**WP7**

Strategy, Vision and Advocacy

***ISBE WP7 report***

*draft*

**Deliverable No: D7.3**

# A report on a portfolio of case/feasibility studies

**July 2015**

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SEVENTH FRAMEWORK PROGRAMME

Project funded by the European Commission under the Seventh Framework program for Research and Technological Development

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|---|---|
| **Project ref. no.** | INFRA-2012-2.2.4: 312455 |
| **Project title** | ISBE – Infrastructure for Systems Biology Europe |
| **Nature of Deliverable** | R= Report |
| **Contractual date of delivery** | Month 36 |
| **Actual date of delivery** | Month 35 |
| **Deliverable number** | D7.3 |
| **Deliverable title** | A report on a portfolio of case/feasibility studies |
| **Dissemination Level** | PU |
| **Status & version** | Version 6 |
| **Number of pages** | 16 pages |
| **WP relevant to deliverable** | WP7 |
| **Lead Participant** | WU-ATV (Vitor Martins dos Santos) |
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Dissemination level: PU = Public, RE = Restricted to a group specified by the Consortium (including Commission services), PP = Restricted to other programme participants (including Commission Services), CO= Confidential, only for members of the Consortium (including the Commission Services)

Nature of Deliverable: P= Prototype, R= Report, D=Demonstrator, O = Other.

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# Background Information on WP7

## *Objectives of WP7*

The objective of WP7 within the ISBE Preparatory Phase is to lay down a strategy, vision and advocacy framework for the implementation of the ISBE in a subsequent phase. This WP aims to attain a community-supported view on the needs, bottlenecks and potential of the various aspects of systems biology for area of research and development.

**Deliverable 7.3** is a report on a portfolio of case/feasibility studies on the ISBE concept. Objectives of the D7.3 are related to task 7.3 (from the DoW):

- To monitor, assess and where relevant, identify and foster the implementation of case studies, testing whether ISBE methodologies work
- Compilation and translation of success stories in lay language in the field of the life sciences (i.e. from gene to ecosystems, including, e.g. the Virtual Patient, production of new pharmaceuticals, novel animal and plant breeding systems, industrial production of microbe and algae-based chemicals, etc.).
- Prepare the science case arguments and evidence to elucidate governments, policy-makers, fundersand industry

WP7 assisted in a series of Europe-wide surveys and interviews to elucidate the feasibility of the infrastructure and assess its relevance for different life science fields.

## *Relationship of WP7 to other work packages for D7.3*

WP7 aligns closely with the following WPs:

- WP1 Project Management and Co-ordination: WP1 is essential for the integration of results and information of all WPs and coordinates the development of the overall ISBE business case and business plan.
- WP2 Model and Data Management: Specifically standardization and SOPs have been mentioned by many participants in interviews and survey being one of the most relevant tasks of an infrastructure.
- WP3 Overall Infrastructure, Eligibility and Accessibility: This WP is the core driver for developing the infrastructure concept, and derived from the WP3 results the case and feasibility assessment have been compiled.
- WP5 Community Building and Synergies: The interaction and cross-cutting activities with other European infrastructures has advanced the development of the ISBE concept and provides a sound knowledge base for new issues arising that could be addressed on a horizontal level.

- WP8 Modelling Infrastructure and Expertise: WP8 provided relevant state-of-the-art information and availability of the respective expertise across Europe to focus the case and feasibility studies in WP7.
- WP9 Technology and Science Watch: This WP is relevant for the development of a concept how to use and integrate existing repositories, storage of data/information/models etc.
- WP10 Training and Education: As training and education in systems biology have been identified as topic with highest relevance for the scientific community, both WP7 and 10 work in close relationship and inform each to drive progress.
- WP11 Funding, Governance and Legal: WP7 is providing input to the business case and business plan contents resulting from the feasibility studies and evidence from the case studies.
- WP13 Connections: WP13 results feed into the feasibility studies, whereas also WP7 results feed back into WP13 activities.
- WP15: Industry relations are highly relevant for the infrastructure concept, as users, network partners and drivers for innovation activities relate to the infrastructure. Also here, results from WP7 and W15 relate and influence and drive each other in the development process.

