wealth of its community by promoting the culture of innovation and the competitiveness of its associated businesses and knowledge-based institutions. To enable these goals to be met, a Science Park stimulates and manages the flow of knowledge and technology amongst universities, R&D institutions, companies and markets; it facilitates the creation and growth of innovation-based companies through incubation and spin-off processes; and provides other value-added services together with high quality space and facilities."[53]

The lowest common denominator seems to be that such parks gather producers of high technology products and services, and provide the opportunity for a degree of institutional co-operation between university and industry. The most commonly used definition for a Science Park in Europe is that of the UKSPA, the United Kingdom Science Parks Association, also used by the International Association of Science Parks (IASP)[54]:

A Science Park is a business support and technology transfer initiative that:

- Encourages and supports the start up and incubation of innovation led, high growth, knowledge based businesses;

[51] Europe INNOVA Sectoral Innovation Foresight:Biotechnology, July 2009

[52] Chiesa V., Chiaroni, D. (eds.) (2005) Industrial Clusters in Biotechnology: Driving Forces, Development Processes and Management Practices. London, Imperial College Press.

[53] International Association of Science Parks (IASP), IASP International Board, 6 February 2002, accessed at http://www.iasp.ws/publico.

[54] Regional Research Intensive Clusters and Science Parks, European Commission, 2007

- Provides an environment where larger and international businesses can develop specific and close interactions with a particular centre of knowledge creation for their mutual benefit;
- Has formal and operational links with centres of knowledge creation such as universities, higher education institutes and research organisations.

The critical factors to make the science parks successful are indicated as a strong scientific base; a supportive policy environment; effective networks; a skilled workforce; entrepreneurial culture; supportive services/large companies; growing company base; ability to attract staff; premises and infrastructure (e.g. incubators); and the availability of finance[55].

As presented in the proposal, the concept of biotech science parks was not used independently in this study, but rather to consolidate observations drawn on the clusters under analysis. Some of the bioclusters have developed around a science park structure such as the Saint-Hyacinthe Technopole in Canada analysed under model bioclusters. The list of major biotech science parks in Europe focusing on KBBE is provided in **Annex 1.**

Bioclusters

The work of Marshall on locational choice models and industrial districts pioneered research into agglomeration economies (clusters' predecessors) and only recently had such research been reinvigorated by Porter[56] and Enright[57]. Indeed, one needs to understand the mechanisms of innovation in order to either improve competitiveness of commercial companies or stimulate economic growth on a country-wide scale.[58] It is believed that both regional growth and innovation stem from agglomerations of various firms and organisations.

Thus, the successful establishment of an efficiently operating industry sector through value-added growth and an increase in employment take place within geographically localised networks – called "clusters". There are many formal definitions of clusters given by different authors.

Essentially, clusters can be considered as geographical concentrations of different players which simultaneously compete and cooperate within the same industry sector.

The genesis of clusters and their further development are complex processes and are often dependent on a number of players including governmental agencies, public organisations, academic, educational and research institutions, different types of cooperating companies, suppliers, providers, and financial structures.

Spatial clustering and regional innovation theories are reflected upon in a number of approaches from different schools of thought: endogenous growth theory, new economic geography, regional innovation systems studies, innovative milieus concept, etc.[59] A common opinion from all of these theories is that geographical proximity provides a platform for strong cooperation and the flow of knowledge and expertise. Particularly important for the transfer of tacit knowledge is the personal (direct) interaction had between research institutions, companies and policy makers. It is also widely believed that of crucial importance are the following two attributes:

- Institutional setting supporting entrepreneurial culture and innovation, and hence fostering start-up activities;

---

55 Regional Research Intensive Clusters and Science Parks, European Commission, 2007

56 Porter, M.E. (1990) The Competitive Advantage of Nations. Free Press, New York.

57 Enright, M. (1990) Geographic Concentration and Industrial Organization. Cambridge MA, Harvard University Press.

58 Organisation for Economic Co-Operation and Development, OECD (1999) Boosting innovation: the Cluster Approach. OECD Publishing, Paris.

59 Adapted from Bergman, E. (2001) In Pursuit of Innovation Clusters: Main Findings from the OECD Cluster Focus Group. Part A. Proceedings of the NIS Conference on Network- and Cluster-oriented Policies, Vienna, October 15-16.

- Defined market orientation of a cluster provided by overlapping competition and cooperation within the structure[60].

This makes regions possessing innovation clusters strategically advantageous in competition for mobile factors of production. It is, however, discussible under which conditions such cluster-based industries are capable of enhancing economic growth, and there is a variety of opinions on this subject among different researchers.

Different dimensions of a cluster have been described by different authors [61],[62, 63, 64] (reviewed in [65]):

- Spatially (predominantly regionally) concentrated economic activities in related economic areas, usually interconnected with the local scientific system (research institutions, universities, etc.);
- Vertical production chains: narrowly defined industries with the neighbouring activities of production process forming the core of the cluster. This also includes various groups around core enterprises;
- Highly aggregated groups of industries or high level agglomerations of sectors.

The latter dimension will be useful for the analysis of both "super-/megaclusters" and "virtual clusters".

In adopting a definition of a cluster for this study we have chosen a theoretical framework that would satisfy the following two criteria:

- It would address in full the functional structure of a cluster;
- It has already been proven functional in a recent study of biotechnological clusters.

With this in mind we will employ the theoretical framework previously developed successfully by the Cleverbio Project[66] funded by the European Commission.

A Cluster is "a geographical concentration of actors in vertical and horizontal relationships, showing a clear tendency of cooperating and sharing their competencies, all involved in a localised infrastructure of support".

The list of bioclusters evaluated in this study to choose the model bioclusters is given under **Annex 2.**

The number of bioclusters in Europe is growing rapidly. The list of major bioclusters in Europe as well as the ones in North America and Asia can be found in **Annex 3.**

---

[60] Broecker J, Dohse D, Soltwedel R. (2003) Clusters and Competition as Engines of Innovation – An Introduction. Broecker J., Dohse D., Soltwedel R. (eds.) Innovation Clusters and Interregional Competition. Berlin Heidelberg, Springer-Verlag.

[61] Enright, M. J. (1996) Regional Clusters and Economic Development: A Reasearch Agenda. In: Staber, U.H., Schaefer, N.V., Sharma, B. (eds) Business Networks. Prospects for Regional Development. de Gruyter, Berlin, New York.

[62] Jacobs, D. (1997) Wissenintensive Innovation: Das Potential des Cluster-Ansatzes. Institute for Prospective Technological Studies, IPTS Report 16, Sevilla.

[63] Markusen, A.R. (1996) Sticky Places in Slippery Space: A Typology of Industrial Districts. Economic Geography 72, 293-313.

[64] Porter, M. (1998) On Competition. Harvard Business School Publishing, Boston.

[65] Sternberg R. (2003) New Firms, Regional Development and the Cluster Approach – What Can Technology Policies Achieve? Broecker J., Dohse D., Soltwedel R. (eds.) Innovation Clusters and Interregional Competition. Berlin Heidelberg, Springer-Verlag.

[66] Chiesa V., Chiaroni, D. (eds.) (2005) Industrial Clusters in Biotechnology: Driving Forces, Development Processes and Management Practices. London, Imperial College Press.

World- Class Clusters

It seems like there are two types of cluster formations. For the first one known as "Area Cluster", Cluster is a matter of observation in the form of an ecosystem with a particular mix of innovation activities brought together by the proximity of businesses, research centres, and universities. In the second type referred as "Power Cluster", the cluster is a matter of action that is created by a pro-active endeavour either initiated by public authorities, or by local initiatives, which aims at eliciting cooperation between its members (business, universities, research centres) with the goal of promoting innovation. It is suggested that the attainment of world-class status may arise from the art of superimposing these two dimensions[67]. While the concept of Cluster is multifaceted, at the moment, a "world-class cluster" is in many ways an imprecise concept. Since there is not even a common understanding about cluster concept yet, it seems very difficult to agree on a harmonised definition of a WCC which could be accepted by the majority of cluster practitioners and policy makers. Thus, Europa Intercluster initiated the preparation of the White paper on the emergence of European WCC in 2009 and aimed to define specific criteria to describe WCC and to determine which kind of requirements should be fulfilled on the White Paper. Under three categories, 15 criteria have been defined as favourable conditions enabling the emergence of high performing clusters as indicated below;

1. Criteria for cluster framework conditions:
    - Quality of cluster sector relevant R&D;
    - Quality of the education in relevant fields;
    - Dynamics of creating new and innovative companies in the region;
    - Attractiveness of the region for high potentials and world-class researchers as well as for foreign investments;
    - Existence of innovation stimulating regulation and public sector demand.

2. Criteria for cluster actors:
    - Critical mass of market and technology leaders developing or manufacturing high tech products, components, applications (or processes) or providing innovative services;
    - International visibility and reputation of the cluster and its actors;
    - Commitment and active involvement of key actors (industrial, academic and public) in the cluster work;
    - Involvement of competitors;
    - Involvement of cluster actors in international co-operations and linkages to key actors outside the cluster.

3. Criteria for cluster organisations:
    - Cluster strategy and its implementation;
    - Professionalisation of cluster management services;
    - Sustainability of financing and appropriate staffing of the cluster organization;
    - Coherence between educational actors, R&D institutions and cluster actors;
    - Added value.

[67] White Paper: The Emerging of European World –Class Clusters, 2010: http://www.intercluster.eu/images/stories/white_paper/white_paper_the_emerging_of_european_world_class_clusters.pdf

Bioregions

As mentioned in the Concept Paper on Regional Biotechnology[68], the term "region" has different and diverse meanings in different EU Member States and in our opinion even more so internationally. Therefore, for the purpose of this study we will follow the definition of the bioregion proposed by the EC. Thus, a bioregion will be defined as:

"Any geographically meaningful entity which can, but has not necessarily to, be a political or administrative entity for which the promotion of biotech and/or Life Sciences has been defined as a priority. Such a bioregion can, but need not, contain one or several bioclusters and biotech/bioscience/Life Sciences parks, which are supposed to interact in order to enhance their efficiency. A bioregion may [also] reach across political borders".

In contrast to the definition of the Concept Paper, our proposed definition of the bioregion does not include, nor is it equal to, the concepts of "supercluster" and "megacluster". A bioregion is stated to be always smaller than a complete country, but may include parts of neighbouring countries.

Our opinion also corresponds to that of the authors of the above mentioned Concept Paper that "biotech or Life Sciences activities inside a politically defined region do not automatically qualify for the label 'bioregion', unless they are attaining a threshold defined by the quantity and quality of the interactions between the different players, and which might enable the region to become competitive in this field." We will follow this extended definition in the research to be conducted within the framework outlined by this proposal.

Within the scope of the study we will further investigate the concept of bioregions, and will summarise the differences in their definitions within the EU Member States, as well as in other biotechnologically active regions in North America and Asia. Firstly, this will allow the examination of the clusters to be studied within a broader political and legal context, and secondly, this will enable identification of common data points that may be crucial for the future analysis of cluster activities by the Commission.

A detailed overview of the three bioregions covered under this study (BioValley in CH, DE, FR; Medicon Valley in SE and DK; Flanders Bioregion in Belgium) can be found in **Annex 4.**

[68] Zechendorf B., DG Research E. (2008) Regional Biotechnology: Establishing performance indicators for bioclusters and bioregions relevant to the KBBE area. The Concept. Directorate E – Biotechnologies, Agriculture, Food. Research Directorate General, European Commission.

Superclusters and Megaclusters

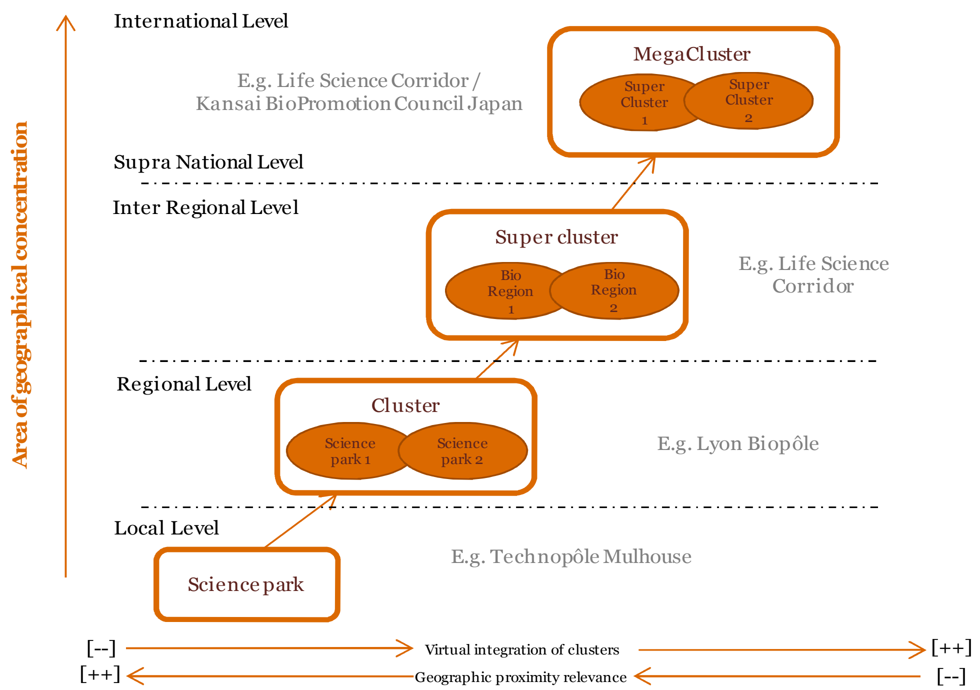
As mentioned above (see bioclusters), the third dimension of clusters described in the literature on clustering includes highly aggregated groups of industries or high level agglomerations of sectors.[69] Such high order organisation of clusters can cross regional and national borders and may also exist between clusters on different continents being geographically separated in space.

In this study we will use the following definition:

"Superclusters" are the clusters crossing regional borders, and "megaclusters" are supranational clusters crossing country borders.

We will use the following model to chart the importance of the agglomeration activities in the formation of super- and megaclusters (figure below). It is also important to note that this model is simplified, as the existence of all the elements in the agglomeration chain is not essential to achieve a higher order association.

Figure 2: Model of the agglomeration of association activities



[69] Sternberg R. (2003) New Firms, Regional Development and the Cluster Approach – What Can Technology Policies Achieve? Broecker J., Dohse D., Soltwedel R. (eds.) Innovation Clusters and Interregional Competition. Berlin Heidelberg, Springer-Verlag.

Reasons for Biotech Clustering

The formation of clusters may lead to momentous advantages for firms. A strong demand in the location, a large supply of qualified labour force, and the use of networks and expertise of neighbouring firms may all provide significant advantages. Especially in hi-tech industries, geographical proximity was described to play a central role in the early stages of the life cycle of a product (or technology), assisting the transfer of tacit knowledge between individual actors.

Porter[70] has described three advantages of clustering: (1) productivity advantages; (2) innovation advantages; and (3) new business advantages. Productivity advantages arise possibly due to better and cheaper input (components or services). They occur because of reduced inventory requirements and lower purchase prices due to closeness and functional relationships based on trust between companies within the cluster. Also joint operation and maintenance of shared infrastructures (especially, in the case of hi-tech facilities) significantly reduce fixed costs for participating companies, as well as required volumes of start-up investment for new businesses. Close proximity between customers and suppliers promotes the transfer of tacit knowledge, hence boosting innovation. This is particularly the case for the so-called pre-competitive operations – the fundamental research. Moreover, localized research within the cluster and the availability of a qualified labour force can significantly contribute to innovation. An improved exchange of information about the market opportunities and general situation, reduces the risks for the new firms, and improves awareness of the unfilled needs.

Impact of virtual clustering

Firms within the cluster have been found to benefit from the presence of high quality local internet access. It can enable more flexible work arrangements and lowers the cost of firms supporting distributed workers that need to collaborate.

Connection to a global ICT infrastructure like the internet benefits clusters by improving access to distant markets without harming internal cluster dynamics. It may promote cluster innovation by facilitating the transfer of technology from distant markets to firms in the cluster, which can then diffuse through informal channels even when firms in the cluster have little trade with each other. Smaller firms in clusters may be able to benefit from ICT infrastructure investments, despite a common finding that they are less likely to gain from technology innovations. In new knowledge-intensive clusters, an important use of ICTs is to help promote and maintain cluster brand identity, as well as to facilitate information sharing within the cluster. [71]

Genesis of clusters: Regional potential necessary to spur clustering

It is thought that technology policies stimulate cluster development, and clusters then support regional growth. Unlike large companies, start-ups are considered to be vital for regional development due to their relative spatial immobility. According to Sternberg[72] and others, the emergence and development of clusters (either as a result of directed policies or not) is a consequence of an enduring entrepreneurial environment that supports appearance of start-ups and fosters their growth. Moreover, for the technology and knowledge-based clusters such an environment is considered to be of even greater importance. This entrepreneurial environment can be supported by various national or local technology policies.

---

[70] Porter, M. (1998) The Adam Smith address: location, clusters, and the "new" microeconomic competition. Business Economics 23 (1).

[71] http://www.dest.gov.au/NR/rdonlyres/194EF998-BF98-40BA-8269-8210A8C410F7/1361/clusters.pdf (p.9)

[72] Sternberg R. (2003) New Firms, Regional Development and the Cluster Approach – What Can Technology Policies Achieve? Broecker J., Dohse D., Soltwedel R. (eds.) Innovation Clusters and Interregional Competition. Berlin Heidelberg, Springer-Verlag.

The concept of a cluster first appeared in the works of Marshall[73]. Many researchers since then have extended the concept, and proposed numerous theories that would explain their development. A considerably more articulate summary of factors important for clustering was given by Sternberg et al.74 This research group has emphasized many of the already mentioned factors in the context of the development of hi-tech regions. These include: (1) government policies (with explicit regional goals); (2) federal R&D expenditure (with implicit regional impact); (3) technology policy of the region (with explicit regional goals); (4) public demand for technology-intensive new products (especially military demand); (5) amenities (e.g. environment, culture, living conditions, etc.); (6) research and educational infrastructure (and, therefore, availability of qualified labour); (7) Innovation Centres and, Science Parks; (8) availability of large enterprises and their attitude towards small and young technology-oriented firms, also intraregional production networks; (9) role of key persons; and (10) decentralization processes in large agglomerations.

Three location factors have been underlined to be particularly advantageous for the development of specific hi-tech industries[75]. The first is the availability of large enterprises, important for a particular sector of industry. Such enterprises are often not only suppliers, but also customers from smaller firms. The second factor is a considerable regional demand potential for the products of a particular industry. The third, and particularly important prerequisite, has been defined as the availability of a highly qualified workforce. Thus, every knowledge-based industry is argued to be dependent on the quality of educational facilities and/or the attractiveness of the region as a living location. Due to a positive location image, workers and especially scientists may be attracted from other regions. Localized labour markets provide pools of highly skilled workers and these, together with universities and public laboratories, anchor graduates and others in the locality, diffusing both highly-skilled labour and technical knowledge to local firms[76].

The Cleverbio project underlined the importance of many of these factors for biotechnology clusters, focusing further on regional models of clustering[77]. Key features of a cluster were defined as: (1) formal input-output relationships; (2) buyer-seller linkages; (3) geographic concentrations of firms; and (4) shared specialized infrastructure.

The following factors have been identified as being of crucial importance in each biotech cluster:

- Science base: implementation of results of scientific research (exploitation mechanisms)
- Industrial base: implementation of results of industrial research activities (exploitation mechanisms);
- Financial base: presence of funding agencies and availability of funds aimed at new hi-tech companies;
- Support base: presence of a positive and supportive general environment (normative, social, historical and infrastructural context).

---

[73] Marshall A. (1920) Principles of Economics. Macmillan, London, 8th Edition

[74] Sternberg, R. (1996a) Reasons for the Genesis of High-Tech Regions - Theoretical Explanation and Empirical Evidence. Geoforum 27 (2), 205-224.

[75] Sternberg, R., Tamásy, C. (1999) Munich as Germany's No.1 High Technology Region - Empirical Evidence, Theoretical Explanations and the Role of Small Firm/Large Firm Relationships. Regional Studies 33 (4), 367-377.

[76] Appold S.J. (1998) Labor-market imperfections and the agglomeration of firms: evidence from the emergent period of the US semiconductor industry. Environ. Plann. A 30, 439- 62.

[77] Chiesa V., Chiaroni, D. (eds.) (2005) Industrial Clusters in Biotechnology: Driving Forces, Development Processes and Management Practices. London, Imperial College Press.

Cluster typologies

Even though the process of its birth and development, the clusters examined vary markedly from case to case, which can be categorised under three different typologies [78]:

1) Spontaneous clusters: genesis is based on a spontaneous agglomeration of key enabling factors without direct commitment of public actors: this is mostly seen in the US and the UK. The factors that played a role in the appearance and enlargement of spontaneous clusters are:

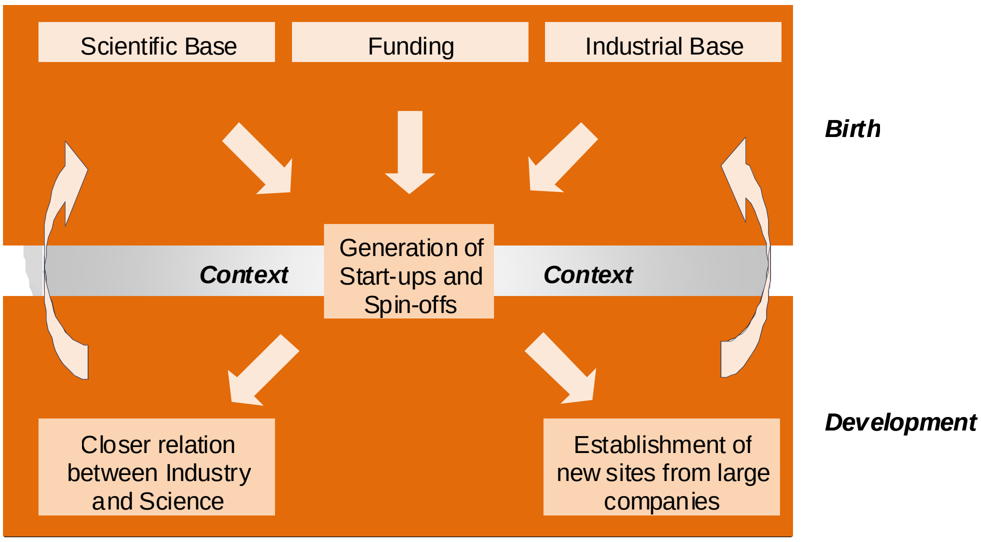
   - Availability of the strong scientific base;
   - Effective exploitation mechanisms of scientific research, especially by means of effective technology transfer mechanisms and a strong diffusion of the entrepreneurial culture among scientists and researchers;
   - Existence of multiple innovative funding mechanisms (e.g. seed funds, angel capital, venture capital, etc.);
   - The presence of a well-defined legal framework (e.g. Cambridge/UK).

2) Policy-driven clusters: formation is a consequence of active efforts and policies of governmental agencies aimed at cluster development. The types of policies that are usually implemented can be divided into:

   - Industry restructuring policies: emerge as a reactive response to an industrial crisis;
   - Industry development policies: applied for a focused establishment of an industry sector.

3) Hybrid clusters: where the features of both of the above types are observed (e.g. San Diego/US).

Figure 3: The forces behind cluster expansion[79]



[78] Chiesa V., Chiaroni, D. (eds.) (2005) Industrial Clusters in Biotechnology: Driving Forces, Development Processes and Management Practices. London, Imperial College Press.

[79] Chiesa V., Chiaroni, D. (eds.) (2005) Industrial Clusters in Biotechnology: Driving Forces, Development Processes and Management Practices. London, Imperial College Press.

Biocluster Lifecycle

As with every social system, clusters experience birth, growth, decline and death, as shown in Figure 4,as described by Sölvell in the Red Book of Clusters[80].

Birth of a Cluster: Emerging Phase

The emergence of a cluster in a particular location can be explained in one of two ways. One type of explanation refers to a natural factor advantage, such as that of a particular climate, soil, ore deposit, forest resource, transportation route or port. In the modern economy, the university often plays the role of the "brain trust" on which emerging clusters thrive. A second type of explanation has to do with historical accidents, where an entrepreneurial person in a particular location who happened to start a business, which in due time led to increasing local demand, new firm formation, spin-off firms and so on, and ultimately to a cluster. Once the cluster reaches critical mass and starts to grow, there is often a strong cumulative process, or path dependence, that locks in the cluster. In order for clusters to grow and prosper, many ingredients are needed, including demand sophistication, factor upgrading and specialisation, emerging strategies of competition and cooperation, institutional conditions favouring innovation and change, political actions, etc. Many clusters have an identifiable "hero".

Growth of a Cluster: Development Phase

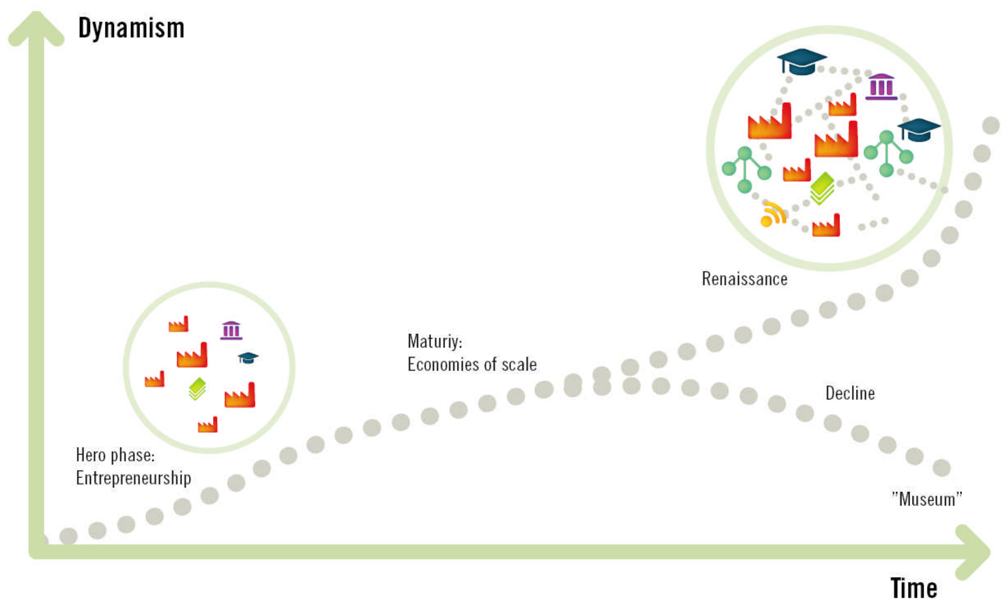
In some cases, an emerging cluster is built around many small firms, competing on one hand while cooperating on the other. In other cases, a cluster is dominated by one or a few large, so-called anchor firms, as was the case with Hybritech in San Diego. In addition to the emergence of new entrants and the addition of new strategies, cluster growth involves networking and emerging social capital. If the cluster is to grow, the more general social capital within a region must expand via formation of cluster-specific networks. If the right circumstances are present (rivalry, cooperation, openness to international markets, lead customers, etc.), the cluster will interact with labour markets and universities to enhance factor specialisation and upgrading, and increase demand sophistication. When all four drivers begin to interact through upstream and downstream linkages, a larger cluster will emerge. It is difficult to detect any particular sequence in the different drivers of cluster evolution at this stage. Many clusters clearly originate from factor advantages such as natural resources or particular skills, but again, some peculiarities in local demand might constitute the initial ground.

Clusters exhibit different evolutionary patterns. The general success factors include the existence of massive university research; clear and supportive legislation on technology transfer (e.g. the Bayh-Dole act or "University and Small Business Patent Procedures Act" of 1980 in the USA dealing with intellectual property arising from federal-government funded research); favourable economic conditions (e.g. high deal flows); attractiveness of the location to attract the highly skilled workforce from all around the world and keep them in-place; and the availability of venture capital. A multitude of linkages across institutions, as well as knowledge transfer between public and private entities, and the commercialisation of new knowledge, have all been observed as important factors in the growth of clusters. The ease in the mobility of scientists and experts from academia and industry also plays a critical role. VCs offer money, but more importantly, they offer skills and close monitoring (close proximity). Policy and evolution of cluster-specific institutions also play a role. Cluster growth takes place within a particular political setting. Regulations and political actions range from antitrust, regional policies, industry policies, and science and innovation policies, including patents and IPR (e.g. rules for how to share license fees between researchers and the university). More general framework policies affect the overall attractiveness of a region (e.g. housing, transportation, recreation

[80] Clusters Balancing Evolutionary and Constructive Forces, Örjan Sölvell, January 2009, Second Edition (http://www.cluster-research.org/dldocs/ClustersJan09.pdf?bcsi_scan_24DE0A96D2B59F70=1)

and culture) to people as well as to companies (e.g. land, investment attraction packages, skilled people, running and labour costs etc). For a cluster to continue to prosper, it needs an inflow of people with different skills, inward investments (FDI and VC), imports of materials, components and products, and new technologies. Both people and firms must be attracted to the cluster. Conversely, the cluster must reach out to international markets (outward FDI, exports etc.). Dynamic clusters experience a circulation of ideas, skills and resources, including "brain" circulation.

Figure 4: Presentation of Cluster Lifecycle



entrepreneurship, social capital, strong linkages to international markets, and a portion of good policy. Unfortunately, this is not sustainable in the long term. Some clusters experience a rather short life cycle before they decline, whereas others survive for centuries. Established clusters typically enter a more static phase at some point, including concentration into fewer firms through mergers and acquisitions and sharply declining rates of entry of new firms. This phase is characterized by efficiency and economies of scale.

The Demise of Clusters: Declining Phase

At some point clusters ultimately "die", and often a museum is the only remnant.
The decline of a cluster is generally caused by:

- Excessive concentration;
- Lack of private investment and mainly government involvement in saving and subsidizing companies;
- Radical technological shifts originating from other locations;
- Radical shifts in demand at other locations;
- War and other extreme circumstances.

Performance Indicators for Clusters

Bioclusters represent a complex system, where small firms, start-ups, large companies, universities, hospitals and research centres, as well as industrial associations and public institutions interact and evolve in a unique way. In management literature, a cluster has often been compared to a "living" ecosystem, whose growth is ensured not only by the growth of each actor but also by the fact that their growth is "simultaneous", i.e. every actor (organ) follows stage by stage the development of the whole system (living organism).[81] Understanding this complexity would therefore be crucial when measuring cluster performance, as clusters are multi-faceted. Measuring one or two dimensions of a cluster would provide a limited picture and is likely to miss important aspects of performance.[82]

Performance measurement of clusters can be viewed from different perspectives. First of all, cluster performance can refer to various economic effects such as employment growth, wealth creation and innovation (i.e., *outcome/effect-related* indicators). On the other hand, cluster performance may also include *process-related* activities like, for example, frequency of interaction within and between clusters, number of leading research organisations involved, and level of commercial awareness and entrepreneurship within a cluster. The second group of performance indicators refers to the critical success factors that need to be present in order to achieve economic cluster performance (measured using the first group of performance indicators) as shown in Figure 5.

Measuring only one of these two groups of performance indicators would provide policy-makers with a limited perspective. For example, looking only at economic cluster performance would allow for the comparison of clusters according to their level of success (i.e. how successful these clusters are in terms of creation of employment, wealth and innovation). However, this approach would not provide sufficient explanation for the reasons behind the differences in performance of those bioclusters whereas looking also at the critical success factors would provide valuable insights into the organisation of clusters, and thus *explain* the difference in performance. Furthermore, the latter group of indicators is expected to allow a projection of the cluster performance in the future.

However, considering only the last group of indicators would imply a lack of information regarding actual cluster performance. Therefore, a combination of both approaches needs to be applied. It is important for policy-makers to know both whether interventions adopted to improve cluster performance have achieved their intended goals and what the reasons are behind such cluster performance.[83]

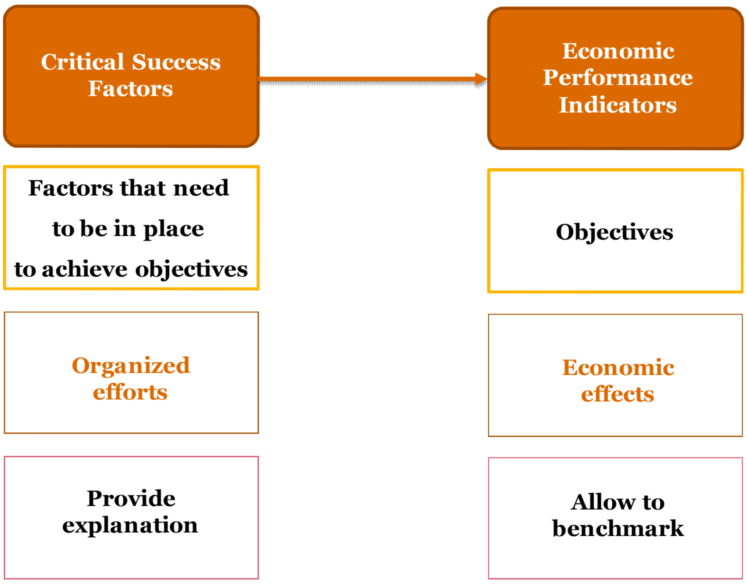
The ***Critical Success Factors (CSFs)*** thus refer to the contextual factors and process-related cluster performance indicators. The examples of critical success factors include networking and entrepreneurial culture, scientific base, presence of cluster organisations and other supporting structures. As a result, these critical success factors are often considered enablers rather than direct indicators of cluster performance. However, understanding the nature of the critical success factors and their link to the economic cluster performance is crucial for targeted policy initiatives and activities of cluster organisations.

[81] Do's and don'ts for biotech cluster development: the results of NetBioCluE (2008). NetBioCluE report

[82] A Practical Guide to Cluster Development. A Report to the Department of Trade and Industry and the English RDAs by Ecotec Research & Consulting

[83] A Practical Guide to Cluster Development. A Report to the Department of Trade and Industry and the English RDAs by Ecotec Research & Consulting

Figure 5: Distinction between two types of indicators



The ***Economic Performance Indicators (EPIs)*** include the direct indicators of cluster performance, and allow for the assessment of cluster success. These indicators refer to the dimensions of innovation, employment and productivity.

