

Report with steps required to establish a long-term funding and governance strategy

Deliverable D11.3

Work package 11

Funding Governance and Legal

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Executive summary

WP11 was established to deliver a proposal for “*a long-term funding and governance strategy that supports the objectives and priorities of funding organisations participating in ISBE.*” Based on project partners’ prior experience from other ESFRIs, ISBE identified the need to consider an interim phase immediately following the preparatory phase prior to the legal phase.

A key aspect for the structure of the interim phase was what opportunities for greater coherence and cohesion to maximise links across existing infrastructure elements it might enable. Any agreement for this phase would also need to encompass existing cross-border and potential bi/multilateral funding and legal agreements. Significantly, the Systems Biology community provides scope to build on activities supported through existing European funding programmes (e.g. ERANETS), and synergies with other ESFRI BMS projects.

For these goals, WP11 has developed an initial funding structure and legal mechanism for ISBE to immediately follow the preparatory phase, being the “Interim Phase”. This is intended to include elements for early investment for delivering a pilot phase infrastructure resource, and developing associated co-ordination structure. This interim phase could aide identification and integration of potential ministries and funding agencies expressing their interest in long term strategic support.

This is intended to be a combined process of transitional steps to establish operations in advance of the legal phase of ISBE, and engage in negotiations with funding agencies and other bodies previously expressing an interest in supporting ISBE. WP11 identified the establishment of a Memorandum of Understanding as the best form of agreement to support the interim phase.

Finally, WP11 outlined a process whereby expressions of interest and/or the identification of ISBE candidate national systems biology centres could be approved through transparent review that also responded to the strategic and financial expectations of ISBE funding organisations.

Plans for developing this interim phase were developed through discussions with WP11 Funding Governance and Legal Advisory Committee (FGLAC), then via Focus Group 5 (2014) followed by joint Focus Groups 4 and 5 (2015).

Introduction

1. During the development of the long-term Funding Governance and Legal structures by WP11, it was apparent to partners that a stepwise process would be needed following the end of the preparatory phase, and in advance of the long term sustainable operation infrastructure elements. This would enable early operations between centres planning to become ISBE centres, as well as maintaining a platform for discussion and negotiation across national ministries and funding agencies wishing to support ISBE and establish the legal phase of ISBE.
2. In mid-2013, the ESFRI Assessment Group Report also recognised that the development of pan-European infrastructures require an interim phase. WP11 therefore agreed to explore a “Memorandum of Understanding” (MoU) mechanism as the most appropriate mechanism for national funding agencies to confirm their interest in developing ISBE during and after the preparatory phase.
3. In November 2013, WP11 asserted that national contributions would be required to support a core/central operational budget during the interim phase, to be obtained from member states expecting to host ISBE centres in the legal phase. Specific funding for an ISBE ‘central office’ would support links and communication between each component centre, as well as commissioning of services resources and activities; and managing agreements between the centres.
4. During 2014, the activities of ISBE Work Packages were reorganised into ‘Focused Groups’, with Focus group 5 taking forward the entirety of WP11 activities and stakeholder participation. This included the coordination of the WP11 working group to develop a public document setting about the case for ISBE. In addition BBSRC continued to seek inputs, perspectives, national positions regarding ISBE with WP11 members who represented national ministries and funding agencies.

Developing the Memorandum of Understanding for the Interim Phase, and potential Governance structures

5. Early considerations of a suitable mechanism for developing ISBE in the interim phase by WP11 Funding Governance and Legal Advisory Committee (FGLAC) agreed that a Memorandum of Understanding (MoU) should be developed to engage potential funders in negotiations for financial support, and enable the identification of candidate ISBE centres.
6. It was agreed that the MoU should include a clear statement on intention of signatories to:
 - **link current funding activities in systems biology**, whilst exploring how ISBE could improve international competitiveness
 - **expand membership** to involve communities and countries not presently represented.
 - **establish boards and panels** required to enable due consideration and advice for implementation of the legal agreement, and the mechanism to support collaborative operation of centres .
 - **provide financial contributions** for the support of the appointment of a Director in part to develop the advocacy and outreach activities of ISBE, with admin support following the preparatory phase.
 - **explore the potential for possible pilot studies** that might advance the establishment of links between national centres, and with other ESFRIs, notably ELIXIR.
7. In September 2014, and following the development of a draft MoU by BBSRC and NWO, ISBE partners (via Focus Group 5 discussion) agreed that ISBE should aim for early establishment of the MoU. This should provide the basis for consolidating existing partnerships and explore potential for links with other coordinated European activities in systems biology i.e. CASyM and ERASysAPP, and ESFRIs.
8. A copy of the current draft MoU is provided at **annex 1**

Interim phase - Establishing ISBE standing bodies

9. It is expected that many, if not all of the standing bodies that would be required for the legal phase, together with associated management and secretariat functions would need to be established during the interim phase to allow commencement of operations while the long-term model is developed.
10. For other ESFRI projects, this phase has been used to support the negotiations with potential member states required to create a dedicated long-term legal entity, and had also enabled strong commitments, including financial, from member states.