## Overall Approach

During the development of the business case and later the business plan, issues were raised that need consideration in the context of stakeholder involvement and broader relevance of ISBE - not only for science, but also for society and the European economy. The aspects will be explained and discussed in the context of advocacy and how these aspects will be relevant in the concept development and add value to the infrastructure once established.

**Context**

European Research Infrastructures (RI) as defined by the European Commission (EC) are expected to

- Extend the frontiers of knowledge
- Exchange and transmit knowledge
- Train the next generation of top researchers
- Support industrial innovation

Derived from these principle goals, the RIs must demonstrate that they give rise to

- Scientific value
- Economic value
- Human Capital
- Societal impact

Success factors have been defined for already existing RIs that are very helpful while developing the business plan for ISBE. The success factors include

- User/supplier relationship: the pre-existence of networks and business models support the establishment of a good relationship with both groups, users and suppliers; these networks and business models provided by the RIs must be efficient for technology transfer and must have the potential to create impact for both groups
- Relevant expertise: mix of knowledge on socio-economic, technological and managerial issues is key to follow-up successful technology transfer actions

- Awareness and data: knowledge and technology transfer is only possible if data are collected and retained by the RIs themselves
- Good outreach policy

# Added Value

In the following sections several aspects are introduced and discussed for their relevance to contribute to adding value by ISBE to science, society, economy and human capital.

## *Scientific value*

### ISBE as a hub to translate research strategies across Europe

Systems approaches are currently an urgent need in all life science fields, not only in the medical context: The relationship between genotype and phenotype, and the interaction of an organism with its environment is still an enigma. Only systems-based and integrative approaches can provide the fundamental understanding to address the problems we currently face in all the fields of the life sciences. Although enormous advancements in the knowledge have been made in the past decades, it became clear that only the integration of the genotype, phenotype and environmental interactions will lead to the understanding of the complexity of organisms.

With new technologies and systems-based approaches we will be able to integrate the knowledge and data and develop innovative solutions for the current problems in the animal, plant, health and nutrition fields.

- Animal and livestock research: Current challenges in animal and livestock research are sustainable and safe production including the problems originating from climate change, animal health and the containment of infectious diseases in livestock; with a systems approach concept new precision breeding strategies can be developed; it can contribute to a better understanding about susceptibility and transmission conditions of infectious diseases among a single species, between different livestock species and between livestock and humans.
- Plant research: The last century has seen a huge increase in the food production rate by applying innovative solutions in the field. In the 21$^{th}$ century the need for new approaches for “Feeding the planet” becomes an urgent concern again ? that needs our attention considering that we need to increase the food production until 2050 by 50-70%. In contrast in the same period we expect to have increased stress causing instability and decrease in harvestable yield while at the same time we expect a loss of arable land e.g. through climate change by 40%. Besides maximising the food quantity, in the near future food quality and access to healthy food becomes very important. Only systems-based approaches enable us to develop appropriate precision breeding and precision agriculture concepts to tackle the challenges. Recent advancements in sensor and imaging technologies allow a detailed field monitoring which is providing for the first time the knowledge base to link information about the environment interaction to molecular and physiological data respectively (?).

- Human nutrition: Food has a strong influence on our body and malnutrition, deficiencies or unhealthy lifestyle lead to diseases and threatening increase in number of citizens suffering from obesity, diabetes and other common food-related problems. Although humans are genetically very similar, the phenotype varies tremendously demonstrating the plasticity of the human. The diet-genome interaction has great influence, but our knowledge is currently still scarce on how these two worlds interact. Until recently, the microbiome of the human intestine was not considered appropriately as an essential factor influencing health and disease in the human body. Only a systems-based approach can help to unravel the role of and interaction between all the factors to tackle these urgent challenges and develop concepts how to decrease the disease burden and keep the citizens in a good health state.