Figure 6 presents the conceptual framework employed by this study that is partly based on the normative model of a cluster adapted from Chiesa and Chiaroni (2005)[84].

Recent research by Porter (1998), Audretsch (1998), Krugman (1998), and Best (1999, 2000) confirms the earlier insights of regional scientists like Scott (1993); Saxenian (1994); Storper (1995); Florida (1995); Amin and Thrift (1994); Asheim (1996); Cooke (1995); Braczyk, Cooke, and Heidenreich (1998), and Cooke and Morgan (1998), that clusters offer key competitive advantages with respect to three key competitive variables: productivity, innovation and employment. Productivity is enhanced by lowering transaction costs and untraded interdependencies. Innovation is dependent on an interactive knowledge exchange between varieties of knowledge actors. Employment resulting from new business formation is aided immensely by the mentoring, role-model provision, learning, communication, and commercialization gains that arise from operating in a cluster setting.[85] These reflections are illustrated in the Table 3 below. All three dimensions for analysing economic cluster performance of bioclusters are employed for the needs of the current study.

[84] Chiesa V., Chiaroni D. (2005) Industrial Clusters In Biotechnology: Driving Forces, Development Processes And Management Practices. Business & Economics, 225 p.

[85] Cooke P. (2002) Biotechnology Clusters as Regional, Sectoral Innovation Systems. International Regional science Review 25 (1), 8-37.

Figure 6: Key driving forces of a biotech cluster

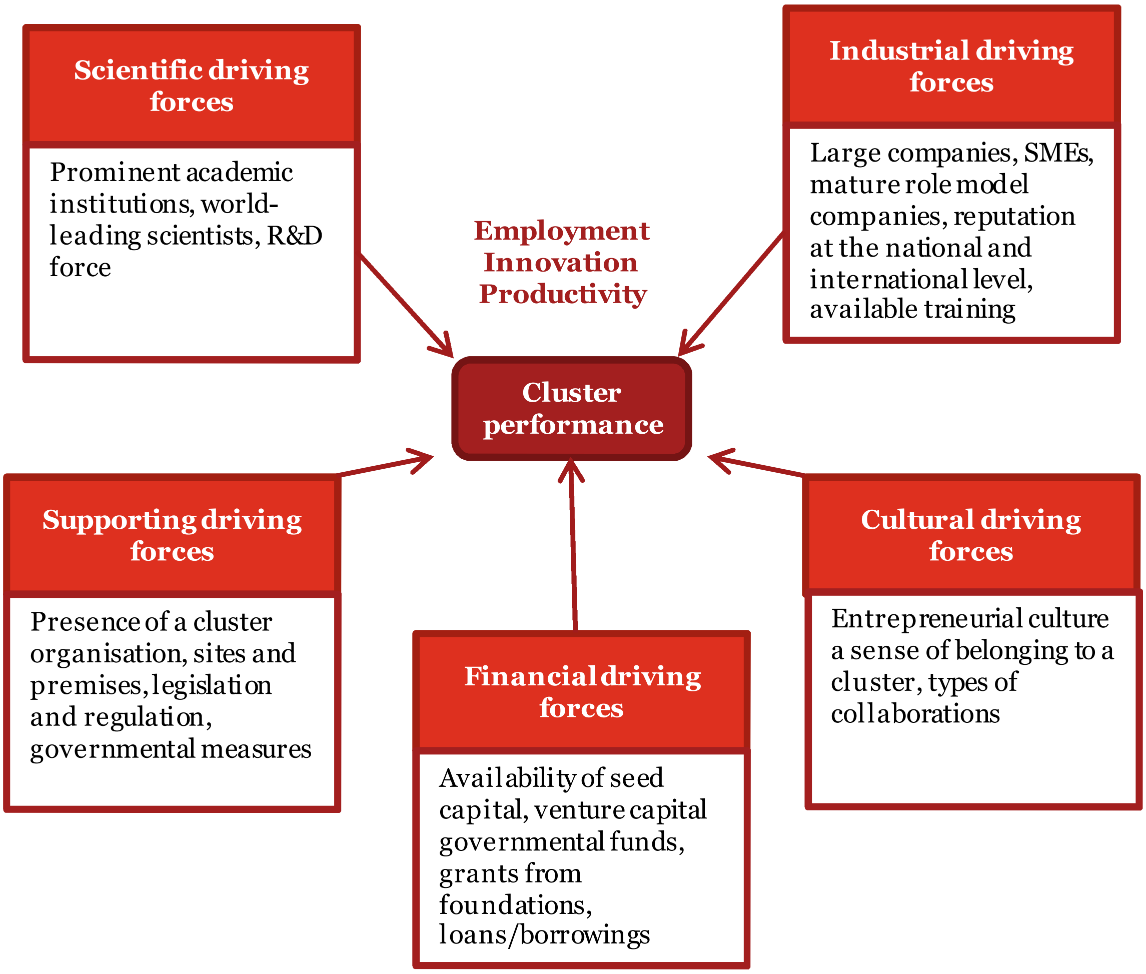


Table 3 - Economic Performance Indicators for biotechnology clusters

Cluster performance	Short description	Indicators	Data source
1. Employment	Employment growth is one of the key indicators of cluster performance. However, data limitations restrict the use of employment data to evaluate clusters.	Total employment in a cluster Employment growth (in terms of absolute number and percent increase) Funds raised by biocluster	European Cluster Observatory Interviews with cluster organisations and other cluster representatives Transaction databases
2. Innovation	There are quite strong indications that clusters foster the innovative activities of firms. Innovation is a highly complex and heterogeneous concept. Therefore, measuring innovation is challenging. Multiple indicators are used for measuring innovation.	New or significantly improved technologies New or significantly improved products and services No. of granted patents No. of registered trademarks No. of newly created spin-offs	Patent databases Product portfolio offered by cluster organisations Annual reports of cluster organisations Interviews with cluster organisations and other cluster representatives Community Innovation Survey
3. Productivity	Productivity as a measure of output per unit of input allows assessing which clusters make best use of scarce resources like capital and labour. Using productivity as a key indicator allows identifying those clusters which are best capable of using resources efficiently for creating value for their customers.	Turnaround per unit of labour Wages per unit of labour (wages/number of hours worked) relative to the average regional wages	Annual reports of cluster organisations Community Innovation Survey Interviews with cluster organisations and other cluster representatives

Methodology

Methodology

The current section describes the methodology used to determine the Performance Indicators examined under Critical Success Factors ((CSFs) and Key Economic Performance Indicators KPIs). The methodology was initially developed based on a rigorous desk-study research and expert opinions. The methodology was developed by using two sets of bioclusters and bioregions. The selected bioclusters included various examples of biotechnology clusters including red, green, white and blue biotech. We began our analysis with examples mainly taken from the red biotech clusters, as this group of clusters is particularly well-developed and were likely to provide valuable insights into the relevant performance indicators. Having built a solid theoretical and empirical base, we then continued our analysis by looking at examples of other biotech clusters such as green, white and blue biotechs. Finally, a two-stage validation procedure was applied to ensure the robustness, reliability and feasibility of the methodology.

Main steps of the Methodology Section

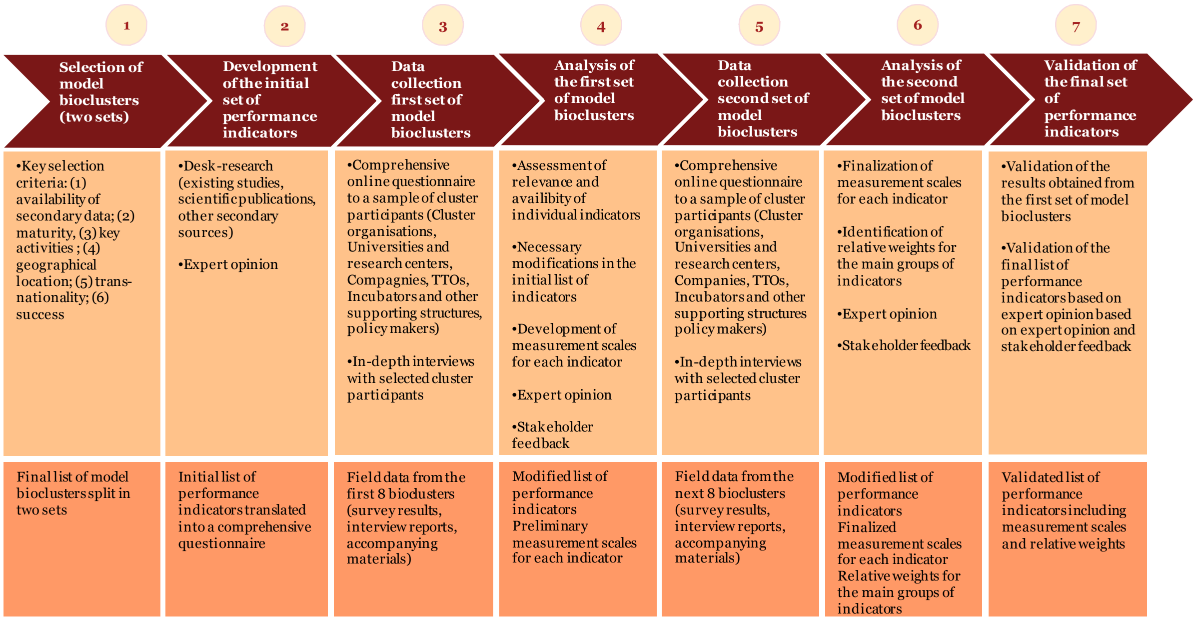
Figure 4 presents seven main steps of the Methodology Section. Those include:

- Selection of model bioclusters (two sets);
- Development of the initial set of performance indicators;
- Data collection from the first set of model bioclusters;
- Analysis of the first set of model bioclusters;
- Data collection from the second set of model bioclusters;
- Analysis of the second set of model bioclusters;
- Validation of the final set of performance indicators.

The figure also shows the main activities performed during each of those stages, as well as the key deliverables resulting from each stage. The remainder of this section contains detailed descriptions of each of these stages, as well as the main findings from both sets of model bioclusters.

The figure also shows the main activities performed during each of those stages, as well as the key deliverables resulting from each stage. The remainder of this section contains detailed descriptions of each of these stages, as well as the main findings from both sets of model bioclusters.

Figure 7: Main steps of the Methodology Section



Selection of Model Bioclusters

Given the large number of factors influencing biocluster growth and success, and the potential problems of limited data-availability in some of the clusters, we tried to incorporate a maximum number of clusters to be included in the sample according to the terms of reference, i.e. 16 bioclusters. In this sub-section, we present our approach towards the selection of model bioclusters. Even though the red biotech clusters are not considered as KBBE[86] clusters by the EC, in the context of this report, the KBBE will include health applications, and where these are excluded, we use the term "non-medical KBBE".

The list of all potential bioclusters with evaluation criteria, including those not chosen is given in **Annex 2**.

Selection criteria

The model bioclusters have been selected according to the following inclusion criteria:

1. **Maturity**: Both well-developed and developing bioclusters were included. The first round was mostly composed of mature clusters due to the nature of the red biotech;
2. **Availability of secondary data**: To draw networking parameters, to identify the maturity of cluster, to identify potential interview partners and to prepare the interviews, it was necessary to gather a basic set of secondary cluster data from defined resources. Secondary data was selected which described the basic structure, main stakeholders and organisations, the geographical dimension, the political and policy background or the history of the biocluster;
3. **Key-activities**: Originally, it was aimed to have a well-balanced distribution between health (red biotech) and non-health (green, white, and blue biotech) KBBE activities in the chosen

[86] KBBE = Knowledge-Based Bio-Economy. The areas comprised by the EC are: agriculture, food, fisheries, forestry, industrial, marine and environmental biotechnology

model bioclusters. However this aim has been reached only to some extent. This can be attributed to the fact that the bioclusters focusing on health applications (red biotech) are the ones heavily represented (approx. 80%) among all others and due to its relatively long history, most of them have already reached the mature level. Subsequently in agreement with the EC, the critical success factors were decided first to be investigated and identified on mature bioclusters that were mostly involved in healthcare applications during the first set of 8 biocluster analyses. Then it was followed by the second set of 8 bioclusters predominantly focusing on "non-medical KBBE" that were industrial, agro-food, agro-environment, bio-energy, and to lesser extent marine biotech applications to verify the CSFs generated during the first set. During our screening procedure to choose model bioclusters for analysis, we observed that it was a common practice to see mixed cluster structures rather than pure ones focusing on one sector only and red biotech was mostly involved in almost all other biocluster structures at different levels. For instance, the bioclusters chosen in the US and Japan as a representative of white and green, respectively, were also heavily involved in red biotech. However, positively, this selection allowed us to make a better comparison on health bioclusters between the EU, the USA and Japan (some relevant key information is also collected from Canada even though the cluster chosen itself was not involved in red, though the region is). Likewise, the US cluster considered as "blue" is actually found to be less developed in blue than in red and white biotech during our analysis. In summary, since blue biotech applications are still in their infancy stage, it has proved difficult to collect relevant information through these limited cluster selections;

4. **Geographical location**: In the first model set, bioclusters from different parts of Europe were examined. In the second set, bioclusters from the USA, Canada, and Japan were included alongside additional clusters in Europe for comparison between Europe and non-European countries;
5. **Transnationality**: Two transnational bioclusters were analysed during the first set, namely BioValley (between bioregions Alsace/FR, Freiburg/DE, and Basel/CH) and Medicon Valley (Sweden-Denmark);
6. **Success**: Biocluster success was examined along all three relevant impact parameters: economic, political and scientific. Both well performing and less well-performing bioclusters were chosen to enable the identification of success indicators along all of these axes.

For the final selection, pre-selected bioclusters have been contacted for a pre-interview. In this interview we checked the following aspects:

- Presence of a central (data-) office/cluster organisations;
- Willingness to participate in the study;
- Information/data availability.

Based on these interviews, the selected initial set of bioclusters was ranked according to on the feasibility of gathering the requested data, bringing us to the final set of 16 investigated bioclusters as listed in Table 4 and 5 below.

Table 4 - List of eight bioclusters analysed during the first set

#	Bioclusters in the first set	Region (country)	Data availability	Maturity	Trans Nation ality	Main focus areas
1	Munich Biocluster	Europe (Germany)	High	Mature	No	Biomedical/ Pharmaceutical, Agro-food
2	Cambridge Biocluster	Europe (UK)	High	Mature	No	Biomedical/ Pharmaceutical
3	Paris Genopole Cluster	Europe (France)	High	Mature	No	Biomedical/ Pharmaceutical
4	Medicon Valley	Europe (Denmark-Sweden)	High	Mature	Yes	Biomedical/ Pharmaceutical, Agro-food, Environment
5	Oslo Teknopol	Europe (Norway)	High	Mature	No	Biomedical/ Pharmaceutical, Marine, Environment, Energy
6	BioCat	Europe (Catalonia/ Spain)	Medium	Emerging	No	Biomedical/ Pharmaceutical, Agro-food
7	Biotech Umeå	Europe (Sweden)	High	Developing	No	Biomedical/ Pharmaceutical, Agro-food
8	BioValley Cluster	Europe (France, Germany , Switzerland)	Medium	Mature	Yes	Biomedical/ Pharmaceutical

Table 5 - List of eight bioclusters analysed during the second set

#	Bioclusters in the second set	Region (country)	Data availability	Maturity	Trans Nation ality	Main focus areas
1	Upper Austrian Food Cluster	Europe (Austria-Linz, Province of Upper Austria)	Medium	Developing	No	Agro-food, Agro-environment
2	Ghent Bio-Energy Valley	Europe (Belgium-Ghent, Flanders Region)	Medium	Developing	No	Bio-energy
3	Industries & Agro-Resources (IAR)	Europe (France-Champagne-Ardenne, Picardie)	Medium	Developing	No	Agro-food, Bio-energy
4	Food Valley Wageningen	Europe (Netherlands)	Medium	Developing	No	Agro-food
5	Bioval - Valencian Biotechnology Cluster	Europe (Spain-Valencia region)	Medium	Emerging	No	Agro-food, Environment
6	Hokkaido BIO Industrial Cluster Forum	Asia (Hokkaido region- Northern Japan)	Medium	Mature	No	Agro-food, Biomedical / Pharmaceutical
7	San Diego -Biocom Cluster	USA-South California	High	Mature	No	Biomedical/ Pharmaceutical, Clean technology
8	Saint-Hyacinthe Technopole	Canada-Quebec	High	Mature	No	Agro-food, Agro-environment, Biotechnology

Data Collection

Data collection from the first set of model bioclusters implied launching a comprehensive online questionnaire to a sample of cluster participants from eight model bioclusters. The approached stakeholders included representatives of cluster organisations, universities and research centres, companies (large, medium and small, including start-ups), TTOs, incubators and other supporting structures, as well as policy makers. The objective of the questionnaire was to collect both general and specific insights from biocluster representatives with regard to the performance of regional biotechnology entities. The questionnaire aimed at collecting data that would allow us to measure cluster performance, as well as to identify which factors contribute to success of bioclusters, what the barriers might be for further development, and how these barriers might be overcome in the future. This data collection tool was complemented by a series of in-depth interviews with selected cluster participants. The main objective of those interviews was to collect accompanying information with regard to the survey responses that would allow for developing detailed measurement scales for each indicator, as well as to collect opinions and suggestions with regard to the list of suggested performance indicators. The main deliverable of this stage of the research refers to a structured dataset collected from the first eight model bioclusters, including survey results, interview reports and accompanying materials.

Data collection from the second set of model bioclusters implied launching a revised comprehensive online questionnaire to a sample of cluster participants from eight new model bioclusters. The approached stakeholders again included representatives of cluster organisations, universities and research centres, companies (large, medium and small, including start-ups), TTOs, incubators and other supporting structures, as well as policy makers. The objective of the questionnaire was to collect both general and specific insights from biocluster representatives with regard to the performance of regional biotechnology entities. This data collection tool was again complemented by a series of in-depth interviews with selected cluster participants. The main objective of these interviews was to collect accompanying information with regard to the survey responses that would allow for a finalisation of detailed measurement scales for each indicator, as well as to collect opinions and suggestions with regard to the modified list of performance indicators. The main deliverable of this stage of the research refers to a structured dataset collected from the second eight model bioclusters, including survey results, interview reports and accompanying materials.

The survey responses belonging to the first and second set are given in **Annex 5**.

In addition to the abovementioned activities, data collection from both sets of clusters implied the need for a series of preliminary interviews with cluster organisations with the aim to acquire the relevant contact details of the potential survey respondents and interview participants. The electronic Interactive Dialogues survey served as a comprehensive technical platform for data collection, storage and analysis.

Figure 8: Approach towards data collection

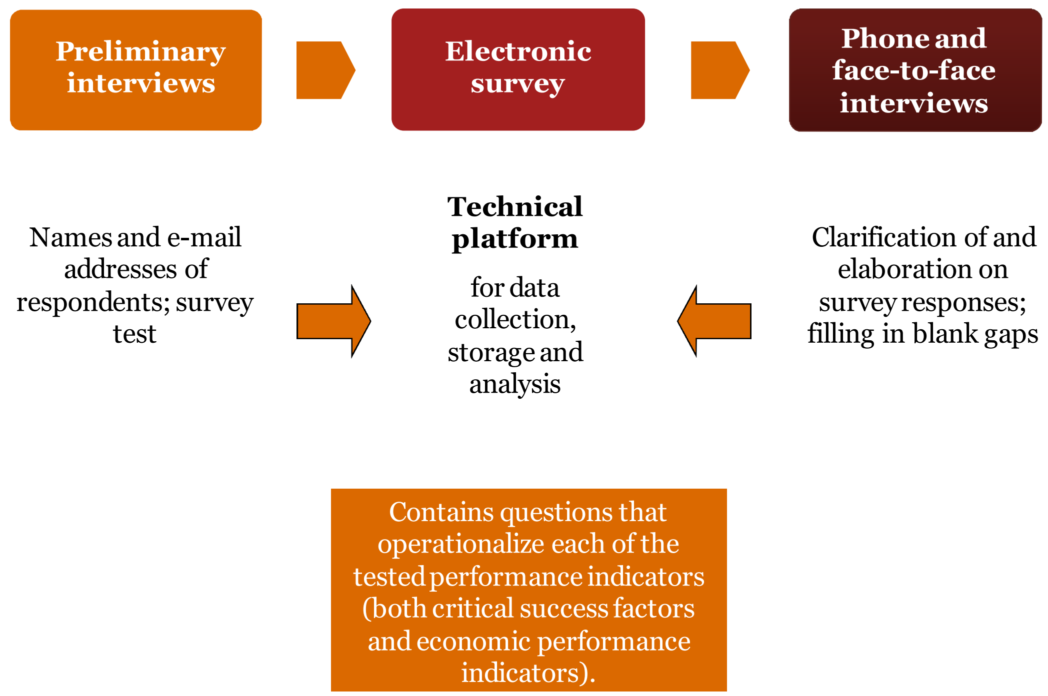


Table 6 provides an overview of the employed data collection types, as well as the information on engaged stakeholders, obtained data and the ways in which the data was used. The consulted stakeholders demonstrated different levels of engagement in cluster activities varying from organisations that hardly participate in any cluster activities to organisations that are highly active in the cluster due to a large number of collaborations.

Table 6 - Employed data collection

	Employed data collection		
	Preliminary Interviews	**Electronic survey**	**Phone/face-to-face interviews**
Engaged stakeholders	Key cluster representatives (e.g. contact point of a cluster organisations)	Key universities and research institutes and several companies per cluster, as well as various supporting structures and policy makers	Key universities and research institutes and several companies per cluster (both large and SMEs), as well as various supporting structures and policy makers
Data	List of respondents for the electronic survey and phone interviews, and their contact details; test of survey questions	Qualitative and quantitative data on performance indicators	Qualitative and quantitative data on performance indicators (covering blank gaps in the survey)
Use of data	Names and addresses for the electronic survey and phone interview; test of survey questions	SMART test of proposed performance indicators	SMART test of proposed performance indicators

Data Analysis

Analysis of the first set of model bioclusters entailed a set of activities related to the analysis and consolidation of obtained qualitative and quantitative data. This stage included the assessment of relevance and availability of individual indicators, necessary modifications in the initial list of indicators, as well as development of standardised measurement scales for each indicator. During this stage, each indicator was evaluated on relevance (importance and significance of collected data) and availability (cost, ease and quality of data collection), and a modified set of performance indicators was derived as a result of this exercise. Only indicators that met the relevance and availability criteria, were re-evaluated and validated in the second model set of bioclusters. The development of measurement scales for each indicator implied concise standardised descriptions of requirements that need to be fulfilled in order to rate a certain indicator as Low, Medium or High. These activities were carried out in consultation with experts and the relevant stakeholders. The main deliverables of this stage of the research include a modified list of performance indicators and preliminary measurement scales for each indicator. During this stage, an initial hypothesis was tested and, when necessary, modifications were made on the next set of hypotheses for the second set of bioclusters.

Analysis of the second set of model bioclusters entailed a set of activities related to the analysis and consolidation of the newly obtained qualitative and quantitative data. This stage included the finalisation of the measurement scales for each indicator and identification of relative weights for the main groups of indicators.

These activities were carried out in consultation with experts and the relevant stakeholders. The main deliverables of this stage of the research include a modified list of performance indicators ready for the final validation, as well as identified relative weights and measurement scales for each indicator.

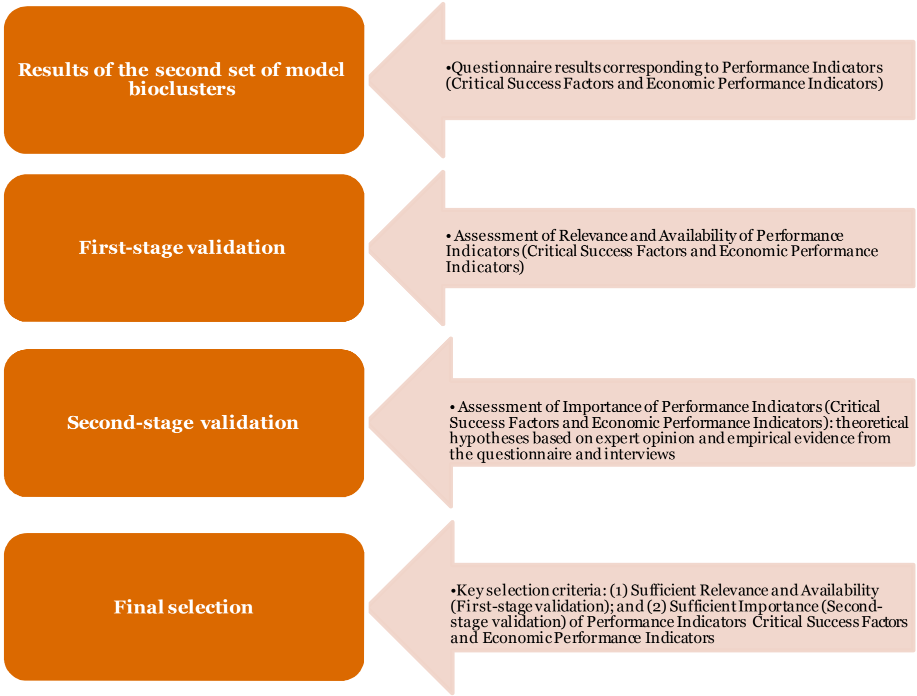
Validation and Assessment of Critical Success Factors and Economic Performance Indicators

For all selected bioclusters, cluster performance will be assessed by two different dimensions: the level of economic cluster performance or actual success and the level of different critical success factors underlying cluster performance.

Validation of the final set of performance indicators implies validation of the results obtained from the first set of model bioclusters and validation of the final list of performance indicators based on expert opinion and stakeholder feedback. During this stage of the research, the consolidated findings were shared with the study participants by means of e-mail communication. Each indicator was evaluated individually. This exercise was expected to lead toward a validated set of both economic performance indicators and critical success factors that are most appropriate for the policy recommendations.

Validation of the final set of performance indicators consisted of two stages (see Figure 9). The first stage of validation implied the assessment of relevance and the availability of performance indicators. An indicator was considered to be relevant if it provided a direct indication of the situation in the cluster, and an indicator was considered to be insignificant if it did not provide any direct indication of the situation in the cluster. Data was considered to be easily available if more than two thirds (66%) of respondents who opened the question also answered the question; data was considered difficult to obtain if less than one third (33%) of respondents who opened the question also answered the question.

Figure 9: Two-stage validation of performance indicators



Validation of Critical Success Factors

Based on the extensive literature analysis and consultation with experts, we have identified five groups of critical success factors for *mature* biotechnology clusters. These critical success factors include:

- ***Scientific driving forces***. Universities, other public research institutes and teaching hospitals are essential components of biotechnology clusters as sources of company formation, skilled personnel and collaborative partners with industry. In addition, research organisations are the major drivers of cluster development through providing services and facilities;
- ***Industrial driving forces***. Large firms act as miniature innovation systems in their own right, providing incubation space to employees, financing their own start-ups, offering technical expertise, product specifications and initial markets. In addition, large firms also provide a steady flow of trained people which small innovating firms can hire, and can share expertise with the supply chain. Biotechnology clusters also need thriving start-ups as well as more mature companies that can act as role models. Small, dedicated biotech firms lead in important parts of the biotech field, especially in healthcare biotech. Academic spin-outs serve as the main vehicles for exploiting biotechnology research;
- ***Cultural driving forces***[87]. Successful clusters usually contain many individuals with an entrepreneurial spirit who are flexible and willing to try new ideas. The teaching of entrepreneurship and management to scientists, engineers and others stimulates the entrepreneurial culture. In addition, business competitions can be a valuable way to boost interest in commercialisation among university students. A fully functioning cluster requires the existence of effective networks. Networks provide a platform for participants to assess the potential for joint working and collaboration in a given area. Cluster organisations play pivotal role as coordinators in creating networks. A strong skill base implies the presence of appropriate mechanisms to attract both key scientific people and key managerial and

[87] This driving force has been identified during the analysis of the1st set of model clusters

commercial people. Clusters can help attract staff by providing an intellectual and business 'buzz' and offering a range of employment opportunities for partners and career development;

- ***Supporting driving forces***. The availability of sites and premises for potential investors and for the expansion of existing businesses is an important component of maintaining the long-term success of a cluster. Science, technology and business parks, as well as manufacturing and distribution parks can encourage opportunities for joint working. Equally, specialised spaces such as incubator and 'grow-on' space could be provided. Cluster organisations are also considered as an important driving force under support mechanisms;
- ***Financial driving forces***. Proximity to intermediaries such as banks, venture capital firms, trading houses (which broker and organise exports) and other financial institutions is viewed as a positive benefit for the development of clusters. In part this reflects the flexibility of financial institutions to respond to the changing needs of the cluster, particularly the emergence of new markets.

Table 7 provides an overview of the critical success factors and the corresponding survey questions used for data gathering and analysis in the final set of bioclusters. In total, the table contains 69 indicators.

Table 7 - Operationalisation of critical success factors for biotechnology clusters

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
	1 Scientific driving forces		
	1.1 Scientific base		
1 (1)	Number of prominent academic actors currently present in the cluster	2.1.1 Please list up to 5 relevant academic actors (universities and research institutes) of the cluster that you consider the most prominent.	All[88]
2 (2)	Total number of R&D employees in the cluster (full time equivalents)	2.1.2 What is the total number of R&D employees in the cluster (full time equivalents)?	Cluster organisations
3 (3)	Total number of R&D employees for Large Companies	2.1.3 When possible, please specify the number of R&D employees for 2009 for the following types of organisations: Large Companies; SMEs; Spin-offs/Start-ups; Research institutions / Universities	Cluster organisations
4 (4)	Total number of R&D employees for SMEs		
5 (5)	Total number of R&D employees for Spin-offs/Start-ups		
6 (6)	Total number of R&D employees for Research institutions / Universities		
	2 Industrial driving forces		
	2.1 Industrial base		
7 (1)	Number of large companies (more than 250 employees) currently present in the cluster	3.1.1a How many large companies (more than 250 employees) are currently present in the cluster?	Cluster organisations
8 (2)	Main industrial focus of large companies currently present in the cluster	3.1.1b What is their main industrial focus?	Cluster organisations
9 (3)	Number of SMEs (less than 250 employees) currently present in the cluster	3.1.2a How many SMEs (less than 250 employees) are currently present in the cluster? What is their main industrial focus?	Cluster organisations
11 (5)	Number of Start-ups /spin-offs (less than 50 employees) currently present in the cluster	3.1.3a How many Start-ups /spin-offs (less than 50 employees) are currently present in the cluster?	Cluster organisations
12 (6)	Main industrial focus of Start-ups /spin-offs currently present in the cluster	3.1.3b What is their main industrial focus?	Cluster organisations

[88] Cluster organisations; Large companies (>250 employees); SMEs (<250 employees); Financial Institutions; Hospitals; Policy makers; Research Centres; Science and Technology Parks; Technology Transfer Offices and Incubators; Universities; Other

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
14 (8)	Average growth rate of SMEs in the cluster in the last 5 years	3.1.4b What is the average growth rate of SMEs in the cluster in the last 5 years?	Cluster organisations
15 (9)	Average growth rate of Start-ups in the cluster the last 5 years	3.1.4c What is the average growth rate of Start-ups in the cluster the last 5 years?	Cluster organisations
16 (10)	Presence of 'role model' companies in the cluster	3.1.5 What 'role model' companies[89] are currently present in the cluster?	All
	2.2 Skill base		
17 (1)	Existence of a reputation that attracts key scientific, managerial and commercial people	3.2.1 Does the cluster have a reputation that attracts key scientific, managerial and commercial people?	All
18 (2)	Reputation of the cluster at the national level	3.2.2 How do you rate the reputation of the cluster at the *national* level? (1 - very low; 5 - very high).	All
19 (3)	Reputation of the cluster at the international level	3.2.3 How do you rate the reputation of the cluster at the *international* level? (1 - very low; 5 - very high).	All
20 (4)	Business trainings offered to the local workforce within the cluster	3.2.4 What kind of business trainings are offered to the local workforce within the cluster?	All
21 (5)	Diversity of organizers of business trainings offered to the local workforce within the cluster	3.2.5 Who provides these training programmes?	All
22 (6)	Perceived impact of those trainings on business development in the cluster	3.2.6 Please rate the impact of those trainings on business development in the cluster.	All
23 (7)	Attractiveness of the location	3.2.7 Please rate the level of availability of the following aspects relevant to the development of the workforce within the cluster: Attractiveness of the location Attractiveness of the organisation Attractive wages Legal job security Incentive systems (e.g. tax incentives) Career development opportunities Training & Education Recruitment support	All
24 (8)	Attractiveness of the organisation		
25 (9)	Attractiveness of wages		
26 (10)	Legal job security		
27 (11)	Incentive systems		
28 (12)	Career development opportunities		
29 (13)	Training & Education		
30 (14)	Recruitment support		
	3. Cultural driving forces		
31 (1)	Presence of business competitions	4.1.1 Which of the following factors related to entrepreneurial culture are present in the cluster? Please rate them according to their level of presence (1 – hardly present; 5 – highly present). Business competitions Teaching of entrepreneurship and management Role model entrepreneurs ("entrepreneurial spirit")	All

[89] Companies that serve as models in a particular entrepreneurial role (e.g. related to R&D, marketing, production, collaboration) for other companies to emulate·

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
32 (2)	Presence of entrepreneurship and management programmes	4.1.2 How strong is the entrepreneurial culture in your cluster? (1 - very weak; 5 - very strong)?	All
33 (3)	Presence of role model entrepreneurs		
34 (4)	Strength of entrepreneurial culture in the cluster		
	3.2 Networking culture		
35 (1)	Sense of belonging to the cluster	4.2.1 Does your organisation feel a sense of belonging to the cluster?	All (except cluster organisations and policy makers)
37 (3)	Main collaboration partners	4.2.3 Please list your main collaboration partners within and outside the cluster (max 10 organisations). Please also indicate the partner type, strength of relationships with each listed partner and type of collaboration.[90] 4.2.4 Please indicate which of those partners work together. The matrix will only appear on the screen if you properly answered the previous question.	All (except cluster organisations and policy makers)
38 (4)	Strength of relationships	4.2.5 What are the top *motivators* for collaboration within your biocluster community? (maximum three options possible)	All
39 (5)	The level of formality of collaborations	4.2.6 What are the top *enablers* for effective collaboration within your biocluster community? (maximum three options possible)	All
40 (6)	Top motivators for collaboration within the cluster		
41 (7)	Top enablers of collaboration within the cluster		
42 (8)	Top barriers of collaboration within the cluster	4.2.7 What are the top *barriers* for effective collaboration within your biocluster community? (maximum three options possible)	All
	4 Financial driving forces		
	4.1 Availability of funds		
43 (1)	Availability of seed capital	5.1.1 On a scale of 1 (low) to 5 (high), please rate the availability of the following types of funds in the cluster. Availability of seed capital Availability of venture capital Availability of governmental funds Availability of grants from foundations Availability of loans/borrowings	All
45 (3)	Availability of governmental funds	5.1.3 What are the main barriers for obtaining financing in the cluster?	All
46 (4)	Availability of grants from foundations		
47 (5)	Availability of loans/borrowings		
48 (6)	Most important types of funds		
49 (7)	Main barriers for obtaining financing in the cluster		

90 (1) weak ties (cost-effective search for codifiable information), (2) medium ties, (3) strong ties (exchange of complex information and tacit knowledge).