Nomination and Evaluation of candidate ISBE centres

11. ISBE aims to build on existing resources and services by asking the community, and with explicit support of their national funders, to express their interest in becoming potential Systems Biology Centres (nSBCs). It is expected that all applications for candidate ISBE centres should go through a similar (pre-agreed) evaluation process, followed by regular (annual) periodic review of additional applications. It is expected that scientific and technical aspects of ISBE centres would be primarily evaluated by the Scientific Advisory Board (SAB) in order to make recommendations for agreement by the Interim Governing Board.
12. ISBE would announce a '*call for nominations*' during the interim phase, designed to capture information on potential interest from the provider community. The responses received would then help ISBE to develop a more feasible and realistic scope for the infrastructure in the legal phase based on realistic interest. ISBE would also engage further with those responding in order to facilitate the formal submission to be recognised as an nSBC once the legal phase began.

Purpose and eligibility

13. The main purpose of this 'call' would therefore be to:-
 - allow Centres of Excellence and associated partners to register interest and detail potential level; nature and timing of provision.
 - provide the project with clear and detailed information on the nature and scope of interest from potential providers, together with indications of support via associated national research funding ministries and funding agencies.
 - identify links to other national and European Research Infrastructures including other ESFRIs, to help identify and promote areas of synergy.

14. This call would not have any associated funding, but rather allow potential centres to express their intention to become involved, and would be targeted at Higher Education Institutions and other research organisations eligible to receive national Research Ministries and Funding Agencies, and any centre of excellence would require the explicit support of a relevant funding body to be considered as an official candidate.
15. It is expected that there will be only one nSBC per country, therefore it would be for the relevant national funding body to agree on the institution eligible to apply. However, it is possible that this might be a single centre of excellence, or a lead centre representing resources at more than one centre (i.e. as part of an existing national collaboration).

Format of responses to the 'call'

16. Responders would be asked to provide information on the following aspects of their proposed nSBC.
 1. General summary of proposed nSBC
 2. Administrative details of those institutions involved
 3. Operational description of nSBC, outlining main aspects of provision, and detailing the potential user community.
 4. Summary of staffing and operational costs, timing and duration (where known)
 5. Financial sustainability of nSBC.
 6. Statement of support from national research ministry, or funding agency (*to be accompanied by letter of interest*)

Defining the interface with ELIXIR

17. Representatives of national funding organisations on WP11 FGLAC noted from the outset of the project that there was a significant interface with the activities of ELIXIR, most notably in the generation, stewardship and interoperability of data with utility to the systems biology community.
18. WP11 FGLAC therefore stated that in order to properly engage national ministries and other funding agencies in consideration of support, ISBE will need to be clear on distinguishing between its services and collaborative projects, as well as describing how they might link with ELIXIR or be delivered in tandem to promote synergy and avoid overlap of activities and funding.
19. Informal discussions between ELIXIR and ISBE partners led to the proposal to develop a joint strategic statement on the interface between the two research Infrastructures that might be finalised during the first year of the interim phase.

Early investments by funders

20. In early 2015, three major investments were identified by ISBE as enabling the operation of key elements needed for the successful formation of ISBE during the interim phase. This collaborative effort will look to take ISBE into implementation of operations that would involve many of the ISBE partners beyond the end of the preparatory phase. Together with a range of other investments these were collectively titled '*ISBE-light*'. These three key investments were:-

- Four funding agencies [BMBF/PtJ, DE; SNSF/SystemsX, CH; NWO, NL; and BBSRC, UK] supported the €2.7M transnational FAIRDOME project, being a joint action of ERA-Net EraSysAPP (ending December 2015) and ISBE to establish a data and model management service facility for Systems Biology. Its prime mission is to support researchers, students, trainers, funders and publishers by enabling Systems Biology projects to make their Data, Operating procedures and Models, Findable, Accessible, Interoperable and Reusable (FAIR). FAIRDOME builds on the outcomes of the successful SysMO-DB and SyBIT data management projects, uniting their tool and database development as well as their experience serving large systems biology projects.
- Two collaborative Horizon H2020 infrastructure development awards, CORBEL and Rltrain, were made across several BMS ESFRIs, including €2.1M for ISBE to harmonise and synergise their activities. Also, ISBE will start offering services during its construction phase that starts Autumn 2015, resulting in a fully operational research infrastructure in 2018.