Applications of systems biology approaches in the medical field are the spearhead of the development; systems medicine has developed as a new specific sector of the systems biology field. Because human health has a high priority in most countries around the world, most efforts have been invested to advance in the development of tools and infrastructure in the medical/human field. To address the current and future challenges in including e.g. agriculture, industrial biotechnology and biodiversity research, it will be of high importance that fundamental tools, maps, models and services are made available also for non-human life science aspects.

For the development of the European landscape, it might be beneficial to enter a debate about best strategies how to best position Europe in the worldwide context. We see that systems-based approaches get increased attention and first use cases successfully demonstrate the benefit of these approaches leading to a fundamentally new understanding of the functioning of cells, tissues, organs and whole organisms and their interaction with the environment. Now it might be the right time to discuss in which areas Europe could gain opinion/technological leadership: Either invest in systems medicine being aware of high competition, especially in USA – or focus/invest more in building of the foundations for efficient systems biology in the other life science fields and be the first to apply the concepts in the practice and become a leader in a new domain.

*Recommendation: The systems biology infrastructure could ideally support a strategic development, will serve as a hub for knowledge exchange and to translate these strategies into practice in the European countries, provide the training for the new generation of experts, and will also serve as an excellent basis for translational research connecting industry for efficient transfer into applications.*

## Systems Biology as ideal horizontal connector between the life science fields and between data acquisition and data integration/modelling

In the conclusions section of D7.2 it was outlined that for the establishment of the infrastructure for systems biology we need to consider that there are differences between the life science fields. Although the fundamental principles and approaches of data integration and modelling appear to be similar in the life science fields or at least easy to transfer and adapt, the scope, approaches and application of models might vary considerably in different areas. We also have to consider that the availability of data, biological maps and models might be different in the various fields of application resulting in different challenges and working culture in each field. Many European countries have defined systems medicine as a high priority research area, therefore we expect that this field might advance faster compared to other life science areas like plant or livestock research.

The life sciences could benefit very much from a more lively communication and interaction between the fields, and systems biology could serve as a catalyser because approaches can easily be translated and adapted for new applications. The systems biology infrastructure could provide the right framework to promote communication, interaction and knowledge exchange between the life science fields. Also other science fields that are relevant for systems biology like mathematics, informatics, physics and engineering could be easily integrated in the communication process via the RI. This process will support the development of a common language to eliminate barriers and increase efficiency. The uniqueness of systems biology approaches is ideal to work across and connect the different life science fields with other science disciplines and will benefit from developments in respective other areas.

*Recommendation: ISBE needs an efficient communication approach and a concept how to raise awareness and engage experts from other relevant science disciplines to connect and interact with ISBE. ISBE could respond with this activity to the expectation that infrastructures are connectors between different stakeholder groups and scientific disciplines.*

### Driver in strengthening Europe's position as opinion leader in systems biology - strategic advice to policy makers on middle- to long-term science strategies across Europe

ISBE will foster a continuous forward look dialogue between relevant stakeholder groups to provide strategic advice in the field of systems biology and systems medicine for decision makers on science policies across Europe. Based on the nSBC positioning in the national research communities we expect that the nSBCs become knowledge hubs, and have access to information about most recent and cutting edge scientific developments and relevant challenges; this knowledge can be translated into strategic advice how Europe can prepare for the future and become opinion leader in the systems biology field on a global context. In regular expert meetings (= "Think Tanks") information gathered from all nSBCs will be analysed; the "Think Tank" participants (including the Technical Working Groups with external experts and stakeholders) will derive recommendations for research strategies and science policies to support Europe to become an opinion leader in systems biology. This process could be supported by e.g. ScienceEurope or other relevant and influential institutions/associations. The "Think Tank" could be implemented as an element first in the interim phase, and - if useful - an annual or bi-annual "Think Tank" could become a regular action within ISBE.

*Recommendation: "Think Tanks" could be initiated by the infrastructure already in the interim phase to take up new development streams worldwide activities develop strategic advice for policy makers and other stakeholder groups. If successful, this high level forum will be established as a continuous process to create a regularly updated forward look for systems biology in Europe.*

## *Economic value*

### ISBE as hub for translational research

In nearly all science fields (e.g. human, plant, microbe and livestock research) we observe barriers or disruption of the value chain when research findings are translated into practice (this includes commercial as well as non-commercial applications).