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
	5. Supporting driving forces		
	5.1 Cluster organisations		
50 (1)	Presence of a central cluster organisation	6.1.1 Does the cluster have a central cluster organisation?	All
51 (2)	Services provided by the cluster organisation	6.1.2 What services are currently provided by the cluster organisation? (check all that apply)	All
52 (3)	Services of the cluster organisation that are crucial for cluster development	6.1.3 Please identify the top 3 services of the cluster organisation that are crucial for cluster development. Please rank them according to their level of importance (1 – most important from the top 3; 3 – least important from the top 3).	All
53 (1)	Availability of incubators and science parks that cater for biotechnology companies	6.2.1 On a scale of 1 (low) to 5 (high), please rate the availability of the following services and infrastructures in the cluster. Incubators and science parks that cater for biotechnology companies Transport infrastructure (e.g. roads, proximity to airport) Communication platforms (e.g. round tables) Group purchasing policies Business advisors Financial advisors Legal advisors Human Resources and recruitment advisors Property advisors Marketing support Mutualised technological platforms (e.g. scientific equipment)	All
54 (2)	Availability of transport infrastructure (e.g. roads, proximity to airport)		
55 (3)	Availability of communication platforms (e.g. round tables)	6.3.1 Please elaborate on specific legislation and regulation that act as *incentives* encouraging cluster development.	All
57 (5)	Availability of business advisors	6.3.2 Please elaborate on specific legislation and regulation that act as *barriers* preventing cluster development.	All
58 (6)	Availability of financial advisors		
59 (7)	Availability of legal advisors		
60 (8)	Availability of Human Resources and recruitment advisors		
61 (9)	Availability of property advisors		
62 (10)	Availability of marketing support		
63 (11)	Availability of mutualised technological platforms (e.g. scientific equipment)		
	5.3 Policy aspects		
64 (1)	Legislation and regulation that act as incentives for cluster development		
65 (2)	Legislation and regulation that act as barriers for cluster development		
66 (3)	Existence of *national* government promotion measures susceptible to be effective in improving cluster development		

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
67 (4)	Existence of *regional* government promotion measures susceptible to be effective in improving cluster development	6.3.3 Are there any *national* government promotion measures susceptible to be effective in improving cluster development? Please elaborate.	All
68 (5)	Favourability of the national tax regulation for innovation in the country	6.3.4 Are there any *regional* government promotion measures susceptible to be effective in improving cluster development? Please elaborate.	All
69 (6)	Favourability of the national law on protection of Intellectual Property for innovation in the country	6.3.5 Does the national tax regulation stimulate innovation in the country? Please elaborate.	All
		6.3.6 Does the national law on protection of Intellectual Property stimulate innovation in the country? Please elaborate.	All

Assessment of Critical Success Factors

Evaluating the importance of the Critical Success Factors

Identified Critical Success Factors (CSFs) have been assessed in terms of importance, by top-down and bottom-up approaches:

- Top-down approach: PwC internal and external experts were asked to rank the importance of each previously identified CSF as low, medium or high. Following this, each evaluation was coded (1 for "low", 2 for "medium" and 3 for "high") to determine the average score of each CSF. Finally, the seven best ranked CSFs were classified as "highly" important, followed by the next seven as "medium", and the remaining ones as "low" importance;
- Bottom-up approach: The CSFs identified as important after the first set of cluster analysis were validated in the second set in three ways:
  - Through the assessment of individual cluster reports by PwC experts. Each CSF is classified as "low", "medium" or of "high" importance as described above;
  - Through the analysis of question 7.4.1 in the second set of the questionnaire (What factors are most important for the success of your cluster?), the importance of the CSF is evaluated. By scoring 3 for the ticked items and 1 for unticked items, we were then able to establish an average of all the scores, and classify the CSFs as "low", "medium" or "high", as per the method described above;
  - Through the analysis of the overall results of the online questionnaire: We used the same methodology as for the analysis of question 7.4.1 (What factors are most important for the success of your cluster?), but using all questions common for both sets of online questionnaires related to the importance of the CSFs, when applicable. The classification followed the same methodology as before.

We then established a final classification: CSFs that were ranked "high" by both top-down and bottom-up approaches, or "high" for one approach and "medium" for the other approach were considered as important. CSFs were considered as *less* important if the combination was "low"/"low" or "medium"/"low". CSFs were considered of medium importance if the combination was "medium"/"medium" or "high"/"low".

Evaluating the availability of the Critical Success Factors

The determination of the availability of each CSF was based on the results we gathered from the online questionnaire. We gave a score of 3 to a CSF which respondents considered available at a "high" degree, 2 when available at a "medium" degree, and 1 when available at a "low" degree. We then determined the average scores for each CSF. We considered as "low" in terms of availability the CSFs whose average score was between 1.00 and 1.66, "medium" the ones whose average score was between 1.67 and 2.33, and "high" whose average score was between 2.34 and 3.

The questions which were used to assess the availability of CSFs are given in Table 8.

Table 8 - Questions used to determine availability of CSFs

Critical Success Factor	Question used
Presence of academic actors	• Please list up to 5 academic actors of the cluster that you consider the most prominent
Existence of world-leading scientists	• How many world-leading scientists (in the field of biotechnology) participate in the cluster?
R&D aspects	• Methodology described in the following paragraph
Aspects of cluster information availability	• What services are currently provided by the cluster organisation? (item: Providing information/signposting (websites, company directories, port of call for inward investors, company visits)
Presence of large companies	• Methodology described in the following paragraph
Presence of SMEs	• Methodology described in the following paragraph
Presence of start-ups /spin-offs	• Methodology described in the following paragraph
Reputation aspects	• How do you rate the reputation of the cluster at the national level? • How do you rate the reputation of the cluster at the international level?
Training aspects	• What kinds of trainings are provided to the local workforce within the cluster? (all items)
Attractiveness factors	• Please rate the level of availability of the following aspects relevant to the development of the workforce within the cluster (items: attractiveness of the location, wage level, legal job security)
Entrepreneurial culture	• Which of the following factors related to entrepreneurial culture are present in the cluster? (all items) • How strong is the entrepreneurial culture in your cluster?
Sense of belonging to a cluster	• Does your organisation feel a sense of belonging to a cluster?
Networking aspects	• Please rate the level of availability of the following aspects relevant to the development of the workforce within the cluster. (item: communication platform) • What types of collaborations is your organisation engaged in (in the context of the biocluster)? (items: Participation in professional networks and boards, Informal contacts/networks (e.g. alumni societies, networks based on friendship, other boards) • What services are currently provided by the cluster organisation? (item: Networking (institutional networks, seminars, workshops, conferences on scientific and business issues, social events, newsletters)
Aspects of collaborations	• What types of collaborations is your organisation engaged in (in the context of the biocluster)? (items: Publications, Cooperation in R&D (joint R&D projects, sponsoring of research, financing of a PhD student, supervision of a PhD student), Cooperation in education (contract education or training, providing scholarships, sponsoring of education, giving information to students, influencing curriculum of university programmes), Contract research and advice)
Funds availability	• On a scale of 1 (low) to 5 (high), please rate the availability of the following types of funds in the cluster. (all items)
Financial barriers	• What are the top barriers for effective collaboration within your biocluster community? (items: culture of risk aversion, regulatory burdens)
Cluster organisation	• Does the cluster have a central cluster organisation? • What services are currently provided by the cluster organisation? (all items)
Availability of incubators & technology transfer	• On a scale of 1 (low) to 5 (high), please rate the availability of the following services and infrastructures in the cluster. (item: Incubators and science parks that cater for biotechnology companies)
Support functions	• On a scale of 1 (low) to 5 (high), please rate the availability of the following services and infrastructures in the cluster. (items: business advisors, financial advisors, legal advisors, human resources and recruitment advisors, property advisors, marketing support)
Policy and regulatory aspects as incentives	• Please elaborate on specific legislation and regulation that act as incentives encouraging cluster development.

A different methodology was used for the determination of the availability for the following critical success factors: presence of large companies, presence of SMEs, presence of start-ups, and R&D aspects. Based on the analysis of all the 16 cluster reports, we extracted information regarding the presence of large companies, SMEs and start-ups. Based on the number of companies (Large, SMEs, and Start-ups/Spin-offs) found in each cluster, ranges were established for high, medium, and low availability, clusters hosting between 6-10 large companies were considered as "medium" in terms of the presence of large companies, clusters between 60 and 80 SMEs were considered as "medium" regarding the presence of SMEs and clusters with between 10-30 start-ups were considered as "medium" for the presence of start-ups. If the number of companies was below the respective ranges, (i.e. less than 6 large companies for presence of large companies, less than 60 SMEs for presence of SMEs and less than 10 start-ups for presence of Start-ups), the cluster was evaluated as "low". If the number of companies was above the respective ranges (i.e. more than 10 large companies for presence of Large Companies, more than 80 SMEs for presence of SMEs and more than 30 start-ups for presence of Start-ups), the cluster was evaluated as "high".

The same methodology was applied to the CSF "R&D aspect", which was evaluated as "high" when the percentage of R&D people involved was above 45% and "low" when it was below 30% ("Medium" between 30% and 45%).

Validation of Economic Performance Indicators

Existing literature suggests that the clusters offer key competitive advantages with respect to three key competitiveness variables: employment, innovation, and productivity. Productivity is enhanced by having lower transaction costs and untraded interdependencies. Innovation is dependent on interactive knowledge exchange between varieties of knowledge actors, especially because of the proximity necessary for tacit knowledge exchange. Employment resulting from new business formation is massively assisted by the mentoring, role-model provision, learning, communication, and commercialisation gains that arise from operating in a cluster setting.[91]

All three dimensions for measuring economic cluster performance of bioclusters were employed in both sets of model bioclusters. However, the economic impact of clusters cannot be easily demonstrated in strict statistical terms. As emphasized by previous studies, any conclusions on the economic impact of clusters must therefore be treated with great care.[92]

Table 9 provides an overview of the economic performance indicators and the corresponding survey questions used for data gathering and analysis in the final set of bioclusters. In total, the table contains 18 different indicators.

[91] Cooke P. (2002) Biotechnology Clusters as Regional, Sectoral Innovation Systems. International Regional science Review 25 (1), 8-37.

[92] The concept of clusters and cluster policies and their role for competitiveness and innovation: Main statistical results and lessons learned. The Commission Staff Working Document SEC (2008) 2637

Table 9 - Operationalisation of economic performance indicators for biotechnology clusters

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
	6.1 Employment		
70 (1)	Number of new jobs created in the cluster in the last 5 years (%)	7.1.1 How many new jobs were created in the cluster in the last 5 years (%)?	Cluster organisations
71 (2)	Average gross wages in the cluster (EUR/year)	7.1.2 What are the average gross wages in the cluster (EUR/year)?	Cluster organisations
72 (3)	Employment rate of the cluster region compared to one of the country	7.1.3 How does the employment rate of the cluster region compare to one of the country?	All[93]
	6.2 Innovation		
73 (1)	Number of new or significantly improved biotechnologies/*products* introduced by the cluster to the market in the last 5 years	7.2.1 How many new or significantly improved biotechnologies/*products* has your cluster introduced to the market in the last 5 years?	Cluster organisations
74 (2)	Number of biotechnology patents granted to the cluster in the last 5 years	7.2.2 How many biotechnology patents were granted to your cluster in the last 5 years (total number)?	Cluster organisations
75 (3)	Average survival rate (%) for Spin-off companies in the cluster in the last 5 years	7.2.3 What is the average survival rate (%) for spin-off companies in the cluster in the last 5 years?	Cluster organisations
	7.3 Productivity		
76 (1)	Total R&D expenses of the cluster in 2009	7.3.1 What were the total R&D expenses of the cluster in 2009?	Cluster organisations
77 (2)	Total R&D expenses of the cluster in 2009 for Large Companies	7.3.2 When possible, please specify for the following types of organisations: Large Companies; SMEs; Spin-offs /start-ups; Research institutions / Universities	Cluster organisations
78 (3)	Total R&D expenses of the cluster in 2009 for SMEs		
79 (4)	Total R&D expenses of the cluster in 2009 for Spin-offs/start-ups		
80 (5)	Total R&D expenses of the cluster in 2009 for Research institutions / Universities		
81 (6)	Total R&D expenses of the cluster in 2009 compared to 5 years ago	7.3.3 How do the total R&D expenses of the cluster in 2009 compare to 5 years ago?	Cluster organisations
82 (7)	Total turnover of the cluster in 2009	7.3.4 What was the total turnover of the cluster in 2009?	Cluster organisations
83 (8)	Total turnover of Large Companies in 2009	7.3.5 When possible, please specify the total turnover for 2009 for the following types of organisations: Large Companies; SMEs; Spin-offs /start-ups; Research institutions / Universities	Cluster organisations
84 (9)	Total turnover of SMEs in 2009		
85	Total turnover of Spin-offs/start-ups		

93 Cluster organisations; Large companies (>250 employees); SMEs (<250 employees); Financial Institutions; Hospitals; Policy makers; Research Centres; Science and Technology Parks; Technology Transfer Offices and Incubators; Universities; Other

Nr	Indicator	Question from the online questionnaire	Relevant stakeholder groups
(10)	in 2009		
86 (11)	Total turnover of Research institutions / Universities in 2009		
87 (12)	Growth of total turnover of the cluster in the last 5 years	What was the growth of total turnover of the cluster in the last 5 years?	Cluster organisations

Assessment of Economic Performance Indicators

The analysis of the first and second set of clusters confirmed the difficulty in gathering data with regards to economic performance indicators at the cluster level; however the little data gathered was of poor quality.

For the online survey and during the interview process, the response rate on EPIs was low due to the unavailability of quantitative data at the cluster level (e.g. number of patents, licenses, improved technologies, registered trademarks, sales, R&D spending, and turnover etc).

Despite these difficulties, a set of EPIs have been developed to measure the performance of the clusters based on desk research, the available literature, the practice in the industry, the suggestion of the cluster members, and the available data from EU statistics and the OECD statistical network.

Following discussions with the EU commission, it was clear that the monitoring of the performance of the cluster organisation is of pivotal importance, which was confirmed by results and interviews carried out during our study. EPIs related to cluster organisation performance was thus considered as relevant and included.

EPIs proposed during the first set of cluster analysis were:

The proposed indicators measure the performance of the industry and the output of research activities:

Private sector:

- No. of employees in the cluster and employment growth;
- No. of jobs created by SMEs, especially dedicated to R&D;
- No. of companies and company growth;
- No. of new companies formed and the survival rate of start-ups and spin-offs;
- No. of drugs in late stage clinical development;
- No. of drug products marketed that were discovered or developed within the cluster, their year of registration, their sales figures, and their sales growth rate;
- Products on the market other than drugs, discovered and developed within the cluster; year of registration; sales figures; sales growth rate;
- Total turnover of companies in the cluster;
- Acquisition and Merger activities;
- Ratio of Private/Public Money received.

Academic centres and Research Institutes:

- Global ranking (absolute level, and any change in ranking);
- No. of global-level awards (e.g. Nobel Prizes);
- Total R&D spending in academia;
- Investment in infrastructure;

- No. of patents;
- No. of licenses;
- Growth in jobs;
- No. of new companies formed as spin-offs;
- Total size of grants received and follow-on funding obtained by the companies.

Clusters such as Biocat, Spain proposed to assess the critical success factors as a measure of cluster performance.

EPIs proposed during the 2nd set of cluster analysis were:

Some indicators that were identified in the study of the first set were validated in the study of the 2nd set. We are therefore hereafter highlighting the list of indicators identified in the first or the second set only.

Indicators suggested in the first set only

- Global ranking of academic institutes;
- No. of global-level awards (e.g. Nobel Prizes);
- Investment in infrastructure in research;
- No. of drugs in late stage clinical development;
- No. of licensed patents;
- Ratio of Private/Public Money received.

Indicators suggested in the second set only

- No. of publications;
- Amounts spent on research;
- Level of funds raised by companies (public/private);
- Level of funds raised by academia;
- No. of projects and partnership with other stakeholders.

Suggested EPIs :

Based on the analysis of the first and the second sets, and on discussions with internal and external experts, as well as with the EC, PwC suggests a set of EPIs to measure the performance of the clusters at three different levels:

- Cluster dynamics:
  - Number of jobs created;
  - Number of companies established (including survival rate within the last 3 years).

- Cluster enablers:
  - Public funds raised;
  - Private funds raised;
  - Framework conditions;
  - Cluster organisations (cluster management/facilitator).

- Cluster outputs:
  - Revenues of companies;
  - Licensing activities on biotechnology products;
  - Newly developed & marketed biotechnology products.

The other presented indicators have been removed from the selection for the following reasons:

- The removed indicator meaning is captured by an indicator of the final selection: e.g. the academic rankings and number of publications economic meanings are captured by public funds raised, number of companies established or revenues of companies;
- The removed indicator constitutes a pure and intermediary enabler factor with no indication of potential output - e.g. investment in research infrastructure;
- The removed indicators could not be easily collected by the cluster organisations.

Table 10 on the following page presents a consolidated overview of the EPIs suggested by the cluster members. These have been integrated with the parameters presented by Eurostat and OECD statistics, and complemented by PwC internal and external experts, further combined with the suggestions made by the EC.

EU statistics were used as a “reference”, in order to understand which parameters are currently present in the public domain, and are currently being used to measure economic performance at the national and regional level. It is however relevant to state that these parameters are measured on a geographic perimeter that is different from those of the clusters. Therefore the data of Eurostat and OECD statistics cannot be used.

Table 10 - Overview of the data source

EPIs	OECD	Eurostat
Private Capital	Regional Statistics => Innovation indicators(large region) => R&D expenditures performance by the business sector	Science and Technology =>(HTEC*) Venture Capital Investment (early stage-expansion-buyout)
		Science and Technology =>Research and development => Business enterprise R&D expenditure (BERD) by economic activity and source of funds
Public Capital	Regional Statistics => Innovation indicators => R&D expenditures performance by the government sector	Science and Technology =>Research and development=>Share of government budget on R&D
		Science and Technology =>Community innovation survey =>Public funding of innovation
Number of organisations established	Industry & Services => Structural Business Statistics [number of enterprises/country]	Structural business statistics =>Business demography statistics =>Business demography indicators
		Structural business statistics =>Business demography statistics => Preliminary results on enterprise death
		Structural business statistics =>Main indicators [Value added by enterprise size classed, number of person employed, by enterprise size classed
Number of jobs created	Industry & Services =>Business demography indicators (by type of industry only) [employment creation and destruction; employer enterprise survival rate; high growth rate enterprises]	Science and Technology=>Human Resources =>Annual data on human resources in Science and Technology and sub-groups, employed, by sector of economic activity (national level & regional level)
	Industry & Services => Structural analysis databases (by country) [number of person employed, number of employees]	Science and Technology =>Human Resources =>Annual data on job-to-job mobility of highly qualified personnel (employees in science and technology) aged 25-64
	Industry & Services => Labour:[full time, part time, by main industry sectors, by sex, wages]	
Revenues on Licensing	Regional Statistics => Innovation indicators => Patent applications (small regions)	Science and Technology =>Community innovation survey=>Turnover from Innovation
Revenues on Sales	Industry & Services => Industry and Services Statistics => Sales	Science and Technology => (HTEC*) =>High tech exports

*HTEC: High-tech industry and knowledge-intensive service
Source:
http://epp.eurostat.ec.europa.eu/portal/page/portal/statistics/themes;http://stats.oecd.org/Index.aspx?DataSetCode=SDBSD

Results, Discussion and Recommendations

Results, Discussion and Recommendations

Results and discussion on the importance and availability of the CSFs

Importance of CSFs
The results of the two sets of cluster analysis are presented hereafter:

Table 11 - Importance of Critical Success Factors

Driving Force	Critical Success Factor	Importance (Top-down approach)	Importance (Bottom-up approach)	Overall importance
Scientific driving forces	Presence of Academic actors	medium	high	high
	Existence of renowned scientists	low	medium	low
	R&D Aspects	medium	high	high
	Aspects of Cluster Information availability	low	low	Low
Industrial driving forces	Presence of Large Companies	medium	medium	medium
	Presence of SMEs	medium	medium	medium
	Presence of Start-ups/Spin-offs	low	medium	low
	Reputation Aspects	high	high	high
	Training Aspects	medium	low	low
	Presence of Attractiveness Factors	high	high	high
Cultural driving forces	Entrepreneurial Cultural Aspects	high	medium	high
	Sense of belonging to a cluster	low	low	low
	Network Aspects	high	high	high
	Collaboration Aspects	medium	high	high
Financial driving forces	Funding Availability	high	medium	high
	Finance Barriers	high	medium	high
Supporting driving forces	Cluster Organisations	low	medium	low
	Availability of Incubators & Technology Transfer	high	low	medium
	Support Functions	low	low	low
	Policy aspects as incentives	high	medium	high

Table 11 illustrates the importance of the CSFs evaluated by our experts' top-down approach, and by the clusters' bottom-up approach. Even though the evaluation is similar for the two approaches for most of the CSFs, there is one major difference in the assessment of "Incubators and Technology Transfer". The availability of incubators & technology transfer offices was not considered as an important CSF by the clusters themselves, although deemed highly important by our experts. Based on our previous experience, and on our expert's opinion, efficiency of incubators and technology transfer is pivotal for improving cluster growth, and could serve as a catalyst for increasing the rate of success in negotiating and finalising partnerships, as well as raising the international visibility of the cluster. This difference in opinion is attributed to the lack of efficiency and awareness on the precise role and activities of incubators and technology transfer organisations, as identified during our phone interviews. Financial and cultural driving forces appear to be two of the most important driving force for cluster development. Some aspects of scientific, industrial and supporting driving forces are determined to be important as well.

Importance and availability of the CSFs

The results of the two sets for the availability of the CSF are presented in the following table. Results for the overall importance of the CSF are also reported.

Table 12 - Overall availability and importance of Critical Success Factors. CSFs considered important but not available have been marked in bold.

Driving Force	Critical Success Factor	Overall importance	Overall Availability
Scientific driving forces	Presence of Academic actors	high	medium
	Existence of renowned scientists	low	medium
	R&D Aspects	high	medium
	Aspects of Cluster Information Availability	low	high
Industrial driving forces	Presence of Large Companies	medium	medium
	Presence of SMEs	medium	medium
	Presence of Start-ups/Spin-offs	low	medium
	Reputation Aspects	high	medium
	Training Aspects	low	medium
	Presence of Attractiveness Factors	high	medium
Cultural driving forces	Entrepreneurial Cultural Aspects	high	medium
	Sense of belonging to a cluster	low	high
	Network Aspects	high	medium
	Collaboration Aspects	high	medium
Financial driving forces	Funding Aspects	**high**	**low**
	Finance Barriers	**high**	**low**
Supporting driving forces	Cluster Organisations	low	high
	Availability of Incubators & Technology Transfer	medium	high
	Support Functions	low	medium
	Policy aspects as incentives	**high**	**low**

For the purpose of our analysis, we will concentrate our attention on the CSFs, which have been identified as important but are not yet available at the cluster level. This exercise will allow us to identify the major needs up to now remaining still uncovered, which are however critical for clusters development, and for which an action should be put in place.

Most of the driving forces and their related CSFs, are reported to have a similar level of importance and availability.

Whilst, the financial driving forces overall are perceived to be important, their availability is reported to be low. The same pattern is shown for the CSF relating to "*policy aspects*". Both financial and policy aspects play a pivotal role in cluster development, and the lack of funds and policies for incentives are perceived as a major barrier by cluster stakeholders. These two shortfalls that we have identified raise an important point of attention to be further analysed, for the development of appropriate corrective measures.

Several CSFs present a difference between the importance and availability assessment, namely the presence of academic actors, R&D aspects, reputational aspects, and presence of attractiveness factors, entrepreneurial culture as well as network and collaborations. These identified discrepancies will be considered as working areas in the policy recommendations section.

Several other CSFs are considered not important, since they are well represented within the cluster (e.g. existence of world-leading scientists, aspects of cluster information availability, presence of start-ups, training aspects, sense of belonging to a cluster, cluster organisational aspects, support functions). As already stated below the importance of cluster organisations, incubators, tech transfer offices, and other support functions is considered to be of low/medium importance, while their availability is set at a medium/high level.

On the opinion of our internal and external experts, the perception of the low importance of these functions is most likely related to the lack of efficiency within their structures, which can be attributed to the sometimes inappropriate skill-set of the management team, and on the poor implementation of activities undertaken.

The data that we collected were about the availability of CSFs, however not on their efficiency. Efficiency for each CSF should be measured to determine whether the impact of the CSF is important for cluster development.

Availability of the CSFs according to the stakeholder groups

In order to be able to assess the needs in terms of cluster development for the different stakeholder groups, we have carried out an analysis on the CSFs data availability for each stakeholder: companies, academic actors, policy makers, and cluster organisations. We have then compared these results against the importance of CSFs. Table 13 shows these results.

Companies and Academia

Most of the results for companies and academia are aligned, presenting in several instances the same picture in terms of a low availability of CSFs, and a lack of policy regulating incentives for cluster stakeholders.

As aforementioned, there is little access to funds, specifically representing a bigger problem in mechanisms addressing specific funding needs (e.g. to the different steps of the company life cycle, to the spin-off process of industry from university), and adapted to the different industry sectors.

This aspect was developed and analysed further during the interview process, during which it emerged that regulatory burdens, and a risk aversive attitude has been experienced by the cluster actors on a regular basis. As an entrepreneurial culture is somewhat present though not considered strong, one hypothesis could be that an underdeveloped risk taking attitude and entrepreneurial culture did not provide sufficient attributes for gaining access to funds, especially if their availability and accessibility is limited. A risk taking attitude at the fund level is also an important issue.

Another aspect which needs to be reinforced is the development of incentives and policies especially for the bioclusters in non-medical KBBE fields since they are newly developing, and too weak to mature on their own accord.

Academic actors often considered that networking is a weak point in clusters, while it is also considered an important cultural critical success factor. On the basis of our experience, networking is the cornerstone of the development of important collaborations, and should not be underestimated.

Policy Makers

On the whole, policy makers seem to think that most of the CSFs are sparsely available. Such a negative general perception of the availability of CSFs at the cluster level may be due to the fact that policy makers are not always part of the cluster, nor closely involved in the policy making process of the cluster and thus may have a misleading idea of what is present, organised, and carried out at cluster level. Up to now, there has not been a harmonised consensus on CSFs or on EPIs, meaning that cluster results have not been tracked, nor are they made visible to any of the stakeholders operating outside the cluster. However, it should be noted that the limited number of respondents does not allow definitive conclusions.

Our view is that policy makers are aware that there are gaps in the cluster performance, however up to now a thorough analysis has not been performed, and so an objective view cannot be given. We hope that our study will contribute to an enlightening of this topic, and that policy makers will take into consideration the elements brought forward by our results.

Cluster Organisations

Cluster organisations themselves provided interesting results: they reported that information availability, networking and collaboration activities are not strong enough within their cluster. While we think the cluster organisations themselves are in part responsible for this failure, this can be ascribed to a certain extent to the lack of funds for their appropriate development, which was identified as a concern during some interviews.

Table 13 - Importance and availability of Critical Success Factors according to the stakeholder groups. CSFs considered important but not available have been marked in bold.

Driving Force	Critical Success Factor	Overall impor tance	Availability (company) n=95	Availability (academic actors) n=38	Availability (policy makers) n=15	Availability (cluster organisation) n=26
Scientific driving forces	Presence of Academic actors	**high**	medium	high	**low**	high
	Existence of renowned leading scientists	low	medium	medium	low	medium
	R&D Aspects	high	medium	high	medium	medium
	Aspects of Cluster Information availability	low	high	medium	low	low
Industrial driving forces	Presence of Large Companies	medium	medium	medium	low	medium
	Presence of SMEs	medium	medium	medium	medium	high
	Presence of Start-ups /Spin-offs	low	low	medium	low	medium
	Reputation Aspects	high	medium	medium	medium	medium
	Training Aspects	low	medium	low	low	medium
	Presence of Attractiveness Factors	**high**	medium	medium	**low**	medium
Cultural driving forces	Entrepreneurial Cultural Aspects	high	medium	medium	medium	medium
	Sense of belonging to a cluster	low	high	high	medium	medium
	Network Aspects	**high**	high	**low**	**low**	**low**
	Collaboration aspects	**high**	medium	medium	**low**	**low**
Financial driving forces	Funding Aspects	**high**	**low**	**low**	**low**	**low**
	Finance Barriers	**high**	**low**	**low**	**low**	**low**
Supporting driving forces	Cluster Organisations	low	high	medium	high	high
	Availability of Incubators & Tech Transfer	medium	medium	high	medium	high
	Support Functions	low	medium	medium	low	medium
	Policy aspects as incentives	**high**	**low**	**low**	medium	medium

Importance and Availability of CSFs depending on the Maturity Level

The same approach described above was used to determine the importance and the availability of the CSFs for emerging, developing and mature clusters. Table 14 shows results for emerging clusters.

Table 14 - Importance and availability of Critical Success Factors for Emerging Clusters (n=2). CSFs considered important but not available have been marked in bold.

Driving Force	Critical Success Factor	Emerging clusters Importance	Emerging clusters Availability
Scientific driving forces	Presence of Academic actors	high	medium
	Existence of renowned leading scientists	medium	medium
	R&D Aspects	high	medium
	Aspects of Cluster Information availability	low	high
Industrial driving forces	Presence of Large Companies	low	low
	Presence of SMEs	medium	low
	Presence of Start-ups /Spin-offs	low	medium
	Reputation Aspects	**high**	**low**
	Training Aspects	medium	medium
	Presence of Attractiveness Factors	high	medium
Cultural driving forces	Entrepreneurial Cultural Aspects	high	medium
	Sense of belonging to a cluster	low	high
	Network Aspects	high	medium
	Collaboration aspects	high	medium
Financial driving forces	Funding Aspects	**high**	**low**
	Finance Barriers	**high**	**low**
Supporting driving forces	Cluster Organisations	low	high
	Availability of Incubators & Technology Transfer	low	medium
	Support Functions	low	low
	Policy aspects as incentives	medium	low

When we analyse the results by comparing the importance of CSFs for emerging clusters with the general picture we outlined in table 14, a few differences appear: scientific, financial and cultural driving forces seem to be more important than industrial and supporting driving forces, for emerging clusters. The presence of renowned-leading scientists seems to be of a fair importance, as well as availability of appropriate training. Most surprisingly, incubators, and tech transfer and policy aspects were reported to be less important in emerging clusters (respectively “medium” and “high” in the overall case compared to “low” and “medium” for emerging clusters).The most available CSFs are *Aspects of Cluster Information Availability* and *Cluster Organisational Aspects*. This may be due to the fact that during the initial stages of cluster development, cluster organisation services are widely used, and play a greater role compared to the ones existing in more mature clusters.

When considering CSFs for emerging clusters the greatest shortfalls are concentrated around two main factors: the availability of funds, and of industry and maturity specific funding mechanisms, and on the reputation. We have discussed the funding issue already in other paragraphs. The need for a strong reputation of emerging clusters is an understandable aim, as we have seen that the ambitious targets these clusters often have mean raising their visibility at international level.

Table 15 - Importance and availability of Critical Success Factors for Developing Clusters (n=5). CSFs considered important but not available have been marked in bold.

Driving Force	Critical Success Factor	Developing Clusters Importance	Developing Clusters Availability
Scientific driving forces	Presence of Academic actors	high	medium
	Existence of renowned leading scientists	low	medium
	R&D Aspects	high	medium
	Aspects of Cluster Information availability	low	high
Industrial driving forces	Presence of Large Companies	medium	medium
	Presence of SMEs	medium	medium
	Presence of Start-ups /Spin-offs	low	medium
	Reputation Aspects	high	medium
	Training Aspects	medium	low
	Presence of Attractiveness Factors	high	medium
Cultural driving forces	Entrepreneurial Cultural Aspects	high	medium
	Sense of belonging to a cluster	low	high
	Network Aspects	high	medium
	Collaboration aspects	high	medium
Financial driving forces	Funding Aspects	**high**	**low**
	Finance Barriers	**high**	**low**
Supporting driving forces	Cluster Organisations	low	high
	Availability of Incubators & Tech Transfer	medium	high
	Support Functions	low	low
	Policy aspects as incentives	**high**	**low**

When we analyse the results by comparing the importance of CSFs for developing clusters with the general picture we outlined in Table 14, we can see that there is a good correlation between the two pictures. The only major difference which appeared concerns training aspects, which are of "medium" importance for developing clusters, whereas of "low" importance in general. The same conclusions can be drawn for the availability of the CSFs. In both general and developing clusters specific pictures, training do not seem to be available in developing clusters, nor do support functions.