There are many aspects contributing to this effect, e.g.

- lack of interest/awareness/incentives for researchers in academia for the translation process;
- lack of expertise and infrastructure to add value to a research result and to make it attractive enough for industry to invest in the further development;
- lack of funding for the translational process from fundamental research into an attractive product/process/service to avoid the “valley of death”;
- still not sufficient communication between academia and industry to understand the current challenges and problems (of the market, of the society etc.) and others.

One of the major constraints for an efficient transfer of research results into practice is the lack of efficient translational research pipelines from invention to innovation.

Europe has excellent science groups performing high level research, but what is missing still are professionalised pipelines to efficiently translate the research findings into practice. Europe and the European countries are promoting programs to support technology transfer activities and to bring innovations into practice for boosting economic development. For some research fields the transfer pipelines exist already, but systems biology as relatively new science discipline still needs professional pipelines and value chains that facilitate and accelerate the translational process. ISBE as an infrastructure and working across all European countries (and beyond) could develop into a central knowledge and expert hub for translational research in systems biology. ISBE could be a facilitator providing access to expertise, to facilities, information and guidance for the translational process including ethical and legal aspects. Building the expertise over the upcoming years, ISBE could become knowledge hub developing guidelines and best practice examples for translational research in all life science areas. This aspect would also serve the idea of the EC that European infrastructures are expected to become innovation hubs to boost economy and serve the societies and improve the life of the European citizen.

A well-established example is the translational cancer research that could serve as a role model for other life science fields covered by ISBE. Although we still face barriers that inhibit or slow down the innovation translation and implementation process of systems medicine approaches into practice, it could be studied in a pilot what could be used from the cancer example.

“Translational research (TR) is a relatively new area of investigation that ideally involves the integrated application of innovative technologies that encompass multiple disciplines including physiology, pathophysiology, natural history of disease, genetics, and proof-of-concept studies of drugs and devices”[1]. TR describes a continuum of research in which basic science discoveries are utilized to prevent or treat human disease. It is an iterative process wherein scientific discoveries are integrated into clinical applications and, conversely, clinical observations are used to generate research foci for basic science: the “bench to bedside and back to bench” approach.

[1] E. A. Zerhouni, “Translational and clinical science—time for a new vision,” *New England Journal of Medicine*, vol. 353, no. 15, pp. 1621–1623, 2005.