As far as the comparison between the importance and availability of CSFs for emerging clusters is concerned, gap analysis shows the fund availability issue is flagged once again. Interestingly, policies supporting cluster development, and incentives for specific industry sectors are perceived as not being as strong as they should be. As previously mentioned policies for incentives, based on our internal and external experts' experience, are indeed a major driver for cluster development, and should be carefully considered as an important point for the development of further corrective actions.

Table 16 - Importance and availability of Critical Success Factors for Mature Clusters (n=9). CSFs considered important but not available have been marked in bold.

Driving Force	Critical Success Factor	Mature clusters Importance	Mature clusters Availability
Scientific driving forces	Presence of academic actors	high	high
	Existence of renowned leading scientists	medium	medium
	R&D Aspects	high	medium
	Aspects of Cluster Information availability	low	medium
Industrial driving forces	Presence of Large Companies	medium	medium
	Presence of SMEs	medium	high
	Presence of Start-ups /Spin-offs	low	medium
	Reputation Aspects	high	medium
	Training Aspects	low	medium
	Presence of Attractiveness Factors	high	medium
Cultural driving forces	Entrepreneurial Cultural Aspects	medium	medium
	Sense of belonging to a cluster	low	high
	Network Aspects	high	medium
	Collaboration aspects	high	medium
Financial driving forces	Funding Aspects	**high**	**low**
	Finance Barriers	medium	low
Supporting driving forces	Cluster Organisations	low	high
	Availability of Incubators & Technology Transfer	high	high
	Support Functions	low	medium
	Policy aspects as incentives	medium	medium

When we analyse the results by comparing the importance of CSFs for mature clusters with the general picture we outlined in Table 16, some differences arise. World-leading scientists, entrepreneurial culture, financial specificities and policy aspects are perceived as having a relative or "medium" importance in mature clusters, underlying less stringent needs in this field. Incubators & technology transfer are perceived as "highly" important ("medium" importance in average for all maturity levels).

As far as the comparison between the importance and availability of CSFs for mature clusters is concerned, once again the need for funding is raised. However, in spite of financing remaining as a key element, it seems to have less important role when compared to what has been outlined for the emerging and developing clusters. This may be due to the importance of having specific funding mechanisms being perceived as less important. The fact still remains however, that customized funding mechanisms to ensure that all needs are met along the company value chain are missing.

Interestingly, it looks as if policies and incentives supporting the development of clusters are more available (at medium level) for the mature clusters than the ones in emerging and developing stages (low level). This may reflect a need for higher level of integration for supportive policies for the emerging and developing clusters. Or it may merely reflect a lower awareness of these factors within the immature clusters.

The overall importance and overall availability of the CSFs against the availability for each 16 clusters are plotted in Spider Graphs and presented under **Annex 6** together with cluster summaries.

Suggested Economic Performance Indicators (EPIs)

Based on the analyses of the first and the second sets, and on discussions with internal and external experts, as well as with the EC, PwC suggests a set of EPIs to measure the performance of the clusters at three levels:

- Cluster dynamics:
  - Number of jobs created;
  - Number of companies established (including survival rate within the last 3 years).

- Cluster enablers:
  - Public funds raised;
  - Private funds raised;
  - Framework conditions;
  - Cluster organisations (cluster management/facilitator).

- Cluster outputs:
  - Revenues of companies;
  - Licensing activities on biotechnology products;
  - Newly developed & marketed biotechnology products.

Cluster Dynamics

Number of jobs created
Number of companies established

EPIs defined in the cluster development are measuring the efficiency or the productivity of the cluster including the number of companies and the number of employment opportunities created.

Employment growth is one of the key indicators of cluster performance. A specific problem arising here concerns the necessary regionalisation of statistical data. Often enough, this data is either not available at the regional level, or the regions that are defined for administrative purposes, and those used for statistical purposes, do not correspond to the regions considered for the development of the biotech sector.[94] Proposed EPIs are illustrated in Table 17.

[94] The concept of clusters and cluster policies and their role for competitiveness and innovation: Main statistical results and lessons learned. The Commission Staff Working Document SEC (2008) 2637

Table 17 - Economic Performance Indicators for clusters – Cluster Dynamics

Proposed					Euro Stat	Suggested by analysed clusters								
CLUSTER DYNAMICS						USA	FR	ES	JP	NL	BE	AT	CA	1st Set
EPI	Parameter	Measure	Actual	Growth 3 y (%)										
JOBS CREATED														
Jobs	Start-ups/Spin offs	FTE				x	x	x			x	x	x	x
Jobs	SMEs	FTE			x	x	x	x			x	x	x	x
Jobs	Large Comp.	FTE			x	x	x	x			x	x	x	x
Jobs	R&D in total	%			x		x	x		x				x
Jobs	Uni. & Res.Inst.	FTE			x	x					x	x		
COMPANIES ESTABLISHED														
Companies	Priv. Fin. sector	No.				x	x	x				x		
Entities	Public sector	No.												
Start-ups/ Spin -offs		No.				x		x		x	x			x
SMEs		No			x	x								x
Large Companies		No.			x	x								x
Survival rate over the last 3 years	Start-ups/Spin -offs	%				x						x	x	x
Survival rate over the last 3 years	SMEs	%				x						x	x	x
Survival rate over the last 3 years	Large Comp.	%			x	x						x	x	x

Cluster Enablers

Public Funds Raised
Private Funds Raised
Framework Conditions
Cluster Organisations

Funds raised are indicative of the level of assets and resources invested in the cluster. They can be measured in terms of total public investments or total private investments in the cluster. Proposed EPIs are illustrated below in Table 18.

Table 18 - Economic Performance Indicators for clusters – Cluster Enablers

Proposed					Euro Stat	Suggested by analysed clusters								
CLUSTER ENABLERS						USA	FR	ES	JP	NL	BE	AT	CA	1st Set
EPI	Parameter	Measure	Actual	Growth 3 y (%)										
RATIO PUBLIC vs. PRIVATE		**%**										x		x
PUBLIC FUNDS RAISED						x	x			x		x	x	
Public funds raised	EU	€												x
Public funds raised	Regional	€			x									x
Public funds raised	State	€			x									x
Public funds raised	Other (NGOs)	€												
Public funds raised	Innovation	€								x				
Speed to obtain funds		Years												
PRIVATE FUNDS RAISED						x	x			x		x	x	
VC investments	early stage	€			x					x				x
VC investments	expan./repl	€			x									x
VC investments	buy-outs	€			x									x
Big companies		€			x									x
Private banks		€												x
Business Angels		€												x
Nr of rounds		Nr												
Speed to obtain funds		Years												
Net income on invested Capital (ROI)		%												
FRAMEWORK CONDITIONS														
Availability of Innovative Incentives &Regulations	Cluster, Regional, National	Yes/No Yes/No Yes/No	N/A** N/A N/A	N/A N/A N/A										
Shared Technology Platforms		Nr												
Incubators tailored to the needs of KBBE		Nr												
Research Centres specialised on KBBE sectors		Nr												
Tech Transfer Efficiency		Nr of biotech Patents Nr of biotech Licenses												

Proposed					Euro Stat	Suggested by analysed clusters								
CLUSTER ORGANISATIONS						USA	FR	ES	JP	NL	BE	AT	CA	1st Set
Existence of Strategic Dev. Plans		Periods Covered												
Sustainable Finance Structure		€ Budget												
Specialised team in-place		Nr of FTEs												
Registered stakeholders		Nr												

* Information & Communication; Business Coaching/Mentoring; Direct Financing; Training (Business, Technical/Scientific); Lobbying; Marketing; Internalisation & Transnational Coop.; Monitoring & Reporting Cluster Performance; Website/Newsletter; Research & Business Databases; Organising National/International Events.
** N/A : not applicable

Cluster Outputs

Revenues
Licensing activities
Newly developed & marketed biotechnology products

Revenues and licensing activities will measure the financial and non-financial results of the cluster activities. Revenues will consider the sales generated by companies.

Revenues will take into account the value of products developed within the cluster, their sales figures and their sales growth.

Licensing activities will measure the transactions with the private sector generated by the Intellectual Property in the cluster. Proposed EPIs are illustrated below in Table 19.

All of the EPIs, including the ones initially chosen and those finally applied as described above are summarised and given under **Annex 7**.

Table 19 - Economic Performance Indicators for clusters – Cluster Outputs

Proposed					**Euro Stat**	**Suggested by interviewed clusters**								
CLUSTER OUTPUTS						USA	FR	ES	JP	NL	BE	AT	CA	1st Set
EPI	***Parameter***	***Measure***	***Actual***	***Growth 3 y (%)***										
SALES						x		x	x		x	x		
Sales	Start-ups/Spin-offs	€										x		
Sales	SMEs	€										x		
Sales	Large	€			x							x		
Products launched		€				x						x		
Sales of new products	Spin-offs	%												
Sales of new product vs. total sales	SMEs	%												
Sales of new product vs. total sales	Large Comp.	%			x									
LICENSING ACTIVITY														
Licenses		Nr											x	
Companies contracts	Licensing in	€									x			
Companies contracts	Licensing out	€									x		x	
Companies contracts	Research	€									x			
M&A	Acquired	Nr												
M&A	Acquiring	Nr												
NEWLY DEVELOPED & MARKETED BIOTECHNOLOGY PRODUCTS														
Newly Developed & Marketed Biotech Products		**Nr**												
Nr of products under Phase I,II&III Clinical Studies (For biomedical clusters only)		**Nr**												

Results and Discussion on the Economic Performance Indicators

The study of the first and the second set of cluster analyses confirm the difficulty in gathering data with regards to economic performance indicators at the cluster level. Furthermore, the little data gathered is of poor quality.

For the online survey and during the interview process, the response rate on EPIs was low due to the unavailability of quantitative data at the cluster level (e.g. number of patents, licenses, improved technologies, registered trademarks, sales, R&D spending, and turnover etc).

Despite these difficulties, a set of EPIs have been developed to measure the performance of the clusters based on literature search, available literature, practice in the industry, the suggestions of cluster members, and available data from EU statistics and the OECD statistical network.

Following discussions with the EC, it was clear that the monitoring of the performance of the cluster organisations are of pivotal importance, which was confirmed by results and interviews carried out during our study. EPIs related to cluster organisations' performance were thus considered as relevant and included.

Comparison between the main findings of the first and the second sets

The results from the first and the second set of bioclusters clearly demonstrate that a "one model fits all" principle is not appropriate for bioclusters. The samples of bioclusters examined in the context of this study contain diverse and sometimes contradicting examples, suggesting that bioclusters should not be treated as a homogenous population. The diversity here refers to, amongst other things, the way that the clusters have emerged and developed, as well as cluster structure, cluster objectives and collaboration with the outside world. Nevertheless, some common trends can also be drawn. The current section aims to highlight both the differences and similarities of bioclusters.

The results belonging to the availability of the CSFs for the first and second set, compared to the overall importance are reported in Table 20. It is clear that there are no differences between the two sets of cluster analysis in terms of the perception of the importance of funding. The same principle could be applied to the need for availability of funding, as there is currently the perception of a severe lack of this critical success factor.

The importance of a CSF of lack of reputation seems to be more apparent from the first set of cluster analysis than the second, as well as the lack of policy as an incentive. This might be due to the different industrial segments which were been targeted by the two sets of cluster analysis. The second set indeed included more green, white, and blue clusters, for which the KBBE segments are most likely, newer, less well known, and less defined by structured legislations and policies.

Table 20 - Comparison of Critical Success Factors between the first and the second set. CSFs considered important but for which data is not available have been marked in bold.

Driving force	Critical Success Factor	Overall importance	Overall availability (1st set)	Overall availability (2nd set)
Scientific driving forces	Presence of Academic actors	high	medium	high
	Existence of world-leading scientists	low	N/A	medium
	R&D Aspects	**high**	**low**	high
	Aspects of Cluster Information Availability	low	high	medium
Industrial driving forces	Presence of Large Companies	medium	medium	low
	Presence of SMEs	medium	medium	high
	Presence of Start-ups	low	medium	low
	Reputation Aspects	**high**	**low**	medium
	Training Aspects	low	low	medium
	Presence of Attractiveness Factors	high	medium	medium
Cultural driving forces	Entrepreneurial Cultural Aspects	high	medium	medium
	Sense of belonging to a cluster	low	high	medium
	Network Aspects	high	medium	medium
	Aspects of Collaborations	high	medium	medium
Financial driving forces	Aspects of Funds Availability	**high**	**low**	**low**
	Finance Barriers	**high**	**low**	**low**
Supporting driving forces	Cluster Organisational Aspects	low	high	high
	Availability of Incubators & Technology Transfer	medium	Medium	high
	Support Functions	low	medium	medium
	Policy aspects as incentives	**high**	**low**	medium

A detailed analysis on the differences between the first and the second sets of analysis will be carried out in the following paragraphs, with a purpose to tackle each of the driving forces in detail.

Results and Discussion on the 5 Major Driving Forces

Scientific Driving Forces

Scientific driving forces overall are found to be important and existing at "medium" level on average based on both the first and the second sets of clusters analysis. Below are discussed the main points came out of our analysis.

Existence of Academic Actors in the cluster

Specific questions addressed on the survey regarding the scientific base allowed us to gather the following results:

Strong Scientific Base

When asked about the most important factors to the success of their cluster (a question in the second set of questionnaires), 65% of the respondents ranked "Strong Scientific Base" in first place, with the main focus of research activities being basic research in the first set dominating red biotech, and applied research dominating the second set.

Respondents suggested that the following factors provide a strong scientific base: the existence of scientific actors (e.g. renowned universities and research institutions, higher education institutions, vocational and training schools, specialised research centres, translational centres) that are able to provide high quality education and R&D in cluster sector relevant fields. For clusters focusing on biomedical/pharmaceutical studies, the existence of University/Research Hospitals, clinical testing centres for human and animal trials was rated important, together with biobanks, systems biology departments/institutions, biocentres, and different -omics platforms. For those in the Agro-Food field, Plant Research stations, Fishery Research stations, Veterinary Sciences and Animal Research facilities (for livestock), Seedbanks, Culture collections, Artificial Insemination and Fertilisation Centres are among essential institutions.

Renowned and specialized scientists in their own fields, critical mass of researchers, highly skilled technical personnel, are also a pre-requisite for developing the know-how required to ensure cluster success.

- Medical Universities and Research Centres provide the medical experience in developing the products to diagnose and treat diseases as well as to develop medical devices;
- Translational Centres bring together specialists allowing a research focus on very specific areas, such as treating one specific disease (e.g. Lung Centre in Munich, Tumour and Gene Centres in Freiburg), or to study specific topics (e.g. "Centre for Biological Signalling Studies-BIOSS" at University of Freiburg). By this means, a transfer of knowledge from fundamental research to practical application can be achieved more quickly, enabling society to reap the benefits earlier. It also creates synergy by bringing together individual scientists with specialization in the same specific area under the same roof;
- General Clinical Research Centres (GCRCs in USA) funded by the National Centre for Research Resources offer specialized research environments to medical investigators, providing infrastructure necessary to conduct patient-oriented (in-patient and out-patient) research on both children and adults, in a safe and controlled way by use of standardized procedures all over the country;
- Biobanks are housing large pools of biological samples offering a treasure grove of biomedical data which can be exploited using standardised procedures, for instance for the identification and validation of individual disease markers;

- Seedbanks, Culture collections, Faculty of Veterinary Sciences and Animal Research facilities (for livestock), Artificial Insemination and Fertilisation Centres, Plant Research and Fishery Research stations offer animal and plant breeding experience;

- Bioreactors and Biorefineries provide services for bioprocessing and production of biochemicals and biofuels.

Top research institutes

When asked about the top enablers, 75% of the respondents in the first set indicated the presence of top Research Institutes (RIs) as a top enabler for effective collaboration within their cluster, compared to only 42% of the respondents in the second set. It can be concluded that Research Institutes focusing on red biotech were much more interested in collaboration than the ones in non-red biotech in the second set. It can be attributed to the maturity, as the cluster gets more matured; the RIs plays increased role as enablers through collaboration with SMEs.

Renowned Universities (especially the ones focusing in biotechnology) and renowned Research Institutions (focusing on the specialised areas of the cluster itself) already existing in the region long before the establishment of cluster are seen as a prerequisite and are advantageous to cluster development. Especially the existence of University hospitals together with their medical schools are considered to create the most stimulating environment for creating or further developing red biotech in the region (e.g. Munich, Cambridge). Due to the relatively long history of Life Sciences and Biotechnology at the universities, their infrastructure is much more advanced at the moment (e.g. experienced academic personnel, well established labs, etc), thus offering:

- High quality research resulting in publications in peer-reviewed journals, patents, and licenses;
- High quality graduates (e.g. proven by a high demand from the industry to hire because of high success rate of the graduates) to generate the scientists of the future;
- Training provided to the skilled technical personnel, meeting the specific needs of the KBBE sector in which the Cluster is focusing on;
- Specialized research centres and state-of-the-art shared technology platforms;
- Efficient technology transfer and IP management consultation via their institutional TTOs.

Development of research capabilities

When asked about the main objectives of the cluster (only in the survey of the second set), 54% of the respondents indicated "Developing Research Capacities/Capabilities" as their second-ranked objective, after the "Establishment of Companies" as top-ranked objective. Based on this, the main objective of the cluster is perceived as to develop the economy by establishing new companies through research. Successful R&D enhances the reputation of the cluster and provides the fuel for job creation via formation of start-ups and spin-offs.

Collaboration

When asked about the type of collaborations that the stakeholders were involved in most through the cluster (see Table 21), the responses between the first and second set seemed to be in-line with each other indicating the importance of "collaboration in R&D", together with the importance of professional networks and supervisory boards and scientific advisory boards as important vehicles for networking.

A strong scientific base should be a driver for collaboration between academia and the industry, geared towards the needs of the market; the collaboration between universities and companies in the design of educational programmes; the collaboration between young research centres and multinational companies to create state-of-the-art facilities, the existence of a robust R&D workforce, which in the end, acts as a source of spin-off formation. Universities are also expected to provide collaborative teaching programmes as in the BioValley (Alsace/France, Basel/Switzerland, Freiburg/Germany), where Faculty of Biology in Freiburg University offers "Tri-national Teaching Programmes in Biotechnology" at the Upper Rhine Universities located in Freiburg, Basel, Karlsruhe and Strasbourg.

Mostly, the cluster structures are observed to develop in the form of specialised campus environments (e.g. Munich, Cambridge), or in the form of Science Parks/Technopoles (e.g. Oslo and Saint-Hyacinthe Technopoles, Pole IRA) with most of the other major industry and public players are located in close proximity (e.g. biomedical campus, life sciences campus, city of agro-food and biotechnology etc). This structure seems to offer the benefits of synergy and collaboration to participants. Bio-incubators are also an active part of these structures allowing inventor-entrepreneurs to incubate and develop their ideas.

Sharing common communication and technology platforms (e.g. animal testing facilities, central labs providing services such as mass spectrometry, NMR, phenotyping, -omics platforms such as genomics, proteomis, and imaging etc) between the cluster members, and having them located in close proximity, preferably on Campus or Science Park/Technopole environments, is reported to increase synergy and efficiency in collaboration.

The existence of multilingual and collaborative education programmes has also been mentioned as a driver for a collaborative approach.

Table 21 - Types of collaborations the stakeholders engaged in (in the context of the biocluster)

	Percent of Total Count 1. set	**Percent of Total Count 2. set**
Publications	8.9%	9.2%
Participation in professional networks and boards	19.0%	18.8%
Mobility of people (mobility from public knowledge institutes to industry and the other way around)	8.6%	6.8%
Informal contacts/networks (e.g. alumni societies, networks based on friendship, other boards)	17.8%	19.9%
Cooperation in R&D (joint R&D projects, sponsoring of research, financing of a PhD student, supervision of a PhD student)	13.0%	16.1%
Sharing of facilities (shared laboratories, common use of machines, common location or building)	8.9%	7.5%
Cooperation in education (contract education or training, providing scholarships, sponsoring of education, giving information to students, influencing curriculum of university programmes)	8.2%	9.9%
Contract research and advisement	10.0%	9.2%
IPR (patent applications)	5.6%	2.4%
Total Count	**100%**	**100%**

Renowned scientists participating in the cluster

The presence of world-leading scientists along with a critical mass of researchers is considered as an important factor in the scientific base of the cluster. They generate cutting edge research and can act as a magnet to attract other high quality scientists into the cluster. Plenty of time is needed to get sufficient experience due to the long timelines associated with its studies and projects; this is typically the case in the field of life sciences. In addition, in the areas of environment and renewable resources of energy, the critical mass of scientists is pivotal since these are newly developing areas of research. The existence of Nobel Prize winning scientists is not considered critical by the study participants, as long as the cluster holds a critical mass of specialized and renowned researchers, in addition to a critical mass of PhD and Post-doctoral students.

In order to be able to attract and retain internationally renowned scientists, the cluster's and region's national/international reputation is considered crucial. The following factors have been mentioned to be attractive to leading scientists:

- Shared technology platforms and state-of-the art labs with skilled technical personnel, and full time employees dedicated to each renowned scientist
- Campus environment allowing proximity and strong collaboration opportunities
- Availability of funding options dedicated to R&D
- Existence of TTOs in place to handle IP management for scientists and to guide them towards commercial application of their research;
- Competitive wages and hiring policies (limited vs. permanent contract policies at the universities)
- Strong HR support for the easy mobility of skilled workforce between EU countries, and between EU and non-EU countries
- Attractive environmental factors such as high quality of life, low cost of living, attractiveness of the location to live in, accessibility and housing options. The existence of international schools and a temperate climate are also considered as important factors to attract key personnel to the area

Allocation of R&D employees in the cluster

Total employment dedicated to R&D is considered an important indicator of the success of the cluster. For companies, it is influenced by the ratio of R&D expenditures to total revenues, and in general it is closely related to the cluster/regional/national policies regulating expenditures allocated to R&D. Tax policies such as R&D tax credits and exemptions on expenditure and R&D personnel allocated for R&D could also represent a driver for R&D employment.

The ratio of R&D employee allocation in total employment is suggested to be used, instead of the number of absolute people employed, since single numbers cannot be judged as high or low without any comparison (e.g. app. **10,000** people are reported to be allocated in R&D activities in Medicon Valley that is **1/4** of the total employment, whereas **1,100** people involved in R&D in Biotech Umea Cluster representing more than **1/2** of total employment). This ratio varies depending on cluster maturity level, and therefore needs to be analysed considering the appropriate parameters. In this study, the number of employees dedicated to R&D was found to vary between 30 - 50% of the total workforce.

Main focus of activities in the cluster

Setting up cluster goals and ensuring coherent resource allocation are considered as keys for achieving cluster growth and success.

Some clusters focus more on basic and applied research while some others focus on economic development by the establishment of start-up companies. For the specific biotech areas (e.g. genomics, proteomics, personalized medicine, nanotechnology, etc), it is quite important to allocate resources properly. This focus is far more important for clusters under development than for the matured ones. For newly established emerging clusters, investments should be prioritized according to the specific needs relating to the intended direction of development and specialisation.

The presence of a shared research database is an important transversal activity, and it is perceived to be a driver for increasing research efficiency and collaboration, for stimulating synergy and for preventing repetition, besides saving research allocated costs.

ICT support is considered to be another critical, transversal activity to be developed and sustained with appropriate investments, infrastructure, and technological tools in all types of clusters, at all maturity levels, and in all sectors. It is almost impossible to capture modern processing data in areas such as protein and gene sequencing, identification and mapping, nanotechnology applications and systems biology without having proper ICT support. This is one reason why the recent use of bioinformatics has become an essential component on the success of bioclusters (e.g. Japanese cluster in close contact with ICT cluster).

Business training of scientists is nowadays of increasing importance and becoming more frequent, as entrepreneurial skills are perceived to be critical for the development of the cluster. Nevertheless, the level of training in this field has not reached a satisfactory level, and should be developed.

Barriers cited for the development of the scientific base include

- Lack of autonomy at the Universities: those having full decisive autonomy in hiring, determining contracts, wages, technology transfer, IPR management, and holding its own research funds are found to be more effective in hiring and retaining leading scientists, in conducting technology transfer, and in determining their own research areas. The ones lacking in full autonomy mostly depend on the state or national governments lowering their efficiency;
- Lack of rights to the scientists for creating their own business;
- Lack of entrepreneurial experience of the scientists to create spin-offs: more training courses are needed for scientists to turn them into entrepreneurs;
- In terms of invention disclosure, the EU has a "First to File" system which delays the time of publication by almost 1 year when compared to the "First to Invent" system present in USA. This leads to an unfavourable position of EU scientists vs. USA ones;
- In some clusters, it has been stated that even though there is collaboration between scientists, there is competition on administrative and presidency levels that can be attributed to historical and personal issues;
- Degree of centralization is another criterion that needs to be improved, as suggested:
    - Centralized research consortium with an established research database belonging to the cluster, and eventually also between different clusters to prevent repetition, to allocate financial resources more effectively, and to create synergy between complementary disciplines, and to facilitate a research focus towards the direction determined by European Research Areas;
    - Centralized technology transfer and IP management systems rather than having them separately on an institutional basis (particularly important in collaborations between companies and public institutions);
    - Centralized clinical research centres (as in the USA) to increase the effectiveness and efficiency of clinical trials (e.g. Munich).

Assessment of Scientific CSFs

When assessing scientific critical success factors, the reputation of universities can be assessed by using some special websites such as Academic Ranking of World Universities (ARWU, http://www.arwu.org/FieldLIFE2010.jsp) depending on their field such as clinical medicine and pharmacy, life and agricultural sciences etc. Likewise, the number and reputation of existing Research Institutions can be checked on Scirus with the numbers of publications and patents they generated on specific fields (http://www.scirus.com) on a specified time frame. One good measure to see the existence of renowned scientists (by name of the researcher or per institution, university or country base) is to check the number of highly cited scientists within specific fields. (e.g. agricultural sciences, pharmacology, molecular biology and genetics, ecology/environment etc) This can be determined by the use of ISI Web of Knowledge (http://hcr3.isiknowledge.com/formBrowse.cgi).

Biotechnology clusters need thriving SMEs as well as large companies, which can act as role models. Small, dedicated biotech firms are found to be leaders in different biotech fields, especially within the red biotech clusters. Academic spin-offs serve as the main vehicles for exploiting research in biotechnology. Large firms mostly provide incubation space to the employees as well as finance the setting-up of their own start-ups and offering them technical expertise. In addition, by providing a steady flow of trained people that small innovating firms can hire, experience sharing becomes possible. Moreover, they support SMEs by bridging innovation in technological applications through deals for product development and commercialization.

Industrial Driving Forces

Biotechnology clusters need thriving SMEs as well as large companies, which can act as role models. Small, dedicated biotech firms are found to be leaders in different biotech fields, especially within the red biotech clusters. Academic spin-offs serve as the main vehicles for exploiting research in biotechnology. Large firms mostly provide incubation space to the employees as well as finance the setting-up of their own start-ups and offering them technical expertise. In addition, by providing a steady flow of trained people that small innovating firms can hire, experience sharing becomes possible. Moreover, they support SMEs by bridging innovation in technological applications through deals for product development and commercialization.

In our study, the Canadian Saint-Hyacinthe Agro-food and Agro-environment Technopole has emerged as an example for its strong industrial base. The abundance of natural resources at a lower cost (e.g. the availability of high quality/low price refined sugar, availability of large fresh water reserves especially for the agro-food industry; the availability of large areas of high yielding, fertile soil for agricultural production; clean, abundant, affordable energy sources such as hydroelectricity); the low labour and manufacturing costs; the low corporation income tax and existence of tax credits for the companies launching at the incubator of the Technopole; the existence of "Going Green" incentives at the Federal and Provincial level are considered critical factors stimulating business creation, and are important industrial driving forces. Additionally, the presence of an effective incubator system is considered to be a key supporting force for the creation of new companies.

The role of Large Companies

Many large companies were reported to be involved in the clusters surveyed during the first set (e.g. large pharma companies), while the majority of clusters in the second set had only few large industrial companies but a strong presence of SMEs and start-ups. This can be explained with the fact that red biotech applications, mostly involved in the first set, have much longer history than the ones involved in white, green, and blue biotech sectors. Exceptions are represented by the Dutch Food Valley Cluster, comprising of more than 30 large companies in the production of food and ingredients, while the IAR Pole in France specialized in agro-transformation and green chemistry with 28 large companies.

Nowadays, the role of large companies within a cluster is controversial. Thought to play a magnetic role by most, for attracting business and talents, large companies might also be a source of negative downturn, if their influence becomes too important, as a percentage of total employment, and if the cluster depends on their decisions in any way. Several respondents voiced the concern that large companies seem to focus on more cost-cutting activities than on innovation.

A high dependence of clusters on multinationals makes the reputation of the cluster potentially vulnerable. In cases where large companies decide to relocate their R&D and other facilities to another region, the cluster may become less attractive to potential newcomers (e.g. Danone in Food Valley, Netherlands).

The current study demonstrated that large companies have different impacts on different clusters. For instance, the presence of large companies does not always mean that they actively participate in cluster activities. Large companies often carry out their R&D activities outside the cluster. As a result, these companies are often less interested in R&D collaborations and licensing deals with other cluster participants. Additionally, since most of the larger companies were in existence in the region long before the cluster was established, they do not necessarily need the support of the cluster for their own development.

Large companies are mostly involved in bulk manufacturing, with a high number of employees dedicated to production rather than R&D. High employment rates dedicated to manufacturing are not considered as valuable as the ones dedicated to R&D, aiming to innovate and create new jobs in the cluster.

Even though there is good collaboration between large pharma companies and SMEs in terms of development of new products and technologies, when it comes to IP sharing, large companies are mentioned to get the loyalty rights. It has been stated that there is a barrier for the biotech SMEs set by large pharma companies by influencing the policy makers not to provide tax credits for SMEs at National and EU level. For instance, the EU Initiative “Innovative Medicine Initiative (IMI)” is stated to support large pharma companies, while not considering biotech SMEs.

The business environment for setting up new co-operations is considered to be good if large companies are in the surroundings. For example, major pharma companies are seeking promising products to fill out their drug pipeline to balance their expiring patent terms. Examples of some major cooperation agreements between big pharma and biotech SMEs took place in recent years in the Munich Biocluster, including long term financial commitments through “co-operations”.

In some cases such as in the Munich Biocluster, the large company existing in the area postulated that the cluster received the “Cutting-Edge Cluster Award” with the support provided by them.

In some instances, large companies started to provide pre-seed capital but lately the trend has switched more towards supporting cluster activities.

In the Upper Austrian Food Cluster, the only major player in the Food Industry is not a member of the cluster, although, some of its key professionals are.

In the Basel part of the BioValley, the cluster organisation expressed its concern about having high reputation due to the existence of a high number of large companies, rather than the cluster itself.

Nevertheless, the recognized role of large companies can be seen in:

- Creating a critical mass of experienced managers and workers;
- Providing a customer and supplier base;
- Having a boosting effect for the regional and local economy (e.g. for materials and services);
- Playing a key role in diffusing knowledge and technology to SMEs, nurturing future entrepreneurs and inspiring start-ups;
- Stimulating sales and exports, and providing a critical ‘route to market’ for SMEs, both directly and as a base for access to world markets;
- Starting-up their own businesses to address specific niche market needs.

Some examples of large companies supporting cluster and SME development are: GDF-Suez group, Desmet Ballestra, Oiltanking - green electricity, Ghent, BE; Pfizer, Johnson&Johnson, Novartis, Eli Lilly - Pharmaceutical, in San Diego, USA; Roche Diagnostics-Pharmaceutical in Munich, DE; Novartis, Basel, CH.

In conclusion, large companies are proven to be beneficial for the cluster by;

- Providing partnering opportunities for product development, manufacturing, and marketing to other cluster members;
- Providing incubation space to employees;
- Financing their own start-ups;
- Offering technical and management expertise;
- Sharing expertise in support functions and systems such as supply chain, customer services, IT, etc;
- Developing product specifications and standards;
- Identifying niche markets and develop strategies to address their needs;
- Providing a steady flow of trained people which small innovating firms can hire.

SMEs

Small, dedicated biotech firms play an important role in almost all fields of biotech applications, especially in healthcare biotech. These small firms are mostly responsible for research and innovation, even though they often depend on external funding. In fact, existing research shows that, as firms expands in size, typically they experience a decreasing number of discoveries. For large companies, many discoveries usually represent slight adaptations of existing products rather than the development of the brand new ones. In contrast, usually truly inspirational ideas come from smaller dedicated firms located in the clusters. Consequently, it can be concluded that big industry is mostly dependent on small firms.

The current study confirms that academic spin-offs are of a particularly important type of new company in the biotechnology sector, and that these companies serve as the main vehicles for exploiting biotechnology research.

The distribution of employees across different categories is an important criterion, especially when evaluating the total number of employees dedicated to R&D. Since SMEs are mostly involved in R&D and responsible for the new jobs created, SMEs role in economic development is pivotal. It is also important to distinguish the main focus of SMEs activities, as they are involved in supplying services or products. Ideally, it would be more valuable to have more SMEs responsible for product development, ending up in generating patents and licenses, than having them involved in supplying services or products.

Besides the creation of new start-up and spin-off companies, a key challenge that clusters face is the strengthening of the survival and growth of established ones and the SMEs. Some clusters such as Upper Austrian Food Cluster mainly focus on stabilising the existing SMEs rather than creating new ones.

Even though support mechanisms seem to be available at the national and EU level to sustain SMEs development and innovation, it was observed that these are not easily accessible for these companies. Support of SMEs in KBBE areas within the FP7 framework is allocated based on an established collaboration between public and private partners.

Start-ups/Spin-offs (Microenterprises)

The clusters having a strong scientific base and especially efficient incubator structures seems to have a high number of spin-offs and start-ups.

In our study, we have seen the university hospitals present in the clusters serving as the major source of spin-off creation in the red biotech, in addition to universities in general.

Depending on large company influence, the existence of start-ups varied between clusters. In some clusters, such as the Upper Austrian Food Cluster, the industrial company base is mostly formed by microenterprises. The start-up mix however depends on the industrial sector in which the cluster is specializing. In this particular example, most of those microenterprises were small family businesses involved in local food production.

Role Model Companies

Generally, in their mature stage, role model companies exhibit unique entrepreneurial features (e.g. related to R&D, marketing, production or collaboration) that can be used by other companies as a unique strategy to follow.

Role models, together with the creation of success awareness mechanisms, can contribute to an entrepreneurial culture by inspiring other companies and sharing experiences and lessons learned.

In this study, we often observed the existence of role model companies, especially in the healthcare sector. For instance, MediGene is acting as a role model SME in Munich Biocluster. It has developed 3 drugs, and brought them to the champion position in drug development among biotech SMEs in Germany. Some other examples from the 2nd set are: Alco Bio Fuel, Oleon and Bioro, active in the area of bio-fuel production, Ghent, Belgium; Amino Up Chemical Co., Ltd. that developed oligonol in Hokkaido, Japan; Hybritech, as the first biotechnology company established in in San Diego, formed the basis of the Biocom cluster in the USA with its former executives.

Cluster organisations are expected to be the facilitator between role model companies and the newly developing ones to create experience sharing platforms.

Barriers cited for the development of the industrial base include:

- The prevailing risk-averse culture;
- The absence of entrepreneurial experience/mentoring to turn business plans into early stage companies;
- The absence of commercial expertise to develop early stage companies into developed companies;
- The low rate of technology transfer on the commercialisation of research results.

Assessment of Industrial CSFs

The indicators for critical success factors regarding the role of large companies within the cluster should refer to the activity and support of large companies present in the cluster, namely related to spin-offs, start-ups, and SMEs development, which could be formalised in deals and cooperation, M&As, education and training, technology sharing, others.

The indicators for critical success factors of SMEs, spin-off, and start-ups refer to the level of activity in deals with larger companies for product development, commercialisation, and distribution, their capability to leverage on EU, national, and regional incentives and policies, and on their capability to leverage on existing collaborative business models.

The presence of efficient cluster organisations, incubators, and opportunities for business training and mentoring are also considered as CSFs for SMEs.

Cultural Driving Forces

A fully functioning cluster requires the existence of both effective networking and entrepreneurial cultures. Strong networking provides a platform for participants to assess the potential for joint work and collaboration in a given area. A strong skill base implies the presence of appropriate mechanisms to attract both key scientific people and key managerial and commercial people. Clusters can help attract staff by providing an intellectual and business ‘buzz’, offering a range of employment opportunities for partners and career development. Finally, successful clusters usually contain many individuals with an entrepreneurial spirit who are flexible and willing to try new ideas. The teaching of entrepreneurship and management to scientists, engineers and others is proven to stimulate the entrepreneurial culture. In addition, business competitions can be a valuable way to boost interest commercial activities and careers among university students.

Entrepreneurial Culture in the Cluster

The presence of entrepreneurial culture plays a pivotal role in driving clusters towards successful development. Such clusters usually leverage on the presence and active participation of various individuals with an entrepreneurial spirit who are flexible, risk-takers and willing to try new ideas. These people are likely to exploit new opportunities and bring innovations to the market. High levels of entrepreneurship are generally reflected in growing companies, business start-ups and spin-offs from existing companies or research institutes. Entrepreneurial culture can be observed in a wide range of contexts within a cluster – within large and small firms, within technology transfer offices or within public institutions (e.g. engagement of universities in entrepreneurial activities). The level of entrepreneurial culture can therefore be seen as a critical success factor acting in measuring the success of a cluster, whereas low levels of entrepreneurship would be a cause for concern.

When stakeholders were asked about the strength of the entrepreneurial culture in their cluster, they indicated this to be equally at a good level in both sets.

Key patterns of entrepreneurial culture in the cluster refer to the existence of business competitions, teaching of entrepreneurship and management, as well as role model entrepreneurs. These factors were reported to exist in the clusters we examined. Rotation of experienced entrepreneurs from successful ventures to new ventures is a key determinant in cluster maturity and success as well.

Barriers to the development of entrepreneurial culture:

- The risk-averse culture is a big component of entrepreneurial culture. For instance, in the bio-energy industry, stakeholders are risk averse as half of the bio-energy producing companies in Europe have quit their business within the first year of their start-up;
- The unclear regulations and lack of incentives promoting the new products/technologies on the market are the major concerns for the white biotech sector. A clear strategy in terms of regulation and incentives would increase the market acceptability and their competitiveness against more traditional business models.

Drivers of entrepreneurial culture:

- Strengthening the incubator structure and services including business mentoring and scouting;
- Teaching entrepreneurship to scientists and researchers to turn them into entrepreneurs, as well as educating researchers to realise the commercial potential of their research and about the importance of technology transfer;
- Incorporating entrepreneurship courses in all scientific faculty programmes;
- Improving the academic regulatory framework for scientists allowing them to become members of the board of the new company created while keeping their academic position;
- Creating platforms for sharing outstanding success stories and case studies;
- Showcasing successful entrepreneurs as Role Models and developing reward systems;
- Strengthening the network with experienced entrepreneurs (e.g. by creating a platform for exchange of experience between retired entrepreneurs and the stakeholders, as done in Munich; by involving an experienced entrepreneur on the experience transfer circle of the cluster organisation as in the Austrian Food Cluster);
- Involving entrepreneurs in the selection of projects and supporting sponsorship deeply;
- Increasing business plan competitions;
- Improving communication platforms between different types of stakeholders (public / private);
- Offering specific trainings tailored according to the different needs of the industry;
- Formalising University / Industry collaborations;
- Organising more frequent forums/seminars/lectures/workshops/courses geared towards entrepreneurship;

- Creating an organisation geared towards life science entrepreneurship (e.g. by becoming a member of "The Industry Entrepreneurs" TiE (http://www.tie.org/), that is the world's largest network of entrepreneurs aiming to foster entrepreneurship globally);
- Improving legal framework;
- Strengthening funding mechanisms especially for start-ups/spin-offs;
- Increasing seed funding, also coming from private sector and not only from government;
- Easing the launching procedures for international companies in the cluster (by offering soft landing structures at the incubators);
- Building a culture of entrepreneurship by setting up attractive measures (e.g. incentives) to encourage entrepreneurs;
- Creating new Initiatives such as:
  - **Startlife** (public private initiative supported by the Dutch Government and province of Gelderland) aiming to bring tools and education to stimulate entrepreneurship;
  - **Bio Base Europe** (joint initiative of Ghent Bio-Energy Valley and BioPark Terneuzen), a leading initiative for the development of the biobased economy in Europe (http://www.biobaseeurope.org/).
- Increasing awareness in innovation as a way to lead economic success;
- Increasing possibilities for employees within the company to establish start-ups if innovation doesn't fit to the portfolio of existing company;
- Increasing national and international marketing campaigns.

The contribution expected from cluster organisations with regards to the above mentioned activities refers to providing entrepreneurship courses, bringing scientists and industry representatives together, as well as promoting the cluster brand.

With regards to this subject, successful examples of specific factors encouraging entrepreneurship include:

- Presence of successful flagship companies in the cluster (e.g. Genetic Lab, Hokkaido, Japan - the first university spin-off with board members made up of national university professors; received Bio-Sector Award at the International Nanotechnology Exhibition in 2002);
- Entrepreneurship programmes offered by the Biotechnology and/or Life Sciences departments of the universities to support business creation and innovation;
- Cluster organisations offering support to start-ups (e.g. the Food Valley Consortia, Food Valley, Netherlands; cluster organisation providing advice and financial support in the product development process from the early stages to the commercialization. The UAFC in Austria; Incubators stimulating the entrepreneurial culture with business mentoring, advise on funding, commercialization and IP management as in Saint-Hyacinthe Technopole, Canada. Also it has been observed that the Technopole structure is ideal for synergy and increased entrepreneurial culture between universities, research organisations, industry, incubators and technology transfer organisations.

Networking Culture

When asked about the sense of belonging to a cluster, on average 82% of the respondents stated that they do feel a sense of belonging to the cluster. Those who did not answer were mostly policy makers who are not actually part of the cluster. Those who did not feel a sense of belonging were either large companies or SMEs, who have more collaboration partners outside the cluster, mostly at national and international level. In this study, a strong networking culture is observed to focus around:

- Collaboration models between all parties in the clusters: Researchers, Government and Industry (e.g. pole IAR, France, academic and industrial worlds collaborate for the valorisation of agro-resources; the main projects include collaboration between the private and public institutions in the pole as in Saint-Hyacinthe Technopole);
- Collaboration at the regional, national and international level (e.g. Development of Bio Base Europe in Ghent - collaboration between Belgium and the Netherlands; collaboration between Saint-Hyacinthe, Canada, with international clusters located in France, Italy, Belgium, China, Vietnam, Morocco, Algeria, and Poland);
- The ability of the cluster to welcome and integrate newcomers, strengthen its collaborative and networking culture (e.g. Hokkaido, Japan; San Diego, USA, Cambridge, UK);
- The proximity of cluster members located in one area.

The current study confirms that the sense of belonging to a cluster and the benefits of being in a cluster depend on the extent and depth of interactions between cluster members. Therefore, a successful cluster requires the existence of a strong networking culture.

A certain relationship can be observed between the cluster development stage, and the level of networking culture in the cluster. As the cluster matures, networking becomes stronger.

A strong networking culture within a cluster has a number of benefits. Networks and partnerships can support new product development, such as the sharing of information between research institutes, between research institutes and firms or between firms. Once a network is established, other benefits are likely to occur. Networks represent a means of building trust and understanding, and above all, of spreading knowledge and experience.

Barriers to the development of networking culture:

- Strong competition between cluster members (e.g. UAFC, Austria);
- Distance from academic actors, located in other regions (e.g. Austria, where the major scientific base is in Vienna, and not in the cluster, UAFC, Austria);
- A lack of synergy among various sectors covered by the cluster (e.g. Bioval, Spain; Ghent Belgium);
- Lack of international culture and lack of adaptability to globalization (e.g. Bioval, Spain - companies emphasized that they look for collaboration partners first within the cluster , if local partners are unavailable than to international alternatives);
- Lack of industrial vision, education, and know-how, especially in the white biotech industry (e.g. Ghent, Belgium where white biotech is still very young and the full potential of the industry is unknown; additionally, the legal framework and the amount of public funding available are uncertain).

Drivers of networking culture:

- Opportunities provided by the network to exchange knowledge;
- Efficiency of knowledge exchange;
- Network expansion beyond the cluster;
- Involvement of international partners in the network.

Collaboration

When the responses to the survey in both sets were consolidated, the ranking on collaboration types being mostly engaged in the cluster was as given below:

- Participation in professional networks and boards (18.9%);
- Informal contacts/networks (18.6%);
- Cooperation in R&D (14.5%);
- Contract research (9.6%);
- Publications (9.1%);
- Cooperation in education (9.0%);
- Sharing of facilities (8.2%);
- Mobility of people (between public and private sectors) (7.7%);
- Patent applications (4.0%).

In order to see the strength of collaboration between different stakeholders groups (e.g. universities, research institutions, industry, cluster organisation etc), Social Network Pictures were used. This is a methodology which allows for a visualisation of collaborations existing between different parties, to identify the partners of collaboration, and the strength of collaboration between them. These pictures have been generated and provided for each individual cluster report. This analysis is useful as it allows identification of where the main gaps in collaboration are located, with the aim of strengthening the weaker links.

Industry and science typically use a broad set of channels when interacting with each other. The relative importance of the channels vary with the type of collaboration activity carried out, the type of knowledge demanded, the absorption and transfer capacities of companies and academic institutions, as well as the type and extent of market failures prevailing on the market.

Differences have been observed with regard to collaboration between different clusters (national and international). Some clusters are actively engaged in collaborating with other national and international clusters (e.g. Biocat, Spain; Saint-Hyacinthe Canada via partnering with other Science Parks located in France, Italy, Belgium, China, Vietnam, Morocco, Algeria, Poland; Cambridge, UK collaborating with USA), while others view them as competitors and avoid having out-of-cluster collaborations (e.g. Biotech Umeå). It is mostly valid at the cluster initiative/organisation level while individual cluster stakeholders are more open for national/international collaborations (e.g. via Biotechnology Industry Organisation (BIO) but not via the cluster itself) because of the difficulty of finding the right collaboration partners in very specific areas. Companies and universities usually do work in partnerships outside their own cluster, and for them not having international relations can be regarded rather as an exception.

Key motivators and enablers for collaboration:

The key motivators for cluster participants to engage in collaboration with each other include:

- Access to additional funding;
- Access to equipment;
- Access to specific knowledge and expertise of collaboration partners;
- Solving internal capacity issues (e.g. HR, space, etc.);
- Access to new markets (e.g. benefiting from the collaboration of a partner that already has established a network, thus sharing experience and access to markets);
- Access to standardisation networks;
- Bonding with powerful actors.

The key enablers for cluster participants to engage in collaboration with each other include the:

- Entrepreneurial culture of the cluster;
- Presence of a cluster organisation;
- Presence of top research institutes;
- Availability of government funding supporting collaboration;
- Presence of platforms for communication with other cluster members.

Key barriers to collaboration:

- High level of competition among cluster members;
- Lack of local venture capital (lack of potential collaboration projects due to the lack of VC)
- Risk-averse culture;
- Cumbersome IP and technology transfer processes;
- Lack of networking events and platforms for communication with other cluster members;
- Regulatory burdens (e.g. IP protection regulations between different institutions such as private-public collaboration on the IP sharing).

Main focus of cluster activities

The objectives and the focus of a cluster seem to be linked to the development stage, as well as to the historical context of the cluster. Hence, relatively young clusters that lack in strong industrial base tend to focus on spin-off creations (e.g. Biotech Umeå, Sweden). Older clusters and the ones having large industrial players in the region tend to focus on applied research, licensing and product development (e.g. Biocat, Spain). It was also suggested that in order to achieve synergy and sustainable cluster development, all these elements have to be stimulated (i.e. basic science research, applied research, generating IP, licensing, product development, and establishment of new companies). They represent the essential building blocks of growth and innovation, and as such, removing one of those blocks would make the whole system incomplete.

Assessment of networking CSFs

The indicators for critical success factors with regards to networking efficiency are listed below:

- The organisation of internal/external events;
- The presence of grants to participate in foreign seminars;
- The presence of sites favouring informal contacts;
- The presence of platforms of communication;
- The concentration of entities within the same campus/structure;
- The possibility of having access to shared platforms.

Assessment of collaboration CSFs

The indicators for critical success factors with regards to collaboration efficiency are listed below:

- The presence of a funding application, having partnerships as a prerequisite, and supporting the collaboration between partners;
- The presence of established collaborations between companies or between research institutions, or other collaboration models, with a diversified range of partners;
- Joint publications between partners in collaboration;
- Joint patent applications;
- Creation of products due to collaboration;
- The presence of Bio-incubators, facilitating partnerships.

Supporting Driving Forces

The major supporting driving forces in the success of bioclusters can be summarised as below;

- The existence of cluster organisations with a professional team capable of providing a large spectrum of services;
- The availability of specific services and infrastructures especially the existence of bio-incubators and technology transfer organisations;
- The availability of the attractiveness factors;
- The existence of regulations and policies favourable to the cluster development.

Cluster organisations as the coordinator of biocluster activities (including networking) play a pivotal role in the cluster development. The availability of sites and premises for potential investors and for the expansion of existing businesses is an important component of maintaining the long-term success of a cluster. Science, technology and business parks can encourage opportunities for joint ventures.

Presence of Cluster Initiatives/Organisations

Cluster initiatives (CIs) are public-private initiatives (initiated by government (32%), by industry (27%), or equally by both (35%)) where financing primarily comes from government (54%), from industry (18%) or equally from both (25%) established to strengthen clusters. Successful initiatives turn into more formal organisations over time. They are organised efforts to enhance competitiveness of a cluster, involving private industry, public authorities and/or academic institutions. CIs involves: cluster organisation (CO) with an office, manager, website etc.; different member organisations; governance of the initiative; and financing of the initiative (EU/ national/regional/local public funding, member fees, consulting etc). CIs, mostly created in early 2000's, have been playing a pivotal role in the development of new clusters[95].

Networking, lobbying, signposting and other forms of cluster promotion were found to be the primarily expected services from all cluster organisations in our study. We have observed different cluster organisational structures with the involvement of one or more cluster organisations as mentioned below:

- One central cluster organisation coordinating all cluster activities (e.g. Biocat, Spain)
- Multiple-level cluster organisations coordinating cluster activities at different levels of the cluster, (e.g. Oslo Technopole, Norway);
- Several cluster organisations functioning at one level, often serving different stakeholder groups and complementing each other, (e.g. Biotech Umeå, Sweden: San Diego,USA);
- Several cluster organisations representing different countries/regions with one organisation on top of them (e.g. BioValley trinational model, one on each country (Germany, France, Switzerland) and a central cluster organisation on top of all).

Our observations on different cluster organisations are as listed below:

- Cluster organisations were initially created as private or government initiatives, and in some cases include representatives from industry, academia, and government in its structure (e.g. Food Valley, the Netherlands). They are usually funded by membership fees, contracts and grants from the local government, sponsorship, and fee-for-service activities provided by the cluster organisation. Through seminars and sessions with elected officials they are active in initiatives related to capital formation, educational programmes, public policy, workforce development, group purchasing, and networking platforms for universities and research institutes. In some cases such as Saint-Hyacinthe Technopole and Munich biocluster, the

[95] Clusters and Cluster Initiatives, C. Ketels, G. Lindqvist, O. Sölvell, June 2008

services are provided to the stakeholders without any membership fees. Also in Austria, the farmers' contribution is free being compensated by the Commerce of Agriculture in order to stimulate their participation in cluster activities;

- Cluster organisations have a marketing role in promoting the cluster and strengthening alliances with regional, state, national, and international partners through collaboration;
- The effectiveness of cluster organisations is mostly correlated to the leadership of the management team. Managers with knowledge, a vision, and a risk taking attitude are always highly desired. The cluster organisation should have a team composed of resources coming both from industry and academia, specialised in diverse fields (business, law, research, regulatory affairs, finance, etc);
- In some clusters such as Upper Austrian Food Cluster, some committees (e.g. Advisory and Scientific ones composed of Industry representatives and Academics, respectively), are incorporated into the cluster organisation structure that is supported by the Chamber of Commerce;
- Some cluster organisations have their own funding and need only a small contribution from the local/regional/national government for their own development (e.g. Saint-Hyacinthe, Canada);
- In some instances, the presence of legal advisors, human resources, and IP and business consultants seem to be weak (e.g. pole IAR); the absence of financial advisors was deemed critical in other clusters (e.g. UAFC, Austria).

A strong and distinguished cluster organisation should be able to provide the following capabilities:

- CO manages, structures, and follows up the cluster strategy and development (incl. cluster administrations) (e.g. clear definition of goals, mission, vision, dashboard for follow up, data gathering, etc.);
- CO emphasizes networking & communication (e.g. communication platforms, networking events, etc.);
- CO is responsible for cluster marketing at regional, national and international levels (e.g. website, annual reports, trade shows, conferences, etc.);
- CO should support public funding structures. This can be done through a number of methods, such as by the presence of a fund managed and controlled by the cluster organisation, or by having specialized personnel within the cluster organisation to provide counselling, or to offer advice on potential funding options available in the region/cluster/EU level.

Most interviewees emphasized that in general, the objective of the cluster organisation is to increase the visibility of the cluster both internally and externally. Internal visibility refers to the sense of belonging to a cluster by its participants, while external visibility refers to the awareness about the cluster in the outside world and the cluster reputation at the international level.

All stakeholders agreed that cluster development and maturity is highly dependent on the work of the cluster organisation with its well structured management and expert team. It is especially regarded as important for the cluster organisation to have a manager with vision, with both a strong scientific and business background.

Our study results and conclusions regarding cluster organisations are in line with the White Paper on "The emerging of European World-Class Clusters"[96] towards the creation of world-class clusters by recognising the excellence in cluster organisations as an essential supporting force in the creation of excellence clusters. The expected structure of an ideal cluster organisation can be summarised as:

- Existence and implementation of strategic plans with short and long term goals determined together with the cluster actors according to their expectations;
- Professionalism in the expected services (e.g. providing specialised and customised business support services and added values to the cluster actors);

[96] White Paper : The emerging of European World-Class Clusters by Europa InterCluster, 2010

- Existence of an identified and sustainable finance structure (e.g. the public and private support) until it reaches the maturity level to finance itself;
- Existence of excellence in Cluster governance (e.g. with a facilitator/manager and team trained and experienced in Cluster Governance and sector specific issues as well as with a broad network of contacts);
- Involvement of relevant stakeholder representatives in the board, with clear processes for strategy definition, and for decision-taking; access to external experts for peer-reviewing process on technical matters;
- Existence of specialised and multidisciplinary team in-place (e.g. finance, business, scientific, legal, recruitment etc. advisors);
- Building the bridge between the actors of the triple helix (industrial, academic, public) for their active involvement and commitment on cluster development to stimulate collaboration and so joint product/technology/service developments;
- Involvement of competitors;
- Involvement of cluster actors in international co-operations and linkages in global value chains.

Services provided by the Cluster Organisations

The strategic objectives and long term orientation of a cluster creates a consensus for its development between its stakeholders. To develop the cluster properly, the establishment of the following services are crucial, and should be supported within the cluster:

- Education & Training (e.g. management skills, entrepreneurship for scientists);
- Market Intelligence (market needs and cluster-pipelines);
- Cluster Marketing (regional/national/international);
- Innovation Management (research valorisation; award-systems);
- Technological Support (providing technical platforms / infrastructure; technology transfer);
- Technology Transfer Research Valorisation (applied research; incubation structures; tech transfer & funding support);
- High quality Human Resources (recruitment support);
- Consultancy (e.g. on business development, funding, IP-management).

Cluster organisations are playing also a central role in leading and motivating a networking culture within the "community" (e.g. BioValley, Munich, etc.). Clusters should cover academia, specialized research institutes, experienced companies and start-ups. It should be inherent to the cluster and within the culture of its members to form a synergy. Geographical proximity with developed communication platforms between stakeholders shows the following capacities:

- High number of networking and communication platforms (e.g. forum on Internet, regular meetings between stakeholders to present future projects and potential collaborations, etc.);
- Presence of networking events (e.g. conferences, seminars, company visits, round tables, etc.);
- Presence of private-public partnerships (e.g. collaboration between universities and start-ups, SMEs and large companies).

Availability of specific services and infrastructures

Regarding infrastructure, it is important to highlight the underestimated role of **incubators** and **science parks** as stated by most of the study participants. The role of the incubators should be stronger than at present, to foster innovation and support the maturation of start-ups/spin-offs. Incubators support technology transfer efficiency, new business creation and growth by offering dedicated infrastructure and human resources to help companies take off. Generally, incubators are privately owned by universities, investment companies or foundations. Their objective is to stimulate entrepreneurship by creating an entrepreneurial climate, offering full support services whilst facilitating start-ups/spin-offs and young companies, as well as by offering tailor-made accommodation to start-ups, young companies and R&D units of multinationals. They provide biotech research facilities, multifunctional facilities that can be used for pilot production, joint biotech R&D,

and the services of professional advisors (e.g. Hokkaido Japan, BioPartner; Food Valley, the Netherlands). They also offer supporting services including coaching, business, and legal advice.

A strong incubator within a cluster should:

- Foster the entrepreneurial culture with the active support they provide to start-ups/spin-offs (e.g. ease of business creation);
- Strengthen the maturity level of a project (e.g. ease of funding, financial stability, etc.);
- Provide flexible infrastructure space (e.g. in different size, specifications, duration, etc.).

The model of management of **Technology Transfer Organisations** (TTOs) differs between countries, and often between entities and public-private organisations. This is a serious barrier in the patenting and commercialization process for start-ups and spin-offs. Study participants suggested that technology transfer should be handled by an independent Scientific Board free from political influence.

Policy Aspects

Legislation and regulations as incentive for cluster development

Favourable policies, regulatory and economic contexts supporting R&D activities are the major key incentives to encourage cluster development. It is one of the principal tools to develop and stimulate a new knowledge based economy (e.g. foster research activities, ease start-up creation, attract venture capital, etc).

The competitiveness of a defined regulatory environment is made up of a combination of the following instruments:

FISCAL (TAX) MEASURES

- National R&D tax credits to foster research projects (e.g. Research tax credit – CIR in France, R&D tax credits in the UK);
- Tax exemptions (e.g. for company's investments, investors willing to invest into a company/ start-ups, etc.);
- National subsidies and incentives to support company establishment (e.g. with tax losses carrying forward to take over the risk carried by newly established companies with innovative projects without proof of concept);
- Level of personnel and corporate taxation;
- Tax incentives (e.g. production of tax free bio-fuels in Belgium; tax credits for R&D expenses and salaries, tax incentives in Canada);
- Research and Development tax credit incentives (e.g. Saint-Hyacinthe, Canada; San Diego, USA).

Recommendations from the cluster participants:

- Need for new policy development to support dedicated KBBE: legislation and regulation that act as incentive for cluster development including reform in tax regulation, IP regulation and protection.

NON-FISCAL MEASURES

- Specific start-up status (e.g. Young Innovative Enterprise Status);
- National funds for collaborative R&D projects in biotech to ease access to funding for start-ups;
- National subsidies and incentives to :
  - Support company development (e.g. export insurance, product commercialization, etc.)
  - Stimulate scientists to engage in entrepreneurial activities (e.g. grant incentives)

- Foster Public Private Partnerships and collaborative R&D projects;
- Law for the protection of intellectual property stimulating innovation (e.g. Hokkaido, Japan; San Diego, USA);
- Various financial instruments of the national government to fund R&D projects and start-ups (e.g. UAFC, Austria; Food Valley, the Netherlands).

Recommendations from the cluster participants:

- Need for new policy to support KBBE by developing stronger HR policies on skilled workforce to attract and keep the key scientists and entrepreneurs to the cluster, also by facilitating mobility regulations for citizens of non-EU countries;
- Industry specific regulations (both local and national policy) are needed to support the development of each industry in red biotech, blue biotech, white biotech, and green biotech;
- Need for continuous government programmes (e.g. Bioval, Spain).

Legislation and regulation as barriers for cluster development

A recurrent regulatory barrier for cluster development refers to, among others, the high level of bureaucracy (administrative procedures) in public institutions; especially European Commission-managed funds (e.g.FP7 funding) that are found to be quite hard to access and manage especially by SMEs.

Tax related concerns have been highlighted by many of the different stakeholders as one of the main barriers when it comes to supporting innovation and the survival of newly established companies especially in the area of Biotech, which has a high Return on Investment (ROI) and subsequently needs a high amount of high risk investment.

Regulations concerning clinical trials, approvals and marketing authorization should be re-evaluated to shorten the lengthy clinical testing time and to increase the competitiveness between Europe and other countries. In Europe, difficulty in accessing the diversified patient populations of varied origins; lack of consistency in clinical standards between different Member States; the high cost of running clinical trials; and high level of bureaucracy have resulted in companies moving out of Europe to conduct clinical trials.

Current issues on Policy and Regulations:

- Some of the existing laws have not yet been enforced (e.g. the rule to have at least 4% of bio-fuel in the fuels used for transport is not fully applied by all the main oil-producing companies because of the fine for infraction is quite low (e.g. Belgium);
- Some IP regulations were seen as being highly ambiguous (e.g. Bioval, Spain);
- The cost of the legalization procedures was reported to be high and unaffordable to small companies (e.g. Bioval, Spain);
- The cost of licensing is too expensive (e.g. San Diego, USA);
- A high level of bureaucracy is also considered to be a key barrier.

Financial Driving Forces

Among all other critical success factors, the lack of pre-seed, seed, and especially Venture Capital (VC) are determined to be the most important critical success factor for the development of companies as well as for cluster development**.** These results are based on the first and the second set of cluster analysis, independent of the maturity level and sector specific areas the clusters are focusing on. Government funds were found to be the most available and important source of funding especially at the pre-seed and seed stages but are not considered to be sufficient. Red biotech (especially drug development) seems to be the sector most in need of high amounts of funding, representing a high-risk and long term (10-12 years) investment, but coupled with a high expected return on investment at the end. In the white biotech sector, since applications and products are relatively new and not yet well supported by the current regulatory framework and the community, most venture capitalists exhibit a reluctance to invest into this new area. For the green biotech, having a low return on investment compared to the health sector is the main reason for investors not being attracted to this sector. Additionally, the unclear regulatory framework especially in food safety and labelling regulations for Novel and Functional Foods is indicated as a key barrier to invest in innovation in this sector. Risk sharing mechanisms in funding are favoured by most of the participants; however they are stated to be uncommon in practice.

Availability and importance of different types of funds

Obtaining sustainable and sufficient investments in the high risk KBBE areas that are newly developing is known to be quite challenging, particularly in recent years due to economic downturns, instability in the financial markets and to insufficient funding resources.

Since funding has been determined as a major and common problem in almost all of the clusters we analysed, we decided to examine the funding resources in detail based on survey responses.

When the availability and importance of different types of funds (e.g. seed, VC, Governmental funds, grants from foundations, loans/borrowings) were examined in detail between the first and the second sets:

- The overall availability of seed and loans were identified to be low to medium;
- The overall availability of venture capital was identified as low;
- The overall availability of governmental funds and grants from foundations were determined to be medium;
- The importance for each funding type differed slightly between the first and second set of clusters. Governmental funds were highly important in both sets; importance of grants from foundations and loans was stated to be low due to unavailability; venture capital and seed capital were considered to be of medium and low importance, respectively.

Availability and importance of different types of funds based on the maturity level:

When the availability and importance of each specific source of funding are examined based on the *maturity level (mature, developing, and emerging)* the following conclusions emerged:

Availability

- Seed capital is found to be more available for mature and emerging clusters (medium availability) rather than for developing clusters (low availability);
- VC is the least available source of funding at all maturity levels;
- Governmental funds are stated to be of medium availability at all levels of cluster maturity (it can be attributed to the fact of getting more governmental support during the early phases of cluster development);
- In general, grants are more available for mature and developing clusters (medium) than for emerging clusters (low);

- Loans are found to be at a better level of availability for developing and emerging clusters (medium) rather than for mature clusters.

Importance

- Governmental funds are stated to be highly important at all maturity levels;
- At the higher maturity levels, the availability of VC and grants from foundations seem to be more important than at the emerging and developing stages (medium for mature and developing clusters, low for emerging clusters). The opposite was observed for seed capital (low importance for mature clusters, medium important for developing and emerging clusters);
- Importance of loans was higher (medium) for developing clusters than for mature and emerging ones (low).

Availability and importance of different types of funds for medical and non-medical KBBE sectors:

When the availability and importance of each specific funding is examined for medical and non-medical *KBEE* areas *(e.g. green and white biotech)*:

- Availability of seed capital and venture capital in Medical/Pharmaceutical area was higher than in Agro-Food, Agro-Environment and Bioenergy, where it was medium and low, respectively;
- Governmental funds, grants from foundations and loans/borrowing were found to be at a medium availability for all types of biotechnology fields;
- In terms of importance, seed capital is ranked low for Medical/Pharmaceutical and Industrial biotechs whereas it is more important (medium) for Agro-Food;
- Venture capital was of medium importance for the Biomedical/Pharmaceutical, but less important for Agro-Food and Industrial biotechs;
- Loans seemed to be more important (medium) for Industrial biotech than Medical and Agro-Food (low);
- Governmental funds are at the highest importance level, for Biomedical and Industrial biotech and medium for Agro-Food biotechs;
- Grants were considered of low importance for all biotech sectors.

Overall conclusions from these statements are:

- No major difference between emerging, developing and mature clusters was observed in terms of access to funds. In general, access to funding is medium or low;
- However, it seems that the medical biotech is more advantageous in terms of funding;
- Government funds have the highest availability for all maturity levels and sectors;
- Venture capital is the least available source for funding;
- Government funds are the most important source of funding on all stages of cluster maturity, and for all types of biotech. This may be due to the fact that government funds have proven to be the most available funds.

Briefly, it can be concluded that, even though the Governmental funds were stated to be the highest available funding source for all KBBE sectors and maturity levels, the investments provided are judged to be still insufficient. The VC sector is found to be more important for Medical than for Agro-Food and Industrial Biotech that might be attributed to the nature of more mature VC industry in this sector investing for long term (app. 10-12 years) at high risk (esp. diagnostics and drug development towards *personalised medicine*) but yielding in higher ROI at the end. For Agro-Food, since the ROI is stated to be lower compared to medical, it was not found attractive by the VC. Moreover, VCs available for investments in this area are few, and are not accessible.

Personalised Nutrition is considered under the green biotech sector. A main research focus under ERA (*Food for Life*) focuses on the prevention of diseases, increasing the wellbeing, life quality and life span of citizens in Europe. Eating and lifestyle habits are analysed to determine each individual's nutritional requirements for a better life, and nutrition-disease correlation at the gene level is carried out. Specialists in this area believe that in terms of funding, personalised nutrition should be treated exactly the same way as drug development: it is a long term, high risk, considerable investment. Since it is a new concept, its consequences are not yet fully recognised by investors or by the general community yet.

For the industrial biotech sector, low attractiveness is attributed to the weakness of current regulations and incentives available, as well as to the unclear future of technology and products innovated. High market prices compared to their traditional counterparts make competition and market acceptability of products coming out of these technologies tougher.

Barriers cited for the development of the financial base include:

Based on combined results of survey responses and interviews from both sets of cluster analysis, we can summarise the main concerns in terms of funding access as described below:

Lack of private investment in all KBBE sectors:
Lack of private investment is mainly due to the:

- Lack of awareness and comprehension on the specificities in all fields of biotech applications, compared to other technological innovations (requiring shorter time, low risk investment with high return on investment) by the investors;
- Unclear governmental policies and regulations towards the use of biobased products and technologies. There is also a lack of governmental subsidies and incentives (especially unattractive tax regulations such as tax loss carrying forward and tax credits) to encourage entrepreneurs and investors;
- Lack of capital in venture capital sector due to the general economic problem;
- Risk averse investment culture especially in mainland Europe though less so in the UK;
- Weaknesses in business plans and an absence of multidisciplinary in-place teams;
- Cluster effect (e.g. the companies not belonging to a cluster are less likely to be funded);
- Company size (e.g. start-ups and spin-offs are much less recognized than SMEs) and
- Reputation of the company (i.e. the lower the reputation of the company, the lower the chances to get funded);
- IP filing cost (difference between US and Europe), long timeframe for patent filing, low motivation of scientists due to lack of economic reward, different disclosure policies between US and Europe;
- Nature of the sector (e.g. non-medical KBBE with low return on investment);
- Type of activities (e.g. service providing companies are not well supported);
- Bureaucracy;
- Lack of interaction between companies and investors (thus proximity is an advantage when those investment companies are located in the cluster);
- Difficulty in obtaining credit guarantees as challenges in providing proof of trust and security.