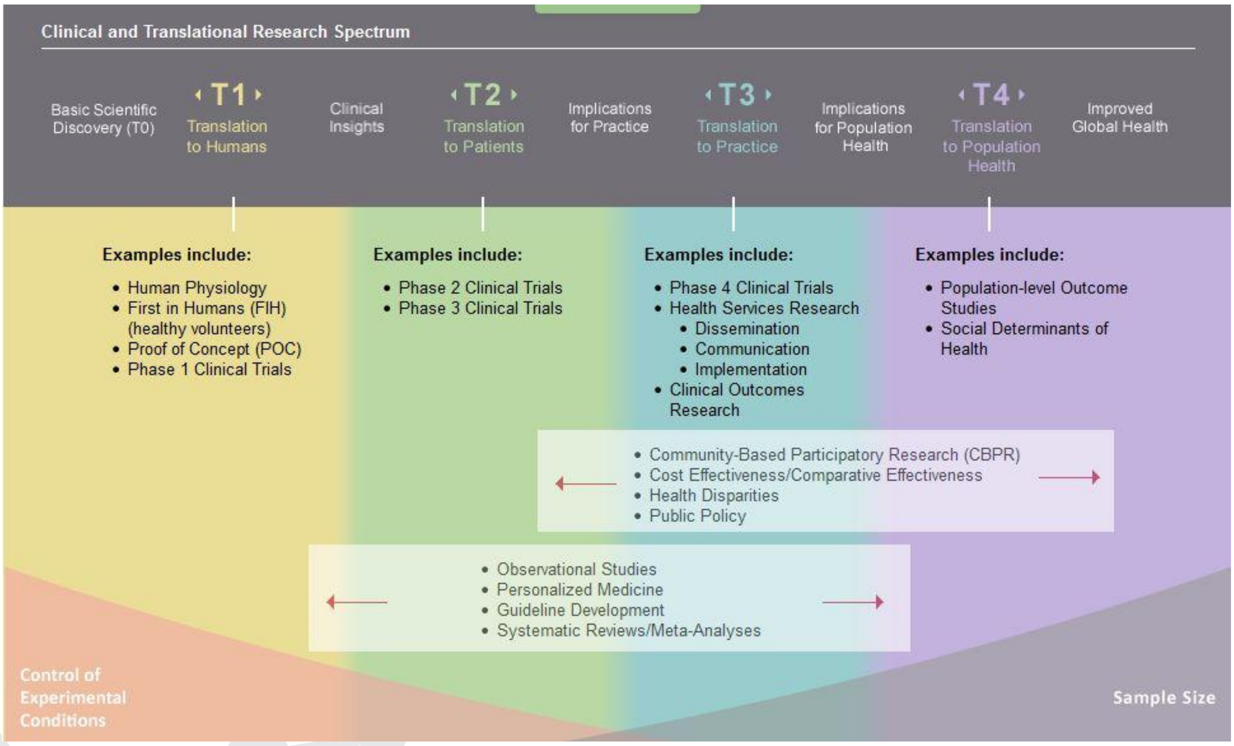


Fig. 1: The Translational Research Model as developed by the Harvard Clinical and Translational Science Centre *[Source: https://catalyst.harvard.edu/pathfinder/]*

For the establishment and optimisation of a translational research pipeline existing barriers need to be identified and solutions need to be found to eliminate the barriers. Besides limitations in the availability of funding/budget there might be other factors influencing the success[23],[4] including human barriers, professional barriers, technical barriers, organizational barriers, legal and regulatory barriers

One fundamental issue also needs to be taken into account: Usually the development pipeline is built leading from bench to bedside; an additional, often underestimated, aspect for Homer-Vanniasinkam is the following: "As discoveries move from "bench to bedside", invaluable information may be gained by moving back from the "bedside to the bench", for example, to understand important underlying mechanisms and unexpected findings and to make improvements. Similar barriers work against this arm of TR, such as poor communication of clinical challenges to basic scientists and lack of funding beyond the clinical trial."

The Excellence Designation Framework for Comprehensive Cancer Centres[13] was designed to improve and professionalise translational research. With a new concept and establishing efficient framework conditions, ISBE might develop into a central centre to remove barriers for the translation and

[2] N. P. Staff N-P , Runge BK, Windebank AJ, Breaking down translation barriers: Investigator's perspective. Sci. Transl. Med. 6, 252cm7 (2014)
[3] Khalifa M, Barriers to Health Information Systems and Electronic Medical Records Implementation. A Field Study of Saudi Arabian Hospitals, Procedia Computer Science 21 ( 2013 ) 335 – 342
[4] Homer-Vanniasinkam S, Tsui J., The continuing challenges of translational research: clinician-scientists' perspective. Cardiol Res Pract. 2012;2012:246710. doi: 10.1155/2012/246710. Epub 2012 Aug 9

implementation of research results from systems biology into practice and remove the existing barriers with specific measures.

Staff et al. report in their study from 2014: "However, challenges arise when assembling a team to build and run a new company and when attempting to procure funding. Also, agreements on the legal relationships among an investigator, the academic institution, and an established company can be a long-drawn-out process. A successful strategy that we have used at the Mayo Clinic is to create a new position called "translational integrator." This professional serves as a project manager whose responsibility is to facilitate negotiations between clinician-investigators, regulatory agencies, funding agencies, commercial sponsors, and contracting suppliers. Making this the "day job" for an appropriately trained person has transformed processes that used to take months or years into ones that can be accomplished in weeks."