Lack of public investment in all KBBE sectors:
Low success rates in accessing public funds in all KBBE sectors can mainly be attributed to:

- The requirements surrounding IP rules and dissemination strategies to disclose certain sensitive information, particularly for strategic innovative projects where a certain degree of confidentiality is required (e.g. BioVal, Spain);
- The administrative burdens in the application of Governmental and EU based funds, and time consuming and costly maintenance for meeting the requirements of funding (e.g. BioVal, Spain; Upper Austrian Food cluster, Austria);
- The fragmented character (not focusing on key areas) of public funding (e.g. Ghent, Belgium);
- The uncertainties regarding the technological and fiscal changes for bio-fuels in the future to obtain financial support (e.g. Ghent, Belgium);

- The prerequisites for granting public funds such as the requirement of matching fund from the private sector, or the involvement of more than 3 collaboration partners (e.g. Munich, Germany; UAFC, Austria, respectively);
- The funding mechanism not designed to cover all stages of the product/technology development lifecycle but mostly limited to pre-seed and seed capital only;
- The late announcement and uncertainty in complete payment;
- The high competition to receive funding;
- The high interest rates offered by public banks;
- The differences in Government policies (e.g. Provincial versus Federal Government in Canada);
- The concerns about the sustainability of public funding due to high level of public debt in most countries;
- The lack of awareness on the existence and usefulness of "Innovation Vouchers" as a source of readily available funding source with less bureaucracy.

Examples of successful funding:
At the cluster and/or country level, we observed different solutions generated to bridge the growing gap named as "Death Valley" between the distribution of seed capital (mostly public) and the arrival of private VC funding at later stages.

Some clusters tend to provide in-house dedicated offices and infrastructures for VCs to use, or a VC-company forum to match funding to companies, and to sign exclusive or "gold" partnerships with VCs, or yet to formalise international agreements.

A new model has been developed by some VCs in the UK and France, in which they provide 'seed' fund to a scientist/entrepreneur with a good project, without any expectation of a new company establishment. The idea is to support the project to go forward (and to avoid paying infrastructure costs involved with the creation of a new company), and to sell the project/ product for a good profit later on.
Another example is the trinational cluster BioValley, where different formulations have been developed in each country to facilitate seed financing and to bridge the gap. In the French part, a "Risky Investment Fund-FCPR" supported by public (deposit office, European funds FEDER) and private funds (local banks) has been created. In the German part, to bridge this innovation cycle gap, "Transfer Companies" have been established by the TTO, with the support of government for 5 years, with the intention of selling afterwards. Finally, in the Basel part of BioValley, the tendency is more towards fostering collaborations between big companies and start-ups/spin-offs, Mergers and Acquisitions and other Alliance strategies as well as in some other clusters.

Funding by Foundations and Business Angels is found to be a common practice in the USA.

In Japan, strong venture capital organisations have been created with the support of local credit unions (i.e. a cooperative financial institution that is owned and controlled by its members and operated for the purpose of promoting thrift, providing credit at reasonable rates, and providing other financial services to its members), hence this source of funding does not prove to be a problem.

In Agro-food Technopole Quebec/Canada, cooperatives created by farmers and the financial support provided by the cluster organisation are the main practices of support mechanisms.

Assessment of Financing CSFs

The indicators for critical success factors regarding the fundraising efficiencies are listed below. Besides the presence of VCs, business angels, government funds specific for the sector, EU funds, and private banks, other elements are considered critical for the raising capital are:

- Innovative financing tools;
- Strategic alliances (licensing activities, joint ventures, M&A);
- Presence of an organisation that helps to obtain funds;
- Capability to leverage on the cluster organisation for gathering access to financial entities;
- Capability to leverage on the cluster organisation for gathering access to favourable nation/region tax policies;
- Specific conditions to receive funding (e.g. interest rates, shares requested, upfront payment etc).

Policy Recommendations

Policy Recommendations

Approach to Policy Recommendations

Introduction

There is a growing strategic interest in the concept of the bioeconomy, both in the OECD and non-OECD countries, to deal with the global challenges such as climate change, environmental concerns, reduction in fossil-fuel resources, shortage on food and arable land to meet the food demand of increasing world population etc. To address these challenges, the higher involvement of biological sciences from the contributions of industrial biotechnology through environmental applications to climate change issues, improved health outcomes, and feeding global populations with better yielding crops involving higher amounts of nutrients is foreseen. Additionally, to meet the increasing consumer demand on individualised medical care and medications (e.g. personalised medicine), biotechnology is expected to make significant contributions in the healthcare sector[97]. The FAO has estimated that a 70% increase in food production would be needed to feed an additional 2.3 billion people by 2050. This larger population will not only increase the world demand for food, but also for animal feed, fibre for clothing, clean water, and energy. In order to meet the increasing world demand for meat, grains and fuels, an important increase in agricultural production is needed to fulfil this growing demand for feed, food and raw material for industrial use sustainably. Sustainable development includes recycling of used products, materials, and organic wastes, by conserving biodiversity. Consequently, management practices in forestry and agriculture will have to be continuously aligned with biodiversity conservation and climate change mitigation targets[98]. Thus, for obtaining full benefits from the bioeconomy, a comprehensive goal-oriented policy will be required. This will require leadership, primarily by governments but also by leading firms, to establish goals for the application of biotechnology to primary production, industry and health; to put in place the structural conditions required to achieve success such as obtaining regional and international agreements and to develop mechanisms to ensure that policy can flexibly adapt to new opportunities.

Innovative EU Policy Frameworks currently need to move forward to meet these global challenges of economic and environmental sustainability, and to be competitive on the world market with an active support from the Governments of the Member States and the public. Pre-existing regional, national and EU policies should be harmonized and improved to stimulate the development of KBBE.

EU Policies

EU support of clusters emanates from 3 different types of policy: regional policy, industrial policy, and research policy[99] (OECD Regional Innovation Report, 2007).

EU Regional Policy seeks to assist the economic and social development of the EU's less-favored regions. Clusters and networks are supported mainly through the Structural Funds (mainly the European Regional Development Fund), and the PHARE Programme [100]. Rural development issues are addressed by the European Agricultural Fund for Rural Development (EAFRD)[101]. Member States

---

[97] OECD International Futures Project: The Bioeconomy to 2030:Defining a Policy Agenda, 2009: www.oecd.org/document/48/0,3343,en_2649_36831301_42864368_1_1_1_1,00.html

[98] The Knowledge Based Bio-Economy (KBBE) in Europe: Achievements and Challenges Full report prepared by Clever Consult BVBA, Brussels, 2010: http://sectie.ewi-vlaanderen.be/sites/default/files/documents/KBBE_A4_1_Full%20report_final.pdf

[99] OECD Reviews of Regional Innovation:Competitive Regional Clusters , National Policy Approaches, 2007: http://www.oecd.org/document/2/0,3746,en_2649_36831301_38174082_1_1_1_1,00.html

[100] European Commission, Enlargement, PHARE Programme: http://ec.europa.eu/enlargement/how-does-it-work/financial-assistance/phare/index_en.htm

[101] European Commission, Agricultural and Rural Development: http://ec.europa.eu/agriculture/fin/index_en.htm

are encouraged to develop regional and national policies for innovation clusters and poles, using the support offered by these different funds.

Enterprise and Industry Policy aims to help creating an environment in which firms can thrive and meet the objectives of the Lisbon Agenda. This agenda seeks to ensure productivity growth, job creation and wealth generation to meet the goal of becoming "the most competitive and dynamic knowledge based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion". This policy also aims to support the **Europe 2020 strategy**[102] for an innovative and resource efficient Europe, highlighting the building up of a bio-economy by 2020 as one of the deliverables under the **Innovation Union Flagship Initiative**. Europe 2020 is the EU's growth strategy for the coming decade to develop a smart, sustainable and inclusive economy for delivering high levels of employment, productivity and social cohesion. The Union has set five ambitious objectives - on employment, innovation, education, social inclusion and climate/energy - to be reached by 2020. Each Member State will adopt its own national targets in each of these areas.

The importance of creating a strong European bioeconomy reflects the concerns of European society to challenges, such as globalisation and economic crisis; guaranteeing food security while adapting to a changing climate; reducing the environmental impact of agriculture and industry; maintaining an affordable, safe, healthy and nutritious food supply[103].

For the successful development of SMEs, cluster policies are regarded as key factors and promoted through Innovation, Industrial and Enterprise policy sub-areas. Most of the policies/activities within the *Innovation and Industrial policy* aim to promote policy learning and cooperation for better understanding and exchange of best practices. For example, the PRO INNO initiative (*http://cordis.europa.eu/innovation/en/policy/pro-inno.htm*) supports, among others, trans-national mutual learning and cooperation between policy authorities responsible for cluster policy development and the Europe INNOVA initiative (*www.europe-innova.org*) is designed to facilitate networking, transnational cooperation and learning between clusters with a view to create world class competitive clusters in Europe. Within the framework of this Europe INNOVA initiative of the European Commission's DG Enterprise and Industry, the "European Cluster Observatory"[104] has been launched in 2007, managed by the Stockholm School of Economics to provide knowledge and collaboration platforms. With its newly designed website since late 2010, it enables cluster mapping according to the sectors in addition to offer a comprehensive cluster library and information on cluster policy in Europe. The Innovation Relay Centres Network, co-funded by the European Commission, that provide technology transfer and innovation support services to European firms, also carries out specific actions in support of European clusters. *All above initiatives and actions* will be continued under the Competitiveness and Innovation Framework Programme (CIP) for the programming period 2007-13.

The third type of EU policy to support clusters is the ***Research and Development Policy*** aiming to activate regional research-driven clusters, mainly through the "Regions of Knowledge" pilot actions (*http://cordis.europa.eu/era/regions_knowreg2.htm*) aimed at supporting experimental actions at the regional level to develop regions of knowledge in the area of technological development, co-operation between universities, and research at the regional level. Built on the above two actions, a new "Regions of Knowledge" scheme is foreseen under the Seventh Framework Programme (FP7) with a focus on supporting research-driven clusters with a view to increase research investment in Europe.

FP7[105] is for funding research in EU, which was designed to cover the period from 2007-2013, with a total budget of more than €50B. 63% (referring to almost €32B of this total budget) of the budget has been allocated to "Cooperation Programme" to cover the whole period in 10 thematic areas, including biomedical R&D (€6.1B, resp. 19%) and non-medical R&D (i.e. KBBE) in the fields of food, agriculture

[102] European Commission, Europe 2020 : http://ec.europa.eu/europe2020/index_en.htm

[103] International Innovation, 2010 : http://www.research-europe.com/index.php/2010/08/maive-rute-director-of-the-biotechnologies-agriculture-and-food-directorate-dg-research-european-commission/

[104] European Cluster Observatory : www.clusterobservatory.eu

[105] FP7: http://cordis.europa.eu/fp7/cooperation/home_en.html

and fisheries, forestry, and biotechnology (€1.9B, resp. 6%). This Cooperation Programme supports transnational cooperation for all themes through a range of instruments, including Collaborative Research and Coordination-type support. Some themes (including Health) also fund research through Joint Technology Initiatives. For 2011, the funding to be allocated to research in KBBE will be approx. one-third (€240 M) of the budget allocated for Health (€682M).

In designing the budget and themes for the next framework programme for research and innovation, we suggest the EC to provide stronger funding support for the development of non-medical KBBE sectors to balance the current 80:20 distribution between medical vs. non-medical bioclusters. Based on our cluster analyses and the comments collected during the December 10th Workshop, we suggest to EC easing the application and administrative procedures required by the framework programmes. It is also advised to increase the existing share of the SMEs to a higher level since the current contribution to SMEs involved in KBBE is stated not to be high enough for them to foster innovation and create a sustainable economic model.

German Biobased Policy

Following approval by the Federal Government on 10th November, 2010, **Germany** became the first country worldwide to implement an approach to KBBE by dedicating total funding of **2.4 billion Euros** to **bioeconomy** over the next 6 years[106]. The initial six year programme will be funded by four Ministries (BMBF, BMELV, BMZ, BMU) with two-thirds allocated to the Ministry of Education and Research (BMBF). First, an information platform “biotechnologie.de” has been created by the BMBF. The BMBF, together with the Ministry of Food, Agricultural and Consumer Protection (BMELV), formed the “**Bioeconomy Council**” (Bioökonomierat) made up of scientists and industry representatives as an independent advisory body to the Federal Government in early 2009. The Bioökonomierat presented its first report 20 months after founding and defined the bioeconomy, which emerged in the context of the EU Lisbon Strategy, in the following way: “KBBE encompasses all industrial and business sectors and their related services which produce, treat, process, and use biological products (plants, animals, microorganisms). This includes agriculture, forestry, food industry, fisheries, aquaculture, sections of the chemical, pharmaceutical, cosmetic and textile industries as well as energy production. The Council have made a plea for openness towards all innovative technologies, including not only breeding research and genetic engineering, but also bioinformatics and systems biology. The Council created 4 Working Groups on Soil, Plant, Animal and Biotechnology. The Biotechnology group discussed the role of industrial biotechnology, i.e. the application of enzymes and microorganisms for the production of biofuels and bioproducts as a central driver for a competitive and sustainable bioeconomy. Thus, as a first concrete support measure, €100M will be invested for industrial (white) biotechnology. €1.1B will be spent for food research while €511M will be dedicated for energy production/utilisation research.

This unique strategy should be taken as a best practice and should be implemented at the EU level as a commonly accepted KBBE policy.

Creating links between existing funding mechanisms (e.g. EIB) and the regional authorities

When funding was investigated in detail, we diagnosed two types of problems causing a major gap within the funding value chain. One was due to the lack of awareness and links on the use of existing funding opportunities, while the other was caused by a lack of funding resources for public and private investors, due to economic crises and a dearth of VC. As far as the lack of awareness of available funds was concerned, the main problem was attributed to missing links between potential funding options (e.g. EIB, EIF) and regional funding sources and needs. As best practice, it has been observed that EIF funding is easily accessible to companies when it is distributed to the companies through National Development Banks (e.g. OSEO in FR) and Regional Offices as an intermediary entities.

[106] http://www.biotechnologie.de/BIO/Navigation/EN/funding,did=118934.html?listBlId=77924&

Traditionally, the funding available by European Investment Bank (EIB) or European Investment Fund (EIF) is distributed by Commercial Banks to the companies. Based on our experience in the finance sector, we have identified that EIF is lacking a fund distribution structure able to understand the needs of local investors (VCs located within the region, investing small amount of money into SMEs or start-ups), to consolidate them, and to make them attractive in terms of size and return on investment. To meet evaluation criteria used by EIF (typically investments >€50M) and other institutional investors, it is suggested that transnational funds should be created, capable of consolidating investment needs at regional level into a critical deal size and an acceptable deal flow. These applicant stakeholders would also need to generate good business plans, and have strong management skills. It is postulated that by the time EU territory is fully covered by Regional and/or National Innovation Banks collaborating with EIB, the problem of accessing to the existing funding would be solved. That's why the creation of trans-regional investment vehicles should be encouraged to serve as intermediary between EIF, other investors, and regional funding sources.

Policy Approach of this Study

Our policy recommendations will be based on the cluster analyses we conducted via on-line survey, and face-to-face/phone interviews with 16 model bio-clusters located in (n=13) and outside (n=3) Europe. In order to suggest relevant policy recommendations and solutions, our first approach is based on the understanding of the major gaps and problems existing within the examined clusters focusing on KBBE within Europe, and then on comparing the existing problems in Europe with the ones located outside Europe (e.g. USA, Canada, Japan). Potential solutions would be based on existing best practices, which will be addressed to the specific responsible authorities at regional/national/EU level.

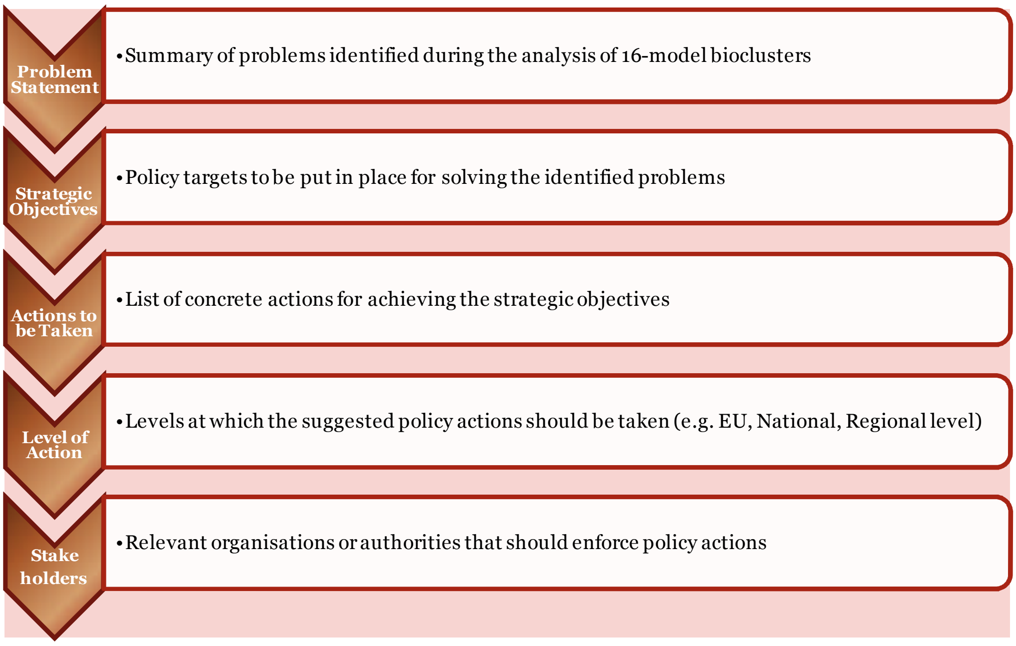
Our policy recommendations were based not only on the gap analysis performed on CSFs that were rated of high importance and low availability, but also based on the evaluation of insights gathered through phone interviews, assessment of the individual cluster reports, and on the need of gathering qualitative and quantitative data for tracking the EPIs. Following this methodology, policy suggestions have been categorised under 6 themes as KBBE aspects, funding, incubators, technology transfer, cluster organisations, and entrepreneurial culture.

The lack of **funding** and the lack of existing policy aspects as incentives and regulations supporting **KBBE** (e.g. tax credits, tax breaks, tax exemptions etc) were identified for all type of bioclusters**.** When looking at the **incubators, technology transfer organisations, and cluster organisations**, they were considered to be highly available while rated of medium/low importance on average. It was clear that while these organisations were considered not to operate in an efficient manner. This is why policy recommendations on these topics were formulated by this group. The major problem with the TTOs was that they are managed in a fragmented way and handled on an institutional basis, rather than using a collaborative model. This way of operating has been causing some confusions and problems in managing IPR between public and private partnerships. Incubators in general were found not to have standardised nor tailored services and adequate skills according to the needs of the specific industry (e.g. only offering empty labs or buildings). The cluster organisation theme has been included under policy recommendations since it has been considered as an important factor in the success of the cluster itself, and categorised under the economic performance indicators as one of the cluster-enabling factors. Cluster organisations are in several instances perceived as providing weak and not standardised services, and funding and entrepreneurial skills are perceived as not sufficient to sustain an adequate service activity and cluster organization governance. **Entrepreneurial Culture** resulted to be highly important (except for mature clusters being medium important) for the bioclusters while available at medium level in all types of clusters. From the interviews and the discussion with the experts and the Commission, it resulted however to be dramatically lacking in the KBBE sector, and key for the achievement of other critical success factors such as availability of funding mechanisms; existence of special regulations and incentives supporting the entrepreneurs; existence of efficient communication platforms between public and private parties offered by cluster organisations; existence of efficient business incubators; efficient technology transfer mechanisms. Moreover, the entrepreneurship dimension was considered as an important point for the development and achievement of most of the dimensions necessary for the tracking of the EPIs. Thus, we have generated policy recommendations on this theme as well.

It was not aimed in this study to conduct a thorough analysis of the total KBBE policy regulations, but instead to suggest policy actions where we spotted a gap within the scope of this study as described above.

In order to formalise the results of our study in a consistent manner and to better structure the actions to be undertaken for policy recommendations, we followed the steps indicated in Figure 10 to structure our policy recommendations;

Figure 10: Policy Steps



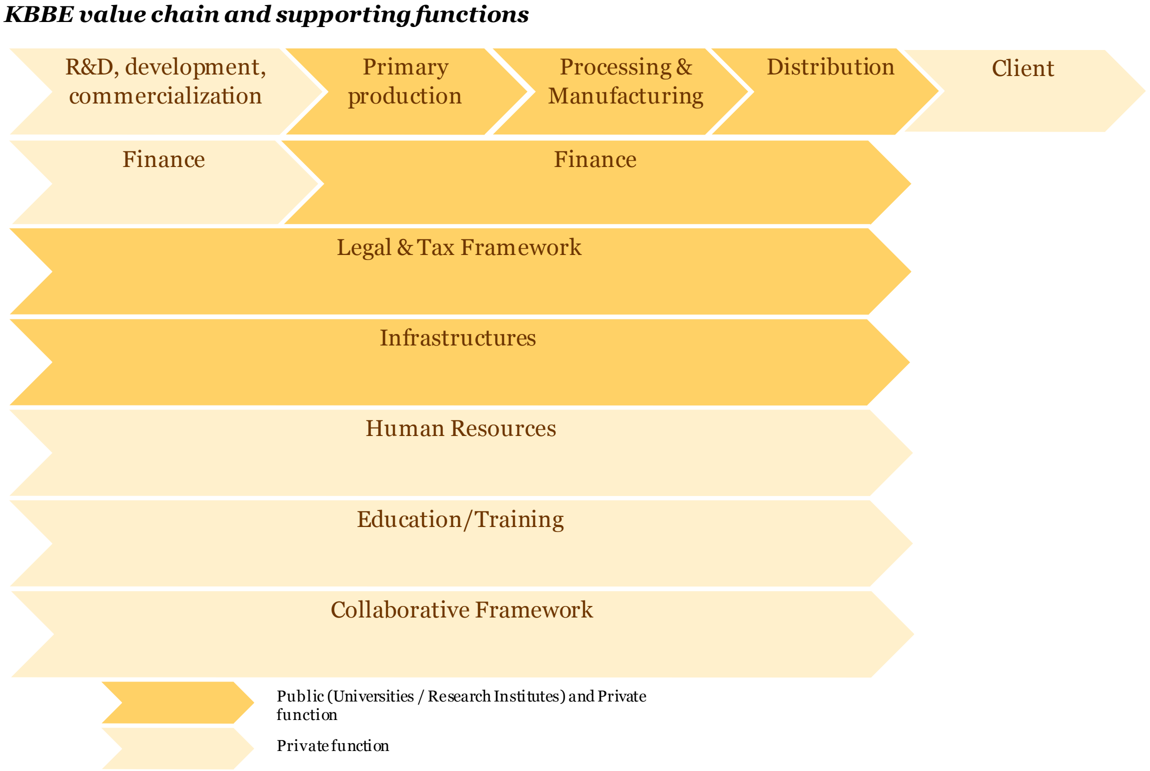
For clarity and track record purposes, we will classify the elements of the problem statement, operational objectives and actions to be undertaken under the following reference sub-sections:

- Market structure;
- Information and communication;
- Operation and communication;
- Regulations and taxing.

In order to better understand the impact of the policies and the selected topics on all functions involved in the cluster, we have illustrated their activities and roles along the whole value chain (see Figure 11).

The impact of the policy operational objectives will therefore touch, when applicable, each of the functions suggested thereafter: finance (both public and private), legal and tax functions, regulatory affairs, human resources, education/training, and national and international supply. R&D (both public and private), manufacturing, marketing/business, and distribution will also be considered.

Figure 11: Total Value Chain



KBBE value chain indication

Given the large scope of KBBE activities, the Research and Development function represents a major challenge and should be further split between Research, Development and Commercialization:

- Research includes early stage, basic, advanced and focused research;
- Development focuses on advanced technology and prototype developments;
- Commercialization includes early stage pre-market activities including prototype production and late stage market entry preparation;
- Primary production represents the industrial-scale preparation of primary products required for processing and end-product manufacturing;
- Processing and manufacturing represents all activities related to transformation of primary product supply into value-added products;
- Distribution constitutes all required stages for bringing products from industrial plant to the ultimate beneficiaries;
- Reaching the client or the end user is the most critical step of the chain. The full value chain is working under the condition that the end user fully recognises the value of the product;
- This structure will allow for checking, linking, and following up on the relevant actions to be undertaken.

This approach can be summarised in the Table 22 presented below:

Table 22 - Problem statement and strategic objectives for the 6 Policy Themes

	Problem Statement	Strategic Objectives
KBBE Policy	**Market structure**	Define and communicate the market potential and scientific potential of an integrated KBBE approach compared to an individualised industry approach Propose an economic and scientific methodology for the development of an integrated approach with the objectives to create several world-class EU bioclusters Define a supportive and harmonised taxing and regulatory framework, to foster the demand for KBBE industry
	Lack of awareness of the development potential of KBBE	
	Fragmented KBBE market structure	
	Agriculture and Energy sectors present a conservative profile and are consequently not fully oriented to grasp the potential of the Biobased economy	
	Information and Communication	
	Lack of awareness on the development potential of KBBE activities and added value on the perception of collaboration	
	Lack of awareness on the technological developments and their implementations on especially non-medical KBBE sector	
	Lack of multidisciplinary education, international training programmes and efficient learning on all bio-based products, which could be created at different levels (EU, National, and Regional)	
	Operations and Implementation	
	Lack of investments particulary for healthcare, agro-food,biotech fields involving genomics, proteomics, metabolomics and nutrigenomics: - *Mechanisms for long term (10-12 years) anfd high risk investments;* - *High upfront payments for R&D and clinical trials, and for production units.*	
	Low rate of results implementation into industrial applications: - *Little prototyping and demonstrations activity;* - *Regulatory constraints (green and white sectors);* - *Lack of market knowledge.*	
	Lack of highly skilled scientific workforce in highly specific sectors undergoing fast technological upgrades and changing regulations	
	Regulations and taxing	
	Presence of ethical barriers both in the medical (e.g stem cell use) and non-medical KBBE sector (e.g use of GMOs in agro-food industry) regarding to safety aspects	
	Need for EU regulatory frameworks regulating incentives to support in all relevant sectors	

	Problem Statement	Strategic Objectives
Funding	**Market structure**	Make better use of, and leverage, the existing public and private funds available along the value chain Develop a strong early stage venture capital or alternative private funding industry with new financing tools to cover the full value chain.
	Gaps of financing along the value chain for start ups and SMEs: - *Lack of pre-seed and seed capital* - *Lack of available finance between seed capital and Venture capital* - *Lack of exit strategies for venture capital ,* Institutional investors pooling large sums of money tend to be reluctant or risk averse	
	Fragmented and too limited European early stage finance industry	
	High risk perception of Bio industries	
	Venture capital structure may be not appropriate to finance Bio industries due to company and product development cycles	
	Information and communication	
	Lack of awareness and available funds	
	Operation and implementation	
	Lack of accessible risk sharing mechanisms	
	Regulations and taxing	
	Early stage finance industry and European VC industry not supported by attractive and incentivized regulatory and tax framework	
	Administrative burdens for raisng funds from public national and supra-national institutions	

	Problem Statement	Strategic Objectives
Incubators	**Market structure**	Develop a new value proposition for European Incubators Strengthen and boost the expansion and sophistication of the European Incubator industry Define the needs of scientific infrastructure depending on the industry specifics of the cluster and deploy the necessary funds
	Incubators perceived of high value by cluster stakeholders are rather rare in Europe	
	Incubator's services are generally available in clusters but are often diversified throughout the clusters, not tailored, and not considered of high importance	
	Information and Communication	
	Low awareness on the role and benefits of incubators	
	Operations and Implementation	
	Incubators are focusing too much on the real estate dimension of their service offering	
	Incubators have not yet the appropriate set of management and market skills and funding to properly address company challenges. They are not tailored according to the specific needs of the industry but are instead rather general	

	Problem Statement	Strategic Objectives
Cluster organisations	Market structure	Create cluster organisations, which can support the development of European leader bioclusters to compete at international level Create cluster organisations, which can support the development of for emerging and developing bioclusters to boost European KBBE growth.
	Lack of critical size of cluster organisations	
	Value proposition of cluster organisation is too weak	
	Lack of leadership of cluster organisations on cluster stakeholders and on regional policy makers and politicians	
	Information and communication	
	Lack of awareness and added value of the cluster organisations' roles, due to the gap between the stakeholders expectations and what Cluster Organisations offer	
	Lack of attractiveness/awareness at the stakeholder level to become an official member of the cluster	
	Lack of sense on belonging to a cluster	
	Lack of interactions and collaborations between different cluster organisations at regional/national/EU level/international level	
	Operations and Implementation	
	Lack of unified definitions and standards on the organisational structure of cluster organisations (e.g. management team, services offered, funding structure, membership fees etc)	
	Lack of experience at the managerial level	
	High dependency on public funds	
	Lack of identified indicators/availability of data to measure the effectiveness of Cluster Organisations	

	Problem Statement	Strategic Objectives
Technology Transfer	Market structure	Valorisation of existing stock of unused technology and IP rights. Boost European technology transfer activities through the creation of an open architecture, with dynamic, cost efficient and transparent platforms and frameworks.
	Highly fragmented landscape for technology transfer structures or offices across Europe	
	There is lack of critical mass	
	There is lack of funding	
	There are wide disparities in terms of performances, management capacities and developing practices	
	There is no listing and trading recognized stock exchange for Intellectual property rights	
	Information and Communication	
	Lack of transparency of stock of patents held by public agencies	
	Operations and Implementation	
	Technology transfer offices are still dependent on public research institutions and not headed by an independent board with multi-disciplinary skills, leading thus to a lack of efficiency in their activities	
	Technology Transfer offices are considered as an hurdle for IP licensing due to indefinite discussions on legal matters and revenue sharing	
	There is a problem in terms of IP: - *For the timeframe and affordability of processes;* - *For revenue shares and IP for the income distribution to scientists.*	
	Regulations and taxing	
	There is discrepancy between European and US policies regulating disclosure of innovation (e.g. first to disclose vs. first to invent, respectively)	

	Problem Statement	Strategic Objectives
Entrepeneurship culture	Market structure	Define the derisking mechanisms along the value chain to enable entrepreneurs and stakeholders to invest more and more rapidly into new projects. Promote and develop entrepreneurship programmes and rewards in private and public sectors. Accelerate the market development and acceptance of new biobased products.
	Lack of structural solutions for authorities to address regulatory, market and financial risks raised by new bio products	
	Lack of entrepreneurial experience in public research institutions and administrations	
	Lack of risk taking attitude in the financial chain and risk sharing structures	
	Lack of international culture	
	Lack of entrepreneurship recognition	
	European entrepeneurs feel no support from European banks as lending policies have been tightened and cost of credit raised	
	Information and Communication	
	Lack of communication on role model entrepreneurs and of reward of their successes	
	Operations and Implementation	
	Risk sharing facilities are not designed for entrepreneurs.	
	Regulations and taxing	
	Lack of regulatory framework regulating incentives to support entrepeneurship	
	Lack of initiatives toward entrepeneurs to reduce the harshness and the consequence personal bankruptcy law	
	Banking lending policies are not favourable for entrepeneurs because of capital ratio regulation (ratio of a bank's capital to risk)	

Policy Recommendations

Policy Theme 1: KBBE

PROBLEM STATEMENT

The absence of KBBE market potential vision, the new technological and scientific developments with the required adaptation of the tax and regulatory framework and the different subsectors features composing the overall KBBE industry constitute strong arguments to ask for a specific KBBE policy at European and national level to fully grasp the overall KBBE opportunity.

Example Ghent, Belgium: bio-energy is still very young and the full potential of the industry is unknown; additionally, the legal framework and the amount of public funding available are uncertain.

Market Structure

- Lack of awareness on the development potential of KBBE;
- Fragmented KBBE market structure:
  - Companies and product development cycles are different within KBBE activities;
  - KBBE activities present different levels of sophistication, critical mass, funding, international development, cooperation and interconnectivities;
  - Lack of role model companies (namely in the energy and marine biotech sectors).
- Agriculture and Energy sectors present a conservative profile and are consequently not fully oriented to grasp the potential of the biobased economy.

Information and Communication

- Lack of collaboration synergies:
  - Between different KBBE sectors;
  - Between different kind of stakeholders (Governments, Universities/Research Institutions, Industry);
  - Within entities inside and outside the cluster (at the national /international level);
  - Between different disciplines (biotechnology, biochemistry, microbiology, agriculture, ICT, etc. For instance, the biorefinery concept requires collaboration between different disciplines such as industrial biotechnology, chemical process technologies, nanotechnology, bioenergy and the technologies regarding the efficient use of raw materials).
- Lack of awareness by cluster organisation:
  - On technology developments in KBBE sectors;
  - On the impact of their implementation on cluster infrastructure.
- Education:
  - Lack of a multidisciplinary education, international training programmes and efficient learning on all biobased products, existing at different levels (EU, National, and Regional).

Operations and Implementation

- Low rate of transferring results into industrial applications:
  - Less support and activity on prototyping and demonstration plants (for up-scaling activities);
  - Regulatory constraints (green and white biotech sectors);
  - Lack of market knowledge.
- Lack of investment particularly for healthcare, agro-food, biotech fields involving genomics, proteomics, metabolomics and nutrigenomics:
  - Mechanisms for long term (10-12 years) and high risk investments;
  - High upfront payments for R&D & clinical trials, and for production units.
- Lack of highly skilled scientific workforce in highly specialised sectors undergoing fast technological upgrades and changing regulations.