In the preparatory phase, ISBE collaborated with the FP7 project CASyM - Coordinating Systems Medicine across Europe (www.casym.eu). In the roadmap of CASyM (*Europe-wide inventory of industry involved in applying Systems Medicine: Identifying areas of successful innovation and exploitation,* October 2013) we find the following actions described as relevant to boost interaction with industry in the chapter 6 (pp.15-16) "Working with Industry: The road map for Systems Medicine aims to speed up innovation in translational activities and to inspire scientists, management and investors with best practice in gaining rationally based cost-effective drug and technology development in their industry and in creating new industries based on a personalised, preventive, predictive and participatory Systems Medicine approach". From the expert interviews strengthening of public-private partnerships (PPP) were named as crucial "…since they combine different areas and traditions in science and health care. PPP should always start and end with the need of the patient." In addition: "*Proving the Concept:* Lack of robust and widespread Proof of Concept restrains industry from making large-scale investments in Systems Medicine approaches".

These aspects that have been identified for the CASyM roadmap also match with the ISBE context. Appropriate concepts for efficient translational research will contribute to improve the leverage of the existing innovation potential and increase the efficiency of research pipelines and value chains.
A recent example shared by Kristina Gruden (NIB, Slovenia) supports strongly the concept of developing and implementing more professional translational research pipelines; this example demonstrates that there is a need that might be covered by the ISBE nSBCs in the future:
Implementing pipelines for predictive modelling in practice: A new cooperation was established with a big pharmaceutical company. This company is currently implementing mathematical modelling for faster optimisation of processes. NIB prepared a proposal merging the need for improving the pipeline for selection of best cell lines based on systems biology and modelling of the actual processes. This strategy was acknowledged as among the top 5% of the approaches with most perspective. Such a pipeline optimisation for development processes might easily be adaptable and applied also for e.g. crop breeding and crop management.

These professionalised translational research pipelines would not only facilitate and professionalise the technology transfer process, but also help to reduce the risk that innovations are killed in general by the "valley of death". This gap often emerges when academic institutions want to translate the research outcomes into application, but the inventions are not yet developed enough to be taken up by the industry. The concept of modelling and linked simulations, if used smartly, can substantially reduce the costs of testing before the result can enter the market; the number of practical experiments needed to confirm a certain property and validate research findings can be considerably reduced and saves resources in terms of time and budget. If within the ISBE infrastructure concepts could be developed for professionalised pipelines for translating innovations into practice, this could be an added value and a USP of ISBE.

*Recommendation: The ISBE infrastructure could close the gap from innovation to application providing access to expert knowledge, experts and – if needed – institutions or instrumentation that is needed to close the innovation gap. All relevant stakeholders (e.g. Technology Transfer Offices, regional knowledge clusters) need to be involved to develop a concept that facilitates and accelerates translational research in the life sciences. Innovation pipelines need to be considered "from bench to bedside" (or e.g. for agriculture: "from plough to plate"), but also the other direction from "bedside to bench" as a so far neglected route must be considered. Staff et al. suggest a new professional career, the "translational integrator" to facilitate translational research and implement new concepts. ISBE as an infrastructure could develop into such a "translational integrator" function and provide the relevant knowledge and expertise to the European community.*

## *Human Capital*

### Incentives and career development in service-oriented work force

Service is normally not the major aim for a researcher/scientist; researchers/scientists are most interested in publications that provide a basis (the only basis so far) to further them in their career development. Our scientific system is not open for other criteria/denominators apart from first authorship in high impact peer-review journals; even patents are normally not considered as valuable as publications.

We need to define incentives and lay the foundations for new career opportunities for experts providing service and induce a change in the scientific system for appreciation of service to the community.
For the development and implementation in the scientific system the research-based institutions and societies as stakeholders have to be involved from the beginning; without their support the new policy will not be possible to implement.

*Recommendation: ISBE could foster/participate in a discussion on that topic. If a suitable strategy is defined to establish new opportunities for service-oriented careers in the life sciences, ISBE – together with the BMS RIs and other relevant institutions – could have an accreditation function and provide specific training courses.*

### Technical training

In all science areas (not only life sciences) big data is an issue, the "data deluge", and related new challenges for data management, curation, mining data, etc. are arising. It is expected that in the very near future all areas of modern life will need to handle increasing amounts of data. This will require not only high-level experts (scientists), but also more technical personnel supporting e.g. data handling and basic analysis of data, towards routine work/services than establishing new systems or developing new breakthrough solutions.