Regulations and Taxing

- Presence of heavy ethical regulations for biotech based products in all sectors;
- Need for EU regulatory frameworks to support in all sectors bio-based products under the following aspects:
  - Tax (e.g. European fiscal harmonisation of the KBBE industry);
  - Establishment of recognized training programmes for each KBBE sector;
  - R&D (lack of visibility on long term impact of certain technologies, which would require a specific regulatory framework for research and development);
  - Technology: for scaling up of KBBE production to compete against established market technologies, and for renewal and modernisation of technology and manufacturing equipment (agro-food, industrial and energy KBBE sectors).

STRATEGIC OBJECTIVES

- Define and communicate the market potential and scientific potential of an integrated KBBE approach compared to an individualized industry approach;
- Propose an economic and scientific methodology for the development of an integrated approach with the objectives to create world-class bioclusters in Europe (as described in the theory section of this report);
- Define a supportive and harmonised tax and regulatory framework (for instance on ethical issues), efficient finance tools, and new expertise building capacity to meet the KBBE industry demand.

STAKEHOLDERS

- EU regulatory bodies;
- National regulatory bodies;
- National governments;
- EIB;
- National development banks;
- National innovation agencies;
- VCs;
- EU Innovation Agencies;
- Regional Governmental Agencies;
- National Government Agencies (Ministry of Education, Ministry of Health, Ministry of Environment and Forests, Ministry of Energy, Ministry of Agriculture, Land and Fisheries);
- Economic Development Agencies at National level;

- EU Directorates-General (e.g. DG Research and Innovation, DG Enterprise and Industry, DG Environment, DG Agriculture and Rural Development, DG Climate Change, DG Education and Culture, DG Energy, DG Mobility and Transport, DG Taxation, DG Health and Consumers, DG Maritime Affairs and Fisheries);
- Cluster organisations;
- Start-ups;
- Spin-offs;
- SMEs;
- Large Companies;
- EU expert groups: KBBE net; ERA net, others.

Level of action

A KBBE policy at EU level (with an emphasis on national level implementation) is required and should be reinforced by a strong national deployment policy implemented appropriately at regional levels.

Table 23 - Policy Actions to be undertaken for KBBE

Market Structure	***Level of action***		
	EU	National	Regional
• Assess the long term economic potential of KBBE areas with the involvement of European leaders, multinationals, industry (both large companies and SMEs), academia, research institutions, regulators and financers	X	X	
• Redesign the strategy for cluster organisations by defining its services and funding mechanism to address the challenges and the opportunities of the biobased economy at the international level	X	X	X
• Define cluster criteria for each maturity level for obtaining the new EU Label for bioclusters (depending on the achievement of CSFs and EPIs)	X	X	X
• Reduce administrative burdens and implement faster procedures to ease the mobility of key personnel (similar to the H1-B visa principle existing in the US: Skilled Worker Visa)	X		
• Define a fund raising strategy for selected bioclusters by leveraging on the presence of institutional funds, and on transregional entities having a consolidated investment strategy	X	X	X
• Define the difference in "value chain" between different KBBE sectors to facilitate the time to the market	X	X	
Information and Communication			
• Identify most relevant advocacy targets at EU, Nat., and Reg. levels	X	X	X
• Communicate in an organized, consolidated, structured and understandable manner to inform all stakeholders on the new scientific challenges and market opportunities, to demonstrate key benefits of biobased economy for and attract investors:	X		X
- Information sessions and workshops covering scientific, business, and fund raising aspects in specific KBBE areas at cluster/regional/national/EU levels;	X	X	X
- KBBE conferences with policy makers, public, cluster organisations, investors, and industry representatives at EU, national and regional levels.	X	X	X
• Communicate on the importance of having technical, business and financing courses at the universities and Higher Education Institutions present within the cluster		X	X
• Raise awareness with better communication on the importance of preventing adverse environmental impacts to increase the acceptance of technologies and related products developed especially in the field of industrial biotechnology	X	X	X

Operation and Implementation			
R&D			
• Launch a competitive bid for the establishment of new translational research centres and required research and technological platforms after examining the existing research centres, their outcomes and lessons learnt.	X	X	
• Recruit specialised scientists with industry background to advice on proposed translational research centres strategy (governance, skills, and infrastructure required to stimulate innovation through collaborative research, and direct industrial application through partnerships)		X	X
• Identify measures to reduce trial costs supported by companies for new KBBE products	X		
• Encourage and stimulate collaboration between different scientific disciplines (e.g. between industrial, environmental, energy, agricultural disciplines)	X	X	

Education			
• Support the creation of an “European Biotechnology Business School”, classes offered by entrepreneurs-professors, and with the specific aim of developing fundraising, regulatory, and market access skills	X		
• Creation of EU training courses in KBBE specific fields, namely in the energy, environment and marine sectors		X	X
• Propose secondary and university trainee programmes to encourage students to study and work in KBBE areas			X
Finance			
• Build up a European Network of investors interested in KBBE activities, particularly in the under-funded blue, white, and green biotech sectors	X		
• Assess the efficiency of national financing mechanisms and assess potential for deployment at EU level	X	X	
• Strengthen the activity and development of transnational investment entities with the aim of consolidating investment needs at regional level and attract institutional investors		X	X
• In collaboration with EIB and EIF, review existing risk sharing mechanisms to extend them to SMEs or consortiums	X	X	
• Dedicate stronger funding support under following framework programme towards non-medical KBBE sectors to balance the gap between medical and non-medical KBBE applications and more towards production and commercialisation	X		
• Increase the funding share for SMEs (>25%) in collaborative projects	X		
Manufacturing and Technology			
• Identify most relevant and urgent (responding to a market demand) prototyping platforms required for KBBE activities (these platforms aim to close the critical gap between scientific feasibility and industrial application) and support the establishment of demonstration plants that has a big importance particularly for industrial biotechnology	X	X	
• Promote existing KBBE patents held by European public research institutions to stimulate licensing activities and company creation through open innovation	X		
• Develop a market monitoring tool in order to follow scientific, technological, financing developments in key competitive areas to determine the existing situation and to satisfy the market needs	X	X	X
Regulations and Taxing			
• Create European passports for all KBBE products (i.e. develop regulatory instruments for the labelling and certification (e.g. Environmental Technology Verification-ETV) of KBBE products, set standards for safety, quality and consumer information on the new products/technologies, and for market approval within European territory) that has a particular importance for industrial biotechnology	X		
• List potential societal issues raised by new KBBE areas, and consider the creation of an EU harmonised framework to address GMO applications for the agro-food, energy, and marine sectors	X		
• List potential ethical issues raised by new medical biotech areas, and consider the creation of an EU harmonised framework to address stem cell applications, pre-natal diagnosis, and nanobiotechnological applications	X		

• Define supportive tax framework and incentive schemes for companies to support the high investment and production costs of the KBBE sector	X	X	
• Ensure coherence between different legislations and encourage “Public Procurement”	X	X	

Assessment criteria

- Number of EU KBBE world class bioclusters;
- Number of new companies, especially in White, Green and Blue sectors;
- Number of KBBE education programmes;
- Number of financiers supporting KBBE activities;
- Funds raised for KBBE activities.

Interaction with other policies

- Environment;
- Energy;
- Consumer protection;
- Agriculture;
- Health;
- Tax;
- Enterprise;
- Market;
- Financial services.

Best Practices

- Ghent-Belgium: As from July 2009, the Federal Government set up legislation on the use of biological fuel (at least 4 %) for transport. Since the Ghent cluster was active from 2005 on with investments in new bio-fuels, and the production facilities ready since 2007, the legislation has therefore been immediately effective;
- Saint-Hyacinthe-Canada: To foster energy efficiency and the discovery of alternative green energy resources, the Federal and Provincial governments offer many different incentives within the scope of “Going Green” measures. The aim of this policy is to support “Scientific Research and Experimental Development”, and then find innovative green KBBE technologies that can fall within the development of a sustainable environment policy at national level.

Policy Theme 2: FUNDING

PROBLEM STATEMENT

Market Structure

- Gaps of financing along the value chain for start ups and SMEs:
  - Lack of pre-seed and seed capital;
  - Lack of available finance between seed capital and Venture capital;
  - Lack of exit strategies for venture capital.
- Fragmented and limited European early stage (Venture Capitalists and Business Angels) financing industry;
- Institutional investors (typically banks or insurances companies) pooling large sums of money tend to be reluctant or risk averse in investing into small companies, critical mass and deal size being perceived as not sufficient;
- Biotech investments are perceived risky by all investors within the current economic climate;
- Venture capital structure may not be the appropriate structure for financing Bio industries, therefore a new biotech funding model is necessary for the survival of the industry.

Information and Communication

- Lack of awareness about available funding opportunities, and consequently low leverage on available funds.

Operation and Implementation

- Lack of accessible risk sharing mechanisms tailored to the biotech SMEs needs.

Regulations and Taxing

- Early stage financing industry and European VC industry are not supported by attractive and incentivised regulations and taxing framework;
- Administrative burdens for raising funds from public national and supra-national institutions.

STRATEGIC OBJECTIVES

- Make better use of, and leverage on, the existing public and private funds available along the value chain;
- Develop a strong early stage venture capital or alternative private funding industry with new financing tools to cover the full value chain.

STAKEHOLDERS

- EIB;
- National development banks;
- EU Innovation Agencies;
- National Innovation Agencies;
- EU VC industry;
- Banks, Insurance companies, pension funds, private investors and business angels.

Table 24 - Policy Actions to be undertaken for Funding

	Level of action		
	EU	National	Regional
Market Structure			
• Assess KBBE European market potential	X	X	
• Assess KBBE funding requirements at the different stages of the value chain in relation to clear economic and scientific objectives	X	X	X
• Strengthen the structure of the seed capital (double), venture capital (double) and investment fund industries, and increase access to foundations, and High Net Worth individuals.	X	X	X
• Develop at European level appropriate financing tools based on best practices for financial risk-sharing management of existing institutions (EIB, EIF, and National Development Banks)	X	X	X
• Develop tools for increasing flow of funds from European institutions to bioregions and bioclusters		X	X
Information and Communication			
• Develop a strong communication policy focusing on KBBE market potential and existing funding solutions	X	X	X
• Draft communication plan on competitive research, development, and innovation (RDI) funding initiatives	X	X	X
Operation and Implementation			
• Review the availability and performance of existing risk sharing platforms	X	X	X
• Design new risk-sharing mechanisms which can increase deployment at European level of successful financing for SMEs in the biotech space	X		
• Create trans-national funds capable of consolidating investment needs at regional level into a critical deal size and an acceptable deal flow, to enable attraction of institutional investors		X	X
• Create additional public funding resources by changing pension plans		X	
• Develop loan guarantee mechanisms tailored to the biotech industry and the SME sector		X	
• To provide competitive funding to the clusters tailored according to their maturity level	X	X	X
Regulations and Taxing			
• Propose tax credits and incentives to the seed, VC and investment fund industry	X	X	X
• Propose creation of a new tax attractive investment fund type to finance RDI and commercialisation	X		
• Propose tax credits and incentives to corporations and individuals investing their funds in KBBE RDI	X	X	X
• Propose regulatory framework to secure the development and financing of KBBE prototypes and proofs of concept when not currently allowed by existing regulations	X	X	

Assessment criteria

- Funds raised for KBBE activities;
- Number of Funds investing in KBBE activities;
- Number of KBBE companies;
- Number of jobs in KBBE companies;
- Volume of tax credits.

Interaction with other policies

- Tax policy;
- Market;
- Enterprise;
- Environment;
- Energy.

Best Practices

- OSEO – France « Contrat de développement participatif »: a 7 years loan, maximum € 3 million without guarantee but with deferred repayment mechanisms to strengthen SMEs balance sheet. The OSEO facility has provided € 650 millions, and banks, funds and private investors have brought € 1 billion to 650 companies. Company's own capital has increased by 15% through this new mechanism;
- FCPR – (BioValley/France) In order to facilitate seed financing, the region has created a fund for high risk investment FCPR (Fond Commun de Placement à Risque) which is fed by public (deposit office, European funds FEDER) and private funds (local banks);
- Funding from Universities (Cambridge, UK). The University has been successful in providing funds for start-up companies. It has three major funds: University of Cambridge Discovery Fund, University Venture Fund and the Challenge Fund;
- The Seed Fund strategy of Paris Genopole was redesigned to expand:
  - The volume of financing from several hundreds of thousands of Euros to millions of Euros;
  - The financing terms;
  - The geographical coverage.

This new strategy was considered as essential to create long term value in the company with the provision of long term visibility and resources for management expertise.

Policy Theme 3: INCUBATORS

The policy theme 3 on incubators focuses on a critical stage of the value chain when the novel research gets a business perspective. The new incubator value proposition should aim at better apprehending the market challenges and accelerating business development.

PROBLEM STATEMENT

"The pole should rely more on the incubator to create more innovative companies. The SMEs should be more integrated in the pole and it could be easier if the pole participates and supports their creation and their development."(Pole IAR-France).

There is no "official" incubator within the pole IAR. CARINNA incubator supports more ICT projects than agro-resources projects developed by the pole IAR.

Market Structure

- Incubators perceived of high value by cluster stakeholders are rather rare in Europe;
- Incubator's services are generally available in clusters but are often diversified throughout the clusters, not tailored, and not considered of high importance.

Information and Communication

- Awareness on the role and benefits of incubators is low.

Operations and Implementation

- Incubators have not yet the appropriate set of management and market skills and funding to properly address stakeholders challenges. They are not tailored according to the specific needs of the industry but are instead rather general;
- Incubators are focusing too much on the real estate dimension of their service offering.

STRATEGIC OBJECTIVES

- Develop a new value proposition for European Incubators;
- Strengthen and boost the expansion and sophistication of the European Incubator industry;
- Define the needs of scientific infrastructure depending on the industry specifics of the cluster and deploy the necessary funds.

STAKEHOLDERS

- National governments;
- Regional governments;
- Universities;
- Investment companies;
- Non-profit organisations;
- Incubators;
- SMEs;
- Start-ups;
- Spin-offs.

Table 25 - Policy Actions to be undertaken for Incubators

	Level of action		
Market structure	EU	National	Regional
• Assess the market needs for incubators		X	X
• Assess and rank the European KBBE incubators by size, sophistication and performance to increase competitiveness	X		
Information and Communication			
• Develop a communication policy for best in class incubators	X	X	
• Promote international partnerships between incubators			X
Operations and Implementation			
• Develop a competitive funding framework for KBBE incubator	X	X	
• Develop governance and service offering models for KBBE incubators	X	X	
• Develop a performance assessment methodology and rating methodology enabling collection of data necessary for (EPIs)		X	X
• Propose a model for RDI infrastructures with certified labs (GMP and GLP), and standard sharing arrangements between incubators		X	X
• Ensure the presence of tailored facilities for prototyping and feasibility studies			X
• Develop "Soft Landing" mechanism for stimulating the international collaboration		X	X
Regulations and Taxing			
• Set up special incentives and tax measures for the companies launched at the incubators			X

Assessment criteria

- Number of eligible KBBE incubators;
- Number of companies at the incubators;
- Number of companies established at the incubators.

Interaction with other policies

- Enterprises;
- RDI.

Best Practices

- Saint-Hyacinthe Technopole, Canada: The Biotechnology Development Centre (BDC) is an incubator building located within the limits of the City aiming to encourage the creation and growth of companies involved in the biotechnology innovation process. It brings together start-up businesses and subsidiaries of existing companies with an innovative biotechnology project. This centre is one of the most dynamic of its kind in Canada and offers rental space at highly competitive rates as well as services and other benefits tailored to the needs of the biotech industry;
- Near Munich, the "IZB Innovation Centre for Biotechnology" was created in 1995 with the support of Bavarian Ministry of Economic Affairs and Bavarian Ministry of Finance, and played a very important role for start-ups as well as for growing companies to accelerate the development in the region. Shortly after, critical mass of application-oriented scientists attained and the incubator has been the birthplace for several world renowned spin-off companies such as Mikrogen, Micromet, MorphoSys and MediGene. Since its establishment, 100 Life-Science companies have been founded under the roof of IZB and the IZB tenants have created more than 1,000 permanent jobs. These results were obtained by the catalysing effect of the "BioRegio" competition in 1996;

- Babraham Research Campus, Cambridge, UK: This is a purpose built bioincubator site which was established during the 1990's and has grown rapidly in recent years. It was founded by the Babraham Institute to commercialise its research via its fully owned subsidiary, Babraham Biotechnology Ltd. The incubator is also home to companies formed from other sources, including some that have moved to Babraham from other countries in Europe. It is now the leading dedicated bio-incubator campus within the Cambridge cluster, offering not only real estate but also a full range of services in support of start-ups and small companies. Over 50 companies have flourished on this incubator site.

Policy Theme 4: CLUSTER ORGANISATIONS

PROBLEM STATEMENT

The value proposition of cluster organisations has to be defined in the future. A concern of cluster organisations is the uncertainty around the value they could provide to cluster members.

Market Structure

- Lack of critical size on cluster organisations (e.g. COs are mostly unable to provide large spectrum of services such as advice on technology transfer, funding access, business coaching, regulatory aspects, scientific advice especially on project applications etc. due to the lack of skilled employees);
- Value proposition of the cluster organisations is too weak;
- Lack of leadership at cluster organisations to be affective on cluster stakeholders, regional policy makers, and politicians.

Information and Communication

- Lack of awareness and added value of the cluster organisations' roles, due to the gap between the stakeholders expectations and what cluster organisations offer;
- Lack of attractiveness at the stakeholder level to become an official member of the cluster
- Lack of sense of belonging to a cluster;
- Lack of interactions and collaborations between different cluster organisations/ stakeholders at regional/national/EU/international levels.

Operations and Implementation

- Lack of unified definitions and standards on the organisational structure and governance of cluster organisations (e.g. management team, services offered, funding structure, membership fees etc);
- Lack of experience at the managerial level;
- High dependency on public funds;
- Lack of identified indicators/availability of data to measure the effectiveness of cluster organisations.

STRATEGIC OBJECTIVES

- Create cluster organisations, which can support the development of European leader bioclusters to compete at international level;
- Create cluster organisations, to strengthen the development of bioclusters with the purpose to build a place where the regional life sciences community can come together, make connections, and work together as a united force to ensure and boost European KBBE growth.

STAKEHOLDERS

- European Cluster Observatory;
- Regional/Local Development Centres;
- European Cluster Alliance;
- European Cluster Excellence Initiative;
- Cluster Partnerships;
- European Cluster Collaboration Platform;
- Chambers of Commerce;
- Research Ministries or Agencies (e.g. "Excellence Cluster Competition launched by the German Federal Ministry of Education and Research").

Assessment criteria

- Economic performance of clusters;
- International recognition of European Bioclusters and Bioclusters organisations;
- Number of cluster organisation members.

Interaction with other policies

- Enterprise;
- RDI.

Table 26 - Policy Actions to be undertaken for Cluster Organisations

	Level of action		
Market Structure	EU	National	Regional
• Identify a list of 20 European clusters and propose a programme for them to become in 3 years time one of the 10 European world class bioclusters (an Ad-Hoc Advisory Committee should be composed of scientists, entrepreneurs and experts across the EU and choose based on the specified performance assessment criteria the candidates for world class bioclusters)	X		
Information and Communication			
• Design cluster organisation communication programme on CSFs and EPIs added value	X	X	
• Design a communication on cluster organisation best practices and competency requirements (governance, services, fundraising)	X	X	X
Governance			
• Define new value proposition for cluster organisations and clarify the role of incubators vs. cluster organisations, their degree of interdependence, and the skill mix of both entities (scientific/technical/business/legal/financial/IT/communication/other)	X	X	X
• Set up unified standards for EU Member States for the expected services from the cluster organisations supported by a large number of stakeholders, to create a "European Label" for Cluster Management Excellence	X		
• Promote, sustain, and develop cluster organisation's roles of keeping track of cluster performance, by collecting high quality data to fulfil EPIs data tracking needs	X	X	X
Funding			
• Use cluster organisation to implement bioclusters and bioregions fundraising strategy by consolidating funding needs to bigger proportions for deploying EU funds through endorsement of transnational funding entities		X	X
• Develop a proactive cluster funding policy - Design fees for services - Launch an European initiative for collecting private funding for best European Bioclusters	X X	 X	X X
• Ensure and monitor sustainability of cluster organisations	X	X	X
• Develop competitive financing mechanisms for best in class clusters, and monitor any possible funding gap		X	X
Training/Education			
• In addition to the existing training programmes for the cluster organisations on cluster governance, offer new training programmes to raise professionalism and achieve excellence, especially in the scientific, business and entrepreneurship fields		X	X
• Development of a certification scheme for cluster managers, to raise the recognition of cluster management as an attractive profession		X	
Advocacy			
• Setting-up an independent association representing cluster organisations at European and international levels	X		
• Organisation of events, to promote networking and facilitate mutual learning between cluster managers from different countries in Europe	X	X	
• Leverage on the newly established communication platform "European Cluster Collaboration Platform" to animate personal contacts, foster transnational cooperation, and networking between cluster organisations in Europe	X	X	
Human Resources			
• Define optimal skill mix for Clusters Organisation management team	X	X	X

Best Practices

- Munich Biocluster, Germany: Cluster Organisation offers guidance on grant writing and funding applications on national level. Recently, 50 grant proposals were supported by the cluster organisation. Special services such as "Internet Portal" as a communication platform for information exchange; "Pre-seed Programme"; "Munich Science Club" aiming to benefit especially from the experience of retired scientists on operational level; newsletter are also offered by cluster organisation;
- Saint-Hyacinthe, Canada: The professionals at the les Maskoutains Local Development Centre (LDC) help the entrepreneurs looking for financing to establish the financial structure of their project by directing their file to the right people at the financial institutions, venture capital funds or government departments and agencies. For venture capital, the professionals at the LDC act as a bridge to connect the entrepreneurs with the representatives of various funds and angel investors as well as register them to the "Carrefour Capital" network.

Policy Theme 5: TECHNOLOGY TRANSFER

"Technology transfer" defines the process of transformation of the Research and Development (R&D) results into marketable products or services.

PROBLEM STATEMENT

Market structure

- TTOs are highly fragmented across Europe;
- There is lack of critical mass, lack of funding;
- Wide disparities in terms of performance, management capacities and governance practices;
- There is no recognized stock exchange market for Intellectual Property Rights.

Information and Communication

- Lack of transparency on the stock of patents held by public agencies.

Operations and Implementation

- TTOs are still dependent on public research institutions and not headed by an independent board with multi-disciplinary skills, leading thus to a lack of efficiency in their activities;
- TTOs are considered as a hurdle for IP licensing due to indefinite discussions on legal matters and revenue sharing;
- There is a problem in terms of IP:
  - For the timeframe and affordability of processes;
  - For revenue shares and IP for the income distribution to scientists.

Regulations and Taxing

- There is discrepancy between European and US policies regulating disclosure of innovation (e.g. EU: first to disclose vs. US: first to invent, respectively), which results in the US products typically reaching the market a year earlier than their European equivalents.

STRATEGIC OBJECTIVES

- Boost European technology transfer activities through the creation of an open architecture, with dynamic, cost efficient and transparent platforms and frameworks;
- Valorisation of existing stock of unused technology and IP rights.

STAKEHOLDERS

- Universities;
- Research Institutes;
- Companies;
- National Governments;
- Institutional and National TTOs, Patent Offices.

Assessment criteria

- Number of TTOs in the new format;
- Number of restructured TTOs;
- TTO activities.

Interaction with other policies

- Enterprise;
- Market;
- Research;
- Financial services.

Table 27 - Policy Actions to be undertaken for Technology Transfer

	Level of action		
Market Structure	EU	National	Regional
• Assess outcomes of the TTO programme implemented by the EIF	X		
• Determine best performing TTOs in Europe and encourage restructuring of existing TTOs towards role model TTOs	X	X	
• Strengthen these TTOs with the provision of management, scientific and financial supports			X
• Encourage regions and state to apply for creation of new European emerging TTOs through competitive funding mechanisms	X	X	X
Information and Communication			
• Document and communicate the inventions (e.g. patents) relevant to KBBE that are not being used in a firm's business to be used by other firms (i.e. open innovation-easy transfer of innovation inward and outward- through licensing, joint ventures, spin-offs)		X	X
• Promote the concept of "role model TTOs", and the importance of CSFs and EPIs		X	
Operations and Implementation			
• Define the governance, skill mix and services within the TTO role model, and organise specific training programmes for TTO leaders and key executives		X	X
• Build up a network of investors to support European TTOs in an open and competitive model	X	X	
• Define a harmonised, independent, centralised patent filing process within the cluster	X	X	
• Develop mechanisms aiming to increase the value perception and the return of the patent filing process to motivate scientists to file patents	X	X	
• Boost and stimulate "Open Innovation" within companies and research institutes		X	X
• Create preferentially patent families rather than individual applications		X	X
Regulations and Taxing			
• Identify and remove regulatory barriers for TTOs	X	X	
• Define processes for simultaneous filing at national and EU levels (e.g. valid in all member states)	X		
• Make the IP filing an affordable and faster process	X		
• Harmonise and create unified "IP Law (i.e. patent, utility model, trademark, copyright, authors' rights etc)" between Member States throughout Europe	X		

Best Practices

- BioValley-France, Germany, Switzerland: The PIPE-Project ("Pooling IP efficiently"), a patent pool focusing on selected competence fields, is a cooperation of the ZFT Freiburg with 3 other German universities and 6 patent agencies;
- Munich-Germany: Entrepreneurship courses are mostly offered by technology transfer organisations to their own scientists to elaborate the need of marketability and commercialization out of their research and encouraging them to be the owner of their own invention;
- Saint-Hyacinthe,Canada: The Institut de Recherche et Développement en Agroenvironnement (IRDA) (www.irda.qc.ca) is a non-profit organisation founded in March 1998. It creates and mobilizes a network of government, academic and industry contributors and research teams. It focuses on research, development and technology transfers in the fields of agriculture and the environment. It currently pursues five research directions: breeding and animal dung management strategies; reducing odour emissions, greenhouse gasses, ammonia and bioaerosols; optimizing the use of fertilizers and amendments; reducing the use of pesticides; and the proposal of cultural practices and hydro-agricultural developments;
- Created in 1972 as one of the first technology transfer offices in Europe, K.U.Leuven Research & Development (LRD) has a long tradition in promoting and supporting the transfer of knowledge and technology from the universities to industry. It provides an integrated approach to technology transfer covering research collaboration, patenting and licensing, and spin-off creation. Key figures for LRD in 2009 are: a total turnover of 136 million euro; about 1200 new contracts managed; 156 invention disclosures resulting in the filing of 73 new patent families; increase of the number of spinoffs created to a cumulative total of 89;
- Bayh-Dole Patent Act (e.g. "University and Small Business Patent Procedures Act") in USA, 1980: It is an internationally recognised best practice since it resulted in a large positive impact on the US economy after 1980 (through increased partnerships between university and industry; increased number of spin-off formation and so new job creation; increased number of university TTOs; increased number of new products etc). It changed the landscape of the technology and venture capital industry and helped to establish the bioscience industry;
- Cambridge Enterprise: is the TTO for Cambridge University. It works in three overlapping areas.

Technology Transfer Services:
Includes invention disclosure management; patent strategy, filing and maintenance; proof of concept funding; research reagents transfer; intellectual property licensing and bespoke marketing.

Consultancy Services:
Includes support for University of Cambridge staff and research groups wishing to provide expert advice or facilities to public and private sector organisations worldwide. This includes negotiation of contract terms, assistance with costing and pricing, formal arrangements for the use of University facilities, invoicing, debt collection and income distribution. In addition, academics may benefit from the University's Professional Indemnity and Public Liability insurance policies.

Seed Funds and New Venture Services:
Includes access to capital and expertise via Cambridge Enterprise Seed Funds, Cambridge Enterprise Venture Partners and local angel investors, business planning, mentoring, surgeries and related programmes.

The University has been successful in providing funds for start-up companies. It has three major funds: (University of Cambridge Discovery Fund, University Venture Fund and the Challenge Fund. During the four-year period 1 August 2005 to 31 July 2009, the university funds had made 50 investments, of which 47 were in new technology companies and 3 were in other early stage technology funds. Portfolio companies raised over £456 M in follow-up funding, plus £19.5 M in grant awards, representing a leverage of 56 times the university investment.

During the 2009 financial year, 22 of the 47 companies having received investment had transferred technology from the University for public or business use via product sales or licensing. Together they have employed over 430 people.

Policy Theme 6: ENTREPRENEURIAL CULTURE

PROBLEM STATEMENT

Market Structure

- Lack of structural solutions for authorities to address regulatory, market and financial risks raised by new bio products;
- Lack of entrepreneurial experience in public research institutions and administration;
- Risk-averse culture in the financial chain and risk sharing structures;
- Lack of international culture and of entrepreneurship recognition;
- Banking sector is not fully supportive of the entrepreneurs in EU as lending policies have been tightened and cost of the credit raised.

Information and Communication

- Lack of communication on role model entrepreneurs and of reward of their successes.

Operations and Implementation

- Risk sharing mechanisms are not designed for entrepreneurs.

Regulations and Taxing

- Lack of regulatory framework including incentives to support entrepreneurs;
- Lack of initiatives toward entrepreneurs to reduce the harshness and the consequence of personal bankruptcy law;
- Lending policies of the banks are not favourable for entrepreneurs because of capital ratio regulation (ratio of a bank's capital to its risk).

STRATEGIC OBJECTIVES

- Define the risk sharing mechanisms along the value chain to enable entrepreneurs and stakeholders to invest more and more rapidly into new projects;
- Promote and develop entrepreneurship programmes and rewards in private and public sectors;
- Accelerate the market development and acceptance of new biobased products.

STAKEHOLDERS

- SMEs (for entrepreneurship culture development);
- Research Institutes and Academia;
- Translational research centres;
- Sector-specific network platforms (for collaboration);
- Large companies (for promoting licensing activities with spin-offs, start ups, and SMEs and academia);

- Agencies responsible for issuing visas to ease mobility of skilled workforce;
- Human Resources Personnel.

Level of action

A policy at EU level is required and should be reinforced by a strong national deployment policy completed with regional adaptations.

Assessment criteria

- Number of entrepreneurs;
- Number of new companies;
- Number of students in Entrepreneurship programme.

Interaction with other policies

- Enterprise;
- RDI;
- Market.

Best Practices

- Integration of Entrepreneurship in the scientific curriculum (Cambridge – UK and IAR - France). For instance, The University of Cambridge has initiated a Masters course in entrepreneurship named "Bioscience Enterprise". In IRA, the business school "Reims Management School" is more and more involved in the pole to provide management trainings to the actors of the pole. Since 1995 RMS proposes, in collaboration with AgroParisTech, a master programme named MASTERNOVA, which is a double competence in management and agro-transformations field including biotechnology, green chemistry, etc;
- Presence of a special structure in the cluster aiming to foster entrepreneurial culture. For instance, The Food Valley Consortia in Netherlands consists of four parties: 1) Food Valley Organisation, 2)Bio Partner (business incubator), 3)Wageningen University and 4) Development Agency Oost Nederland. It is providing:
  - Entrepreneurship-related trainings;
  - Provision of facilities to start a business;
  - Organising meetings with the management of role-model companies, experts or experienced people to give advice and tips for those who are at the very beginning of their business creation process;
  - PhD exchange programme with universities in the USA;
  - Pre-seed loans;
  - IP advice;
  - Coaching for those willing to start a new business.

- **Startlife** (a new public-private initiative supported by the Dutch government and the Province of Gelderland) bringing tools and education to stimulate entrepreneurship together.

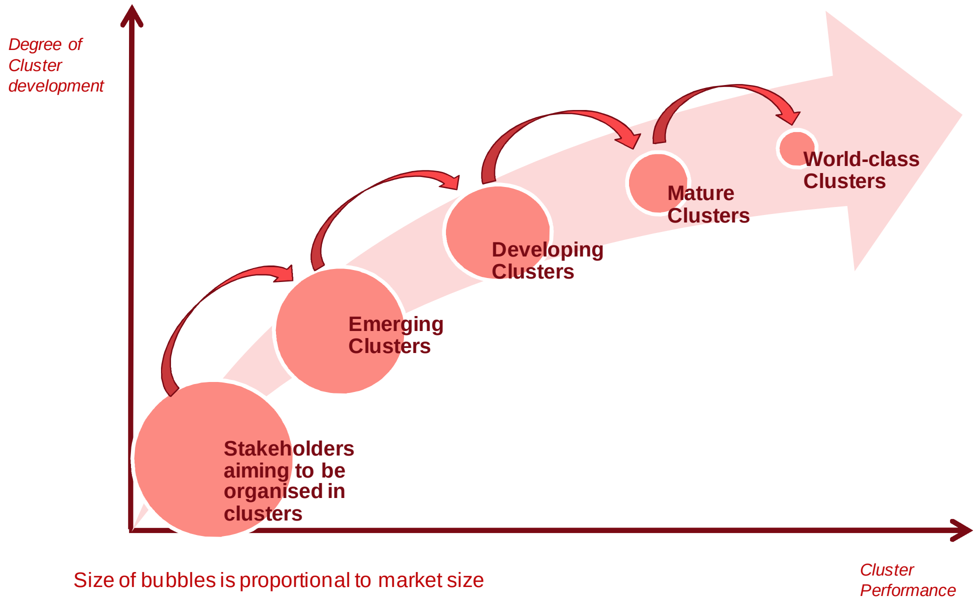
Table 28 - Policy Actions to be undertaken for Entrepreneurial Culture

	Level of action		
Market Structure	EU	National	Regional
• Develop 5 pilot experiments with entrepreneurial labs / entrepreneurship programmes (e.g. through courses within those labs/programmes people will have an opportunity to apply their class work in real-life scenarios by spending weeks in the factories and offices of small businesses within the cluster, using their management expertise to solve the critical problems facing these growing organisations)	X		
• Develop a policy to mitigate all risks supported by entrepreneurs (see Operations and Implementations - financial section)	X	X	
Information and Communication			
• Develop a European Communication policy on Entrepreneurs role to emphasize their role on economic development, innovation and their recognition	X	X	
Operations and Implementation			
Financial			
• Creation of special grants for financing the entrepreneurship programmes (see Education), and for financing the attraction of talented managers/professors			X
• Creation of financing mechanisms on risk sharing: - Which can protect the risk taker: for example guarantees and insurances - Which can protect the company: for instance impact funds and guarantee mechanisms	X		X
Education			
• Creation of education programmes in innovation, entrepreneurship, and business also aiming to strengthen the quality of business plans			X
• Creation of entrepreneurship training programmes for the personnel involved in private as well as public R&D institutions			X
• Arrangement of training courses for teaching: the development of reasonable risk assessment strategies; how to cope with a range of different legislations, and with certain technology-non-acceptance aspects	X	X	
Innovation			
• Creation of innovation stand alone units within public research institutes, centres and academia, managed and run by personnel with industry business background			X
• Remove barriers for collaborative education within countries in specific fields (medicine, biotech, engineering, agriculture, biology, physics, mathematics, etc)	X	X	
Human Resources			
• Creation of a special policy for attracting talented managers from abroad, with a special visa status (less administrative burdens, and faster procedure, similar to the US H1-B Skilled Worker Visa)	X		
• Creation of a coaching structure and network within the cluster with the know-how and track record to provide entrepreneurs with coaching and business advice		X	X
• Creation of Entrepreneurship programmes for public institutions in direct relations with entrepreneurs: policy regulators and administrators		X	X
• Define schemes for boosting an enhanced mobility of talented entrepreneurs, and highly skilled technical personnel and bankers	X		
Regulations and Taxing			
• Draft and define the core elements of the European Entrepreneur status by describing its societal, social and business status, and his rights and obligations	X		
• Assess the opportunity to create a special status for Entrepreneurs-Researchers which would enable a researcher to progressively undertake development of entrepreneurship skills		X	X

Roadmap to Cluster Excellence

After the design of the policy recommendation section, a special focus has been dedicated to develop a roadmap outlining major milestones to be undertaken for reaching the status of "Cluster Excellence" at worldwide level. This was obtained by defining the most important features and recommendations that have to be met at each cluster maturity level. This tool is supposed to guide Regional Decision Makers and Stakeholders to assess current cluster conditions, and to undertake strategic decisions for pushing clusters to develop to excellence. As shown in Figure 12, five different levels of maturity have been identified in total, ranging from the embryonic stage, in which the idea of clustering begins to be shaped among the stakeholders, going up to the world-class cluster performance level.

Figure 12: Roadmap to Cluster Excellence



The key features and key recommendations for each of the five clusters maturity levels are detailed below

1. Embryonic Stage

Some Key Features

- Research and business assets have not been recently and properly inventoried in the region
- Research laboratories continue working in silos
- The region hosts some distinctive research technological platforms, and some SMEs
- Some scientists located in the region are known at the national and European level thanks to impactful publications
- At least one hospital in the region recognised with the excellence in specific clinical disease management
- There is no recognised cluster organisation in the region
- No clear value proposition for attracting talents and companies
- Lack of entrepreneurs for taking the lead to federate the objectives of existing stakeholders around the concept of clustering

Some Key Recommendations

- Undertake a complete inventory of research, education and business resources of the region
- Identify opportunities for development based on local strengths
- Undertake two or three multidisciplinary and translational research projects proposed by qualified researchers located in the region in collaboration with industry
- Encourage researchers to apply for the research competitions at the national and European levels
- Identify research/business and public /private entrepreneurs
- Communicate local strengths and successes on regional level
- Organise and facilitate the formation of seed capital and venture capital funding
- Identify a leading entity, which could lobby at regional and national level

2. Emerging Stage

Some Key Features

- Experience: 5 years
- One focus area
- First Strategic plan has been designed and implemented. New plan is under design
- Cluster organisation has been set up
- Start seeing some good results out of collaborative research projects
- Some funding sources have been mobilized and are available to support new projects
- Jobs have been created and talents outside the regions have heard about the new opportunities
- Some visibility has been achieved at regional/national level

Some Key Recommendations

- Strengthen the distinctive research infrastructures and provide capital for the development of the cluster
- Encourage the university to develop new innovative education programme and ongoing scientific and business trainings required for the long term development of the cluster
- Reward and support role model entrepreneurs , and company transactions
- Encourage active collaboration and networking between the triple helix members of the cluster (e.g. academia, public and private parties) as well as stimulate out-of-cluster collaborations
- Search for partnerships with other regions to reach a critical mass and gain access to additional expertise
- Develop services offered by the cluster such as shared technology platforms, business and bio-incubators, Technology Transfer Offices (TTOs), Human Resources support
- Communicate on regional and national levels on cluster size, key assets and developments

3. Developing Stage

Some Key Features

- Experience: 5-10 years
- One focus area and strong synergies with other areas
- Cluster growth is visible with the set up of new companies and creation of new positions
- Cluster infrastructures have been established: incubator, TTO, training centre, etc
- Cluster has been successful in national and European competition
- Cluster funding is shared with private sources
- The cluster had a critical number of successful funding events
- National reputation is built up, and endorsement of regional and national authorities is ensured
- Key service providers have moved into the cluster
- The cluster is an attracting location for talents

Some Key Recommendations

- Increase visibility through international partnerships
- Finalise industry and research partnerships to increase cluster cash-flow
- Develop new cutting edge translational research centres with strong commonly shared platforms
- Encourage further collaborations between universities and industry
- Develop a Trans-national fund with participation of European Investment Fund
- Participate in national and international research competitions
- Take active part in national and European cluster development and advocacy programmes
- Develop regulations and incentives to support Research, Innovation, Technology Transfer, attraction of talents etc
- Create structured cluster organisation governance, finance and service offering

4. Maturity Stage

Some Key Features

- Experience: 10-20 years
- Two or three focus areas
- Size and growth of the cluster, and activity of the cluster organisations are well monitored and communicated
- Cluster is looking for a new impulse as growth is limited and companies are restructuring and relocating
- Cluster research institutions belong to the top international ranking in the focus areas
- Cluster regroups some key industry leaders and some role model start ups/SMEs
- National reputation is strong, although international reputation can be low
- Cluster financing is ensured but new funds have to be raised to scale up the cluster organisations and reputation
- Cluster relies on strong shared platforms and infrastructures
- Cluster offers several attractiveness factors

Some Key Recommendations

- Review the cluster strategy plan (investments, skills, and resources) and evaluate proposals to address cluster growth challenge
- Ensure company adhesion to, and satisfaction of, cluster services and policy
- Offer favourable conditions for hosting international research programmes to create a new momentum
- Promote cluster role model companies and entrepreneurs
- Develop entrepreneurship programmes
- Create funding resources for self-financing (e.g. through advisory services, renting at the incubators, organising events and training courses)
- Create different advisory committees for scientific, business, legal counselling
- Develop a strong lobbying activity at all EU, national, regional levels
- Collect cluster EPIs (1-2 times per year)

5. World-Class Excellence Stage

Some Key Features

- Experience: 20 -30 years
- Two or three focus areas
- Cluster has a significant market share of key innovations in the industry
- Worldwide scientists and entrepreneurs exist in the cluster
- The cluster is attracting international talents
- Several world class researchers (Nobel prize) and technologies have emerged from the cluster
- Strategy of Regional Universities is fully coherent with the cluster strategy and able to feed cluster with highly qualified work force
- Annual cluster conference is recognised as a major world event in the industry
- Venture capital funds are well established and located inside the cluster and also foreign venture capitalists are regularly visiting/partnering with the cluster
- Companies are successful in raising funds even in difficult times. The cluster has a significant share of national funds raised in the domain
- Cluster funding is shared with private sources
- Cluster growth is visible with the set up of new companies and creation of new positions
- Cluster infrastructures are considered as role model infrastructures
- Best international service providers are located in the cluster
- Cluster organisations' excellence is recognized in different fields: education, networking, communication, training, financial services, legal, and technology transfer advise, human resources, etc

Some Key Recommendations

- Develop a cutting edge strategic plan to address global societal and business challenges
- Develop research technology platforms to address new needs
- Ensure that national and regional research and business climates remain favourable to the cluster members
- Develop a strong national advocacy policy
- Develop international presence and partnerships by organising "Worldwide Partnering Events"
- Develop a cluster talent programme to address the future needs of the cluster
- Organise Venture Capital road shows
- Be part of the board of international networks and platforms

Conclusions

Conclusions

As observed by the Tech America Foundation[107], following the recent economic crisis, the regions with strong clusters have recovered from the downturn much faster than the regions without structured clusters. For this reason, creating strong bioclusters is recognised to be an efficient way for strengthening the bioregions, and for boosting their economic recovery capabilities by creating jobs, and by rapidly attracting skilled workforces.

The "Regional Biotechnology" Study has been launched by the EC with the goals of:

1) Establishing a methodology and performance indicators for assessing bioclusters, and
2) Analysing especially the till now neglected non-medical bioclusters in KBBE-relevant fields.

Based on the elements gathered through the analysis of the CSFs and EPIs, policy recommendations have been generated.

Policy Recommendations

Based on our analysis, we have identified five themes relevant to KBBE areas, which were either lacking or inefficient within the existing bioclusters. The priority areas needing policy actions to be undertaken to trigger biocluster development have been identified as: the lack of KBBE specific framework conditions available at EU level, which should be implemented by all Member States; major lack in funding along the value chain, especially by venture capitalists; lack of entrepreneurial culture mainly due to risk-averse culture; less interaction of entrepreneurs especially with the public stakeholders in the cluster; inefficient and cumbersome technology transfer; inefficient incubator structure and services; lack of bio-incubators tailored to specific KBBE sector's needs; cluster organisations offering a weak value proposition with regards to their services (quality and panel), mainly due to uncertain funding and to an inefficient governance structure.

We prioritised the policy actions that are needed according to their importance and urgency, and we have estimated the range of time required (short, medium, and long term: <2 Y, 2-5 Y, and >5Y, respectively) to start detecting the outcome of the policy implementation, as shown in Table 29.

Table 29 - Prioritisation of Policy Actions and expected timeframe for impact outcome

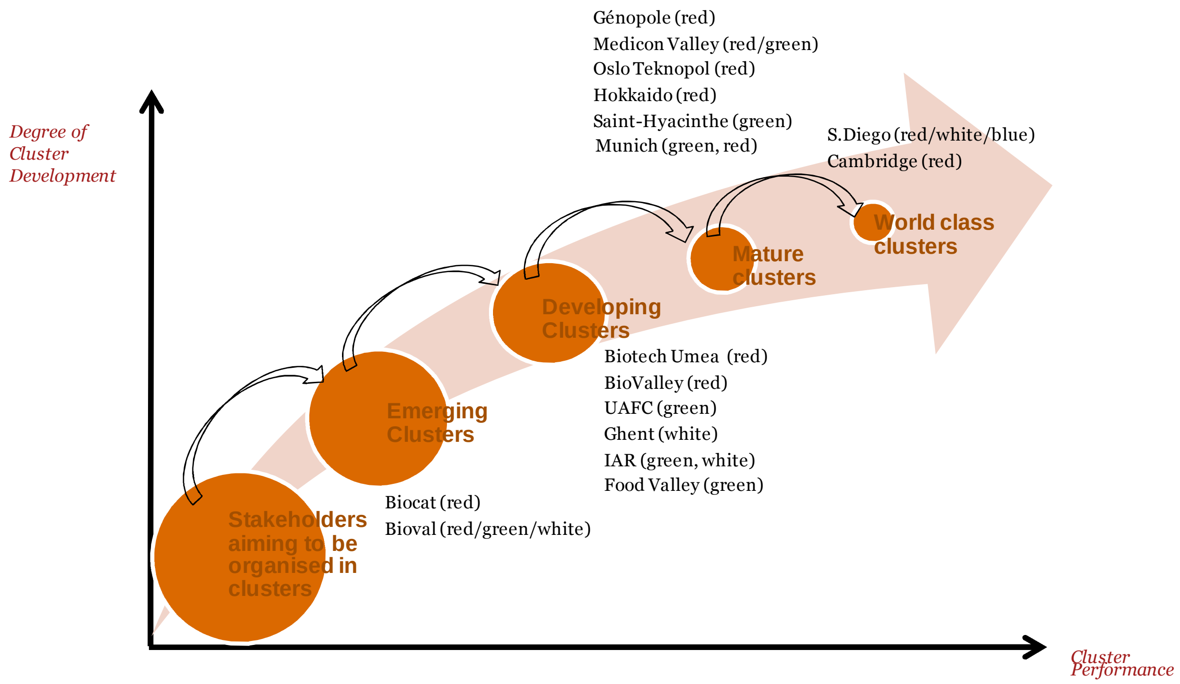
Policy Actions		**First Priority**				**Second Priority**	
	Policy / Time Impact	KBBE	Funding	Cluster Org.	Entrepreneurial Culture	Technology Transfer	Incubators
	Short Term (<2Y)		**X**	**X**			**X**
	Medium Term (2-5Y)	**X**	**X**		**X**	**X**	
	Long Term (>5 Y)				**X**		

[107] Cybercities 2010: The definitive analysis of the High-Technology Industry in the Nation's Top 60 Cities

Proposing a roadmap to cluster excellence

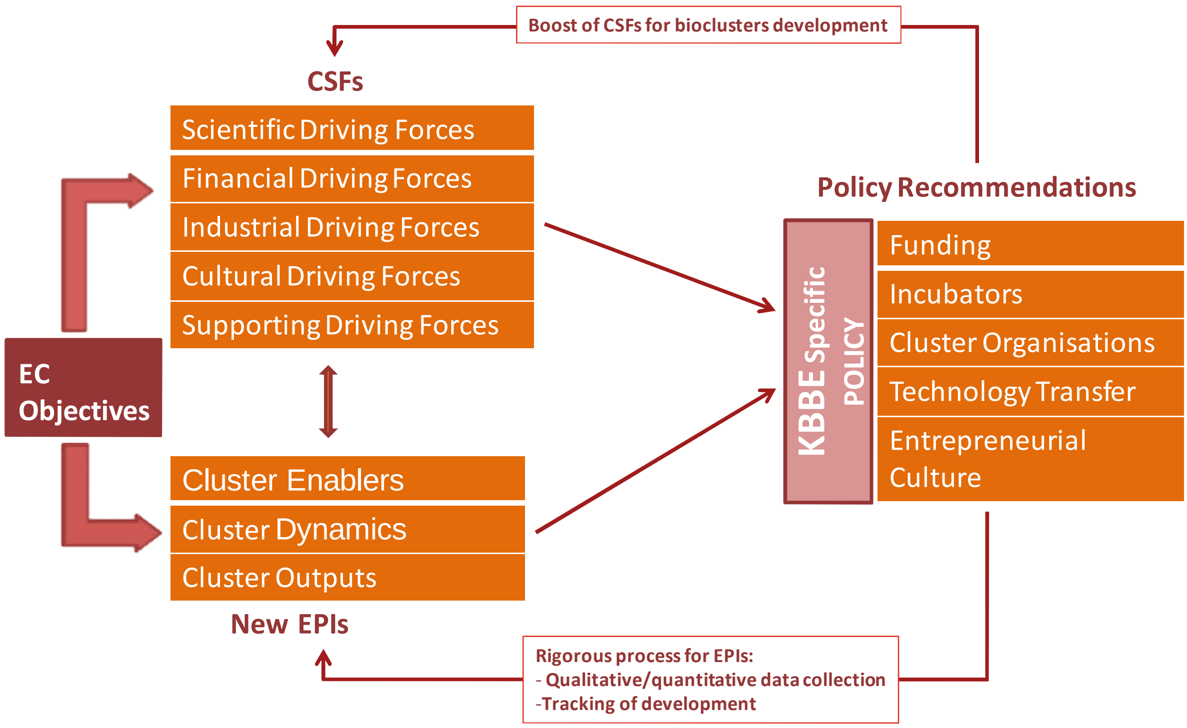
After the design of the policy recommendation section, a special focus has been dedicated to develop a roadmap outlining main milestones to be undertaken for reaching the status of "Cluster Excellence" at worldwide level. This was obtained through the definition of most important features and actions to be met at each cluster maturity level. This tool is supposed to guide Regional Decision Makers and Stakeholders to assess current cluster conditions, and to undertake strategic decisions for reaching biocluster excellence. As shown in Figure 1, five different levels of maturity have been identified in total, ranging from the embryonic stage, in which the idea of clustering begins to be shaped among the stakeholders, to the world-class cluster performance label.

Figure 13: Stages of Cluster Emergence and Development



The main features characterising each biocluster maturity stage have been illustrated in the body of the report, at the end of the policy section. One of the main objectives of the EC has been to identify the elements involved in the biocluster's performance, and to better structure the dynamic process fostering acceleration of their growth and development, through the implementation of specific policy recommendations. The schema contained in **Figure 13** outlines that, the CSFs and EPIs identified in the study are inter-related between themselves, and explains how their detailed analysis can be pivotal to the set up of ad-hoc measures for increasing their development. Once in place, policies can then impact specific CSFs, and boost economic development. The collection of the EPIs set can then occur in a structured manner, thus allowing the monitoring of growth and measuring of results.

Figure 14: Relationship between CSFs, EPIs and Policy Recommendations



Following this reasoning, all clusters aiming to assess their level of maturity and to improve their performance should undergo this kind of analysis, beginning with a status check for the existence of CSFs present in their cluster. This exercise would give a better perception of the main strengths and points of leverage the cluster could build upon, and of the weak points which should be further developed to foster growth, and to increase performance.
The identified CSFs and EPIs have been found to be valid for all bioclusters, in all biotech industry sectors.

Clusters should analyse the different dimensions of the CSFs which are outlined below, with the aim of finding major points of improvement:

- **Scientific** (e.g. existence of renowned universities and research institutions with renowned researchers, percent employees allocated to R&D, availability of cluster info such as research database etc);
- **Industrial** (e.g. existence of large companies, SMEs, start-ups/spin-offs, their survival rate and influence on the cluster development; existence of specialised trainings to support skill base; attractiveness factors);
- **Financial** (e.g. availability, sustainability, and type of funds available, barriers to access)
- **Supporting** (e.g. presence of effective cluster organisations, strong infrastructure offered by the business and bio-incubators, efficient technology transfer mechanism, existence of regulatory and policy framework, support functions such as support in human resources);
- **Cultural** Driving Forces (e.g. presence of entrepreneurial and networking cultures including collaboration aspects).

Meanwhile, measurable EPIs should be set up, for setting parameters at the beginning of the roadmap process, and for keeping the track of the improvements made. The set up of a harmonised approach throughout the EU bioclusters for tracking the EPIs would be necessary not only for the clusters themselves, but also for allowing the EC to identify the most promising and fast growing ones, thus contributing to the promotion of economic development of their region. The EPIs that we recommended are detailed within the body of this report. They have been classified into three categories: “Cluster Enablers”, covering the indicators to measure public and private funds raised, framework conditions and effectiveness of cluster organisation; “Cluster Dynamics”, covering the indicators showing the number of jobs created and the number of companies established, including their growth and survival rate over the last three years; and “Cluster Outputs” covering the indicators for the revenues of the companies coming from sales and licensing activities, and covering the number of newly developed and marketed biotechnology products/technologies in the cluster.

While the determination of the CSFs and EPIs at cluster level has been identified as a priority and this objective has been achieved, the direct correlations existing between these two sets of parameters should be the object of a more detailed analysis. This kind of study can only be carried out through the collection of a high number of well documented ground data on CSFs and EPIs complemented by a desk research, and a statistical analysis aiming at spotting significant correlations. These results would allow the EC, the policy makers, the investors, the cluster organisations and the different stakeholders to recognise in which way a specific CSF could impact a specific dimension of the economic cluster performance, and this within each specific maturity level.

Even though the direct correlation between all dimensions of CSFs and EPIs has not been outlined yet, it is clear that addressing in a structured manner each CSF and keeping track of the EPIs will drive bioclusters to evolve to the further maturity level.

The achievement of this pivotal objective could be ensured through a step-by-step approach, as it is outlined in Figure 14:

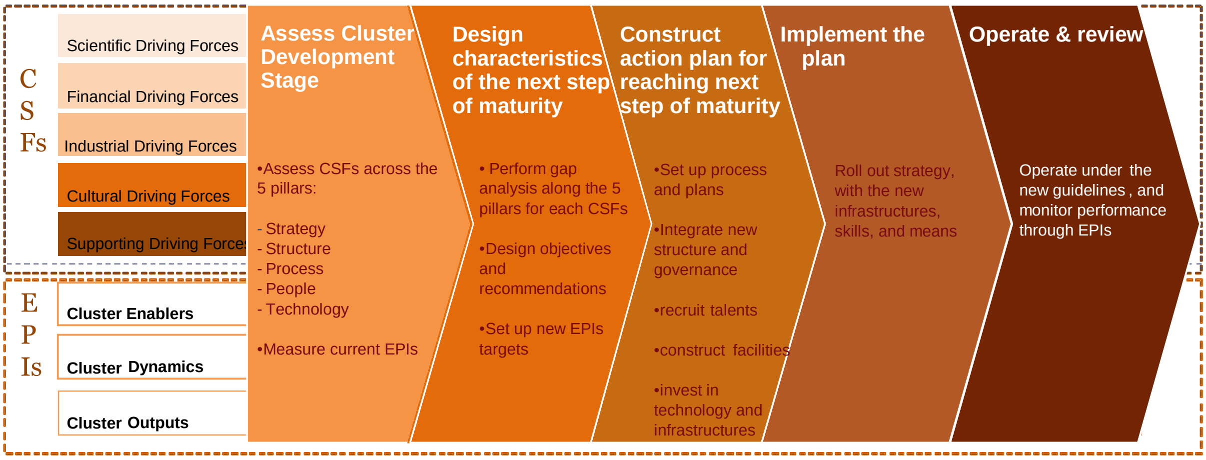
First step: This would foresee a complete cluster assessment, to be performed across all the detailed dimensions for each CSF, and along five main pillars: the current strategy, structure, processes, people, and technology. EPI should be collected, and measures would represent the starting point of the roadmap to cluster excellence process.

Second step: The dimensions of the CSFs should be set for the next point of cluster maturation along the same main pillars, with the help of the main characteristics which have been outlined in the body of the report, and given at the end of the policy section. The target EPIs should be set.

Third step: A plan should be built for tackling the weak points identified by the analysis of CSFs versus the targets which have been set. The plan should be outlined along the following issues: processes, new structures and governance, integration of talents, infrastructures, and technology.

Fourth step: The plan should be implemented according to the points developed in the third step.
Fifth step: The biocluster should operate following the new guidelines, and the progresses should be monitored, to ensure the performance objectives are met, and that they are aligned with the new EPIs set in step Nr 2.

Figure 15: Approach for driving biocluster development to the next level of maturity



The final aim of this study has been to find the pivotal strategy leading to fast development and growth of the European bioclusters, sometimes even up to world-class level. We are convinced that this study represents a step forward in this process, and we hope that the elements contained in the body of the report could serve for the establishment of a reliable strategy leading to a fast evolution and growth of the European bioclusters to the world-class excellence level. The approach for the roadmap to cluster excellence outlined above could also represent a useful tool for the detection of promising bioclusters, expected to be labelled as World-Class Clusters in the next coming years.

References

References

A Practical Guide to Cluster Development. A Report to the Department of Trade and Industry and the English RDAs by Ecotec Research & Consulting: www.webarchive.nationalarchives.gov.uk/tna/+/http://www.dti.gov.uk/clusters/ecotec-report/dti_clusters.pdf/

Biotechnology Clusters as Regional, Sectoral Innovation Systems - International Regional science Review 25 (1), 8-37, Cooke P. (2002)

Biotechnology Information Platform launched by the Federal Ministry of Education and Research, Germany: www.biotechnologie.de

Biotechnology Statistical Framework. Paris, OECD (2005)

Boosting innovation: the Cluster Approach, OECD Publishing, Paris, Organisation for Economic Co-Operation and Development, OECD (1999)

Clusters Balancing Evolutionary and Constructive Forces, Örjan Sölvell, January 2009, Second Edition: www.cluster-research.org/dldocs/ClustersJan09.pdf?bcsi_scan_24DE0A96D2B59F70=1

Clusters and Cluster Initiatives, C. Ketels, G. Lindqvist, O. Sölvell, June 2008

Clusters and Competition as Engines of Innovation – An Introduction, Broecker J, Dohse D, Soltwedel R. (2003), Broecker J., Dohse D., Soltwedel R. (eds.) Innovation Clusters and Interregional Competition. Berlin Heidelberg, Springer-Verlag.

Cluster Policy in Europe: A brief summary of cluster policies in 31 European countries, 2008: www.ekstranett.innovasjonnorge.no/Arena_fs/Synthesis_report_cluster_mapping%20-%20final.pdf

Collins Essential English Dictionary, 2nd Edition. (2006) HarperCollins Publishers.

COM (2008) 652: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0652:REV1:en:PDF

Cybercities 2010 - The definitive analysis of the High-Technology Industry in the Nation's Top 60 Cities, www.techamericafoundation.org/cybercities

Do's and don'ts for biotech cluster development: the results of NetBioCluE (2008) Europe INNOVA, NetBioCluE Report

EC, DG Enterprise and Industry: Bio-based Products: www.ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/biobased-products/index_en.htm

EC, DG Enterprise and Industry: Lead Market initiative for Europe: www.ec.europa.eu/enterprise/policies/innovation/policy/lead-market-initiative/index_en.htm

EC, DG Enterprise and Industry: Regional Innovation Policy: www.ec.europa.eu/enterprise/policies/innovation/policy/regional-innovation/index_en.htm

European Aquaculture Technology & Innovation Platform: www.eatip.eu

European Cluster Collaboration Platform: www.cluster-collaboration.eu

European Cluster Excellence Initiative: www.cluster-excellence.eu

European Cluster Observatory: www.clusterobservatory.eu

European Commission, **Agricultural and Rural Development**: http://ec.europa.eu/agriculture/fin/index_en.htm

European Commission, Europe 2020 : http://ec.europa.eu/europe2020/index_en.htm

Europe INNOVA : www.europe-innova.eu/web/guest/cluster-cooperation/cluster-innovation-platform/abceurope/about

Europe INNOVA Sectoral Innovation Foresight: Biotechnology, July 2009

Europa Intercluster: www.intercluster.eu

European Council of Bioregions (CEBR): www.cebr.net

European Mutual Learning Platform Initiative: www.ec.europa.eu/enterprise/ire/Innovating-regions/www.innovating-regions.org/mlp/index.html

European Technology Platform-Food for Life: www.etp.ciaa.eu

European Technology Platform-Agricultural Engineering: www.manufuture.org

European Technology Platform-Biofuels: www.biofuelstp.eu

European Technology Platform-Sustainable Chemistry: www.suschem.org

European Technology Platform-The Forest-Based Sector: www.forestplatform.org

European Technology Platform-The Sustainable Farm Animal Breeding and Reproduction: www.fabretp.info

European Technology Platform-Plants for the Future: http://www.plantetp.org

European Technology Platform- Aquaculture Technology and Innovation: http://www.eatip.eu

European Technology Platform-Global Animal Health: http://www.ifahsec.org

Federal Ministry of education and research (Germany) www.biotechnologie.de/BIO/Navigation/EN/funding,did=118934.html?listBlId=77924&

Seventh Framework Programme-FP7: www.cordis.europa.eu/fp7/cooperation/home_en.html

Geographic Concentration and Industrial Organization, Cambridge MA, Harvard University Press, Enright, M. (1990)

The International Federation for Animal Health (IFAH): www.ifahsec.org

In Pursuit of Innovation Clusters: Main Findings from the OECD Cluster Focus Group. Part A. Proceedings of the NIS Conference on Network- and Cluster-oriented Policies, Vienna, October 15-16, Bergman, E. (2001)

Industrial Clusters in Biotechnology: Driving Forces, Development Processes and Management Practices, London, Imperial College Press, Chiesa V., Chiaroni, D. (eds.) (2005)

Innovating Regions in Europe (IRE) Network: www.ec.europa.eu/enterprise/ire/Innovating-regions/www.innovating-regions.org/network/presentation/index.html

International Association of Science Parks (IASP), IASP International Board, 6 February 2002, www.iasp.ws/publico.

International Innovation, 2010: www.research-europe.com/index.php/2010/08/maive-rute-director-of-the biotechnologies- agriculture-and-food directorate-dg-research-european-commission/

Knowledge Based Bio-Economy towards 2020 Conference: http://sectie.ewi-vlaanderen.be/en/kbbe2010/home

Knowledge Based Bio-Economy Conference (14 September 2010, Brussels) Report: The Knowledge Based Bio-Economy towards 2020: Turning Challenges into Opportunities: http://sectie.ewi-vlaanderen.be/sites/default/files/documents/KBBE%20Report.pdf

The Knowledge Based Bio-Economy (KBBE) in Europe: Achievements and Challenges Full report prepared by Clever Consult BVBA, Brussels, 2010: http://sectie.ewi-vlaanderen.be/sites/default/files/documents/KBBE_A4_1_Full%20report_final.pdf

Labor-market imperfections and the agglomeration of firms: evidence from the emergent period of the US semiconductor industry. Environ. Plann. A 30, 439- 62, Appold S.J. (1998)

Measures to promote the market introduction of innovative bio-based products, 2009: www.ec.europa.eu/enterprise/sectors/biotechnology/files/docs/bio_based_from_promise_to_market_en.pdf

"Mapping Australian Science and Innovation" Department of Education, Science and Training www.dest.gov.au/NR/rdonlyres/194EF998-BF98-40BA-8269-8210A8C410F7/1361/clusters.pdf (p.9)

Munich as Germany's No.1 High Technology Region - Empirical Evidence, Theoretical Explanations and the Role of Small Firm/Large Firm Relationships. Regional Studies 33 (4), 367-377, Sternberg, R., Tamásy, C. (1999)

New Firms, Regional Development and the Cluster Approach – What Can Technology Policies Achieve? , Sternberg R. (2003) , Broecker J., Dohse D., Soltwedel R. (eds.) Innovation Clusters and Interregional Competition. Berlin Heidelberg, Springer-Verlag.

OECD Reviews of Regional Innovation: Competitive Regional Clusters, National Policy Approaches, 2007: www.oecd.org/document/2/0,3746,en_2649_36831301_38174082_1_1_1_1,00.html

OECD International Futures Project: The Bioeconomy to 2030:Defining a Policy Agenda, 2009: www.oecd.org/document/48/0,3343,en_2649_36831301_42864368_1_1_1_1,00.html

On Competition. Harvard Business School Publishing, Boston, Porter, M. E. (1998)

"Preparing for our future: Developing a common strategy for key enabling technologies in the EU", COM(2009) 512

Principles of Economics. Macmillan, London, 8th Edition, Marshall A. (1920)

PRO INNO Europe®, Innovation Policy Initiative: http://proinno.intrasoft.be/index.cfm?fuseaction=page.display&topicID=87&parentID=0

ProInno Europe, European Cluster Policy Group (ECPG): www.proinno-europe.eu/ecpg

ProInno Europe, European Cluster Alliance (ECA): www.proinno-europe.eu/eca

ProInno Europe, Transnational Alliance of Clusters Towards Improved Cooperation Support (TACTICS): www.proinno-europe.eu/page/project-overview-4

Regional Research Intensive Clusters and Science Parks, European Commission, 2007

Regional Clusters and Economic Development: A Research Agenda, Enright, M. J. (1996), in: Staber, U.H., Schaefer, N.V., Sharma, B. (eds) Business Networks. Prospects for Regional Development. de Gruyter, Berlin, New York.

Reasons for the Genesis of High-Tech Regions - Theoretical Explanation and Empirical Evidence. Geoforum 27 (2), 205-224, Sternberg, R. (1996a)

Sticky Places in Slippery Space: A Typology of Industrial Districts. Economic Geography 72, 293-313, Markusen, A.R. (1996)

The Adam Smith address: location, clusters, and the "new" microeconomic competition. Business Economics 23 (1), Porter, M.E. (1998): http://findarticles.com/p/articles/mi_m1094/is_n1_v33/ai_20405336/

The American Heritage Dictionary of the English Language, Fourth Edition. (2003) Houghton Mifflin Company.

The BIOCHEM-Project: www.biochem-project.eu

The Competitive Advantage of Nations. Free Press, New York, Porter, M.E. (1990)

The Concept of clusters and cluster policies and their role for competitiveness and innovation: Main statistical results and lessons learned, The Commission Staff Working Document SEC (2008) 2637

The Global Technology Revolution 2020, In-Depth Analyses. Bio/Nano/Materials/Information Trends, Drivers, Barriers, and Social Implications, Silberglitt R., Anton P.S., Howell D.R., Wong A. (eds.) Santa Monica CA, accessed atwww.rand.org, RAND (2006)

The Knowledge Based Bio-Economy (KBBE) in Europe: Achievements and Challenges (2010): www.sectie.ewi-vlaanderen.be/sites/default/files/documents/KBBE_A4_1_Full%20report_final.pdf

The Official Journal of the European Union: www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:288:0007:0011:en:PDF

The Sustainable Farm Animal Breeding and Reproduction Technology Platform: www.fabretp.info

"The way forward for European bioclusters"; in: Results of NetBioCluE, INNOVA, 2008, p.10 - Reinhard Büscher

"Towards world-class clusters in the European Union: Implementing the broad-based innovation strategy" COM(2008) 652

Utilization-focused Evaluation. London: Sage, Patton, Michael Quinn. 1986.; Qualitative Evaluation and Research Methods. London: Sage, Patton, Michael Quinn. 1990.

Wissenintensive Innovation: Das Potential des Cluster-Ansatzes, (1997) Institute for Prospective Technological Studies, IPTS Report 16, Sevilla, Jacobs, D.

White Paper: The Emerging of European World –Class Clusters, 2010: www.intercluster.eu/images/stories/white_paper/white_paper_the_emerging_of_european_world_class_clusters.pdf

Zechendorf, B. (1999) Trends in Biotechnology: Vol 17, 219-225. Sustainable development: how can biotechnology contribute?

Zechendorf, B. (2008) Regional Biotechnology: Establishing performance indicators for bioclusters and bioregions relevant to the KBBE area. The Concept. DG Research E – Biotechnologies, Agriculture, Food. Research Directorate General, European Commission.

PwC firms provide industry-focused assurance, tax and advisory services to enhance value for their clients. More than 161,000 people in 154 countries in firms across the PwC network share their thinking, experience and solutions to develop fresh perspectives and practical advice. See www.pwc.com for more information.