Since all science areas face the demand for more technical personnel skilled in routine work for data handling and management it is foreseeable that new job opportunities will arise and more personnel is needed to cover the demand. It might become an issue that the European Research Infrastructures might tackle as a joint horizontal activity to develop a special training program for a new career type. Priority could be given to European countries with high level of unemployment among the young population and try to provide new employment opportunities to this group. Support for executing routine work with models and modelling approaches also needs to be considered as one aspect in this context.

The first step must be an analysis of current demands for personnel type and training in the industry, academic world and society at large to design a training strategy together with other ESFRIs. In the future this type of training would also potentially generate income for the infrastructures thus supporting a sustainability concept.

*Recommendation: An analysis of current demands for technical data experts will provide information about potentially new career opportunities for technical personnel in data management. A new type of training for data experts might accelerate developments, professionalise processes and give rise to a new career path.*

## Early involvement of young researchers in standardisation activities

Standardisation is of major importance for ISBE as detailed in the business plan and the deliverables of WP2. Grass root activities and engagement of scientists have been leading to the establishment of associations/communities developing, maintaining, and updating standards and SOPs for the life sciences. The 'COmputational Modeling in BIology' NEtwork (COMBINE) is an initiative to coordinate the development of the various community standards and formats for computational models. By doing so, it is expected that the federated projects will develop a set of interoperable and non-overlapping standards covering all aspects of modelling in biology (co.mbine.org). Members of the ISBE consortium, namely from Manchester University, EBI and the HITS, are driving forces behind the COMBINE community. COMBINE is a very active community, and the members of COMBINE were very successful to continuously recruit young researchers and engage them in standardization as developers, but also as ambassadors for adoption of standards in their work environment.

It is a challenge to engage young researchers in these type of community efforts on a more broad scale as usually neither the supervisors nor the institutions are very supportive; engaged scientists often participate in meetings in their holidays and also cover the travel costs privately because support from the institutions is missing.

As standardization is of such an utmost importance for performance of systems biology approaches, we need a cultural change in the scientific community that engagement in standardization activities will gain more appreciation and is supported on a broad scale in scientific institutions.
ISBE could be pivotal to develop new concepts and induce this cultural change in the scientific communities.

One example how a cultural change might be supported:
Young researchers in their Master phase or PhD students in structured programs need to gain a number of credit points during their study time. Participation in standardization activities (like the developer meetings of COMBINE, the HARMONY meetings) could be acknowledged with credit points for students. This will be a win-win situation for all parties:

- students get an introduction into the topic and the community and learn in a hands-on experience to work on solutions for real problems; the students get a very good insight knowledge in the context and understand the relevance of standards and SOPs in their research
- standardization community can attract and recruit “new blood” for the community
- the research institutions can offer hands-on experience for their students that is different from usual activities, and they win engaged students and experts in standardization for their institutions without much investment
- all parties have the chance to be authors in relevant publications once a new standard or version release has been developed and is ready to be published; publications concerning relevant standards are potentially publications with high citation rates

It will remain a challenge to create new concepts for non-monetary incentives to engage researchers and institutions in the standardization topic and in the community efforts.

*Recommendation: ISBE as an infrastructure is the ideal hub to accelerate the adoption of standards and support the community efforts in standardisation. A concept for non-monetary incentives to engage young scientists in standardisation efforts will not only be valuable for the training of young scientists, but will also promote a cultural change in institutions towards an appreciation of standardisation efforts.*

## *Societal Impact*

### Translational Research efficiency for increasing Quality of Life

The potential function of ISBE to promote translational research of systems biology in all fields of the life sciences is described under section "Economic impact".

Although primarily economy-driven, translational research especially in the medical field also creates relevant impact on the society level. If ISBE supports an efficient and fast translation of systems medicine approaches into clinical practice, the impact for the society will also be substantial as the increased survivor rate and improvement in the Quality of Life for cancer patients will allow cancer patient the return to work and social life much earlier than before.

Also in other life science fields an efficient translational research pipeline will have a positive impact on society e.g. improvement of sustainable agriculture approaches and maintenance of high production rates despite climate change.

### International relations

Since FP7 we see an increased interest in international cooperation connecting Europe with the rest of the world. In Horizon 2020 it is broadly accepted that other than European Member States and Associated Countries are allowed to participate in European projects.

The basic considerations of the EC for this opening to the rest of the world are:

- Cutting edge research and innovation essential to ensure competitiveness, growth and jobs
- Vital to tackle pressing societal challenges (e.g. climate change, energy security, demographic change)
- But Europe's performance lags behind USA and JP, BRIC countries rapidly catching up
- Coordinated action needed at EU level

In the past, a relevant concern in the international policy for Europe was to support developing countries to leverage national problems and give impulses for economic development. Today, the policy has changed, and Europe is supporting international collaboration when Europe can close a knowledge or technology gap or can gain access to knowledge or technology or resources that are missing in Europe. An open policy of Europe for international cooperation today also acknowledges what poor or developing countries might provide that is missing in Europe. This new openness to international cooperation is also an instrument to strengthen Europe in its competitiveness.

International cooperation is also of high relevance as we face today societal challenges that have global dimensions and can only be solved in a joint effort.

After consolidation of the ISBE as a European infrastructure, it will become an issue to develop an internationalization strategy for participation and use of the infrastructure by non-European countries. Relevant questions here necessary to discuss are:

- Should the ERIC include the option that non-European countries could legally subscribe to ISBE?
- How would a user model look like if non-European users apply for service?

- Are there regions that specifically relevant for ISBE to collaborate? E.g. Asia, USA, Canada, Australia, South Africa…; do some non-European countries have specific infrastructure that we don't have in Europe, but we need to offer for our European communities?
- Is there a specific issue/topic/global challenge that is relevant for ISBE and needs global collaboration of infrastructures?
- Can we gain an advantage for Europe if we couple ISBE to the activities/infrastructures in other global regions?

*Recommendation: In the interim phase of ISBE a workshop on international collaboration should be organized to discuss the relevance of international collaboration and identify the corner stones for a strategy.*

### Capacity Building and National Smart Specialisation Strategies

For a sustainable infrastructure, a capacity building across all areas and including different stakeholder groups will be of relevance. If the translational research becomes an accepted task for ISBE, capacity building and alignment of the efforts with national structural funds strategies (ESIF) and the Smart Specialisation Strategies (RIS3) in each country to increase efficiency and boost innovation.

From the OECD report on "Innovation-driven Growth in Regions: The Role of Smart Specialisation" (2013): "What distinguishes smart specialisation from traditional industrial and innovation policies is mainly the process defined as "entrepreneurial discovery" - an interactive process in which market forces and the private sector are discovering and producing information about new activities and the government- assesses the outcomes and empowers those actors most capable of realising the potential (Foray, 2012; Hausmann and Rodrick 2003). Hence smart specialisation strategies are much more bottom-up than traditional industrial policies. In addition, the focus of the choices is on the "enabling knowledge-based assets", both public (e.g. education, public research) and private, not on particular industries." This definition and background supports the concept to develop expertise and consultancy in translational research for systems biology approaches in all life science areas.

The alignment with the regional ESIF and RIS3 strategies would create advantages of European regions by using synergies/complementarities and support regional profiling and allow "….to grasp emerging opportunities for the future."[5] The methods used to develop the regional and national ESIF and RIS3 strategies including foresight studies will facilitate the decision of regions with nSBCs what will be the topic with highest potential to increase the competitiveness of the whole region.

*Recommendation: A careful analysis of the national and regional ESIF and RIS3 strategies needs to be performed to identify opportunities for alignment and synergies. From this analysis also funding opportunities could arise supporting the establishment and sustainability of the infrastructure in the future.*

[5] OECD report on "Innovation-driven Growth in Regions: The Role of Smart Specialisation" (2013)