21. In addition, the Czech Republic (MSMT); Greece (GSRT) Italy (MIUR); Netherlands (NWO); Norway (RCN); Slovenia (MIZS); and Sweden (VR) have stated their intention to support the incorporation of their relevant infrastructures into ISBE, either through inclusion within their national research infrastructures roadmaps, and/or once national support has been agreed.

Status of ongoing discussions with national funders

22. As of the date of writing (mid-July 2015) no single funding agency is yet in the position to conclude their signature on the MoU for ISBE. However, the project partners are confident that the first year of the interim phase will see the inclusion of three national ministries or funding agencies. Below is a summary of ongoing discussions with the relevant national ministries and funding bodies on involvement in ISBE:-

- BBSRC (UK), BMBF/PtJ (DE), SystemsX (CH), and NWO (NL) contribute to ISBE data stewardship via support of FAIRDOME project, which began in 2014, supporting groups at The University of Manchester, UK, Heidelberg Institute for Theoretical Studies (HITS), Germany, The University of Zürich, and The Eidgenössische

Technische Hochschule (ETH) Zürich, Switzerland, together with The University of Leiden, Netherlands. The four funding bodies have also signed an MoU which indicates their long-term commitment to data stewardship for systems biology to be a building block of ISBE, as part of their continuing national and transnational support for systems biology since 2008.

- In the Czech Republic, the Centre for Systems Biology (C4SYS) has been a priority project on the national roadmap since 2011, and gained national infrastructure status in 2015. 70% of the overall costs are now met by the Ministry of Education, Youth and Sports (MEYS) until 2022 with the specific intention of supporting both systems biology research community in the Czech Republic, and more broadly via ISBE.
- In Italy, SYSBIO Italy, has been funded by the Italian Ministry of Education, University, and Research (MIUR), and is included in the Italian Roadmap for Research Infrastructure.
- Funding by the Norwegian Research Council of the Norwegian national ISBE centre is presently under review as part of support Norwegian National Centre for Digital Life from 2015.
- In Sweden, the renewal and extension proposal for the national bioinformatics and systems biology infrastructure to the Swedish Research Council expresses that the infrastructure wishes to become the Swedish node in ISBE, in the same way as it is the Swedish node in ELIXIR.

Public statement on the operation of ISBE during the interim phase

23. ISBE publicly announced its ongoing deliberations on establishing an interim phase within the ISBE Business Case (section 10) in November 2014, and subsequently revised and set out in greater detail within the current business plan (section 6). This section is presented in its entirety, within this report below. This Business Plan is due for publication and the near final draft of the text also forms the summary of deliberations with ISBE to date.

Extract from
the draft
ISBE Business Plan
(*as of 27 July 2015*)

◦ 6. The Interim Phase: building the infrastructure

By the end of the ISBE Interim Phase (2015-2018) a fully functional ISBE will be established as a legal identity. This section describes the mechanisms and timeframe of how ISBE will be rolled out up until its formal start in 2018.

The Interim Phase has five major objectives:

- reach formal agreement with national funding organisations about ISBE's legal structure and budget for the Legal Phase
- make available an initial portfolio of services and resources to European scientists: ISBE-light
- establish ISBE's governance and management structure
- establish the European distributed knowledge-based infrastructure of interconnected nSBCs
- harmonise ISBE's operations with those of other research infrastructures in the life sciences, primarily through the CORBEL and RItrain programmes



Figure 6.1 Timeline of the Interim Phase

6.1 Two-stage structure of the Interim Phase

The Interim Phase will consist of two distinct stages. Interim Phase Stage 1 starts in August 2015, immediately after the end of the Preparatory Phase (see figure 6.1). The aim of Stage 1 is to have at least three national funding organisations signing a Memorandum of Understanding (MoU) within the first year of the interim phase. This stage will establish an interim governance and management structure capable of commencing delivery of the 'ISBE-light' operational portfolio. Negotiations with funders will continue to establish commitment for financial support. This should ensure an adequate budget for the construction of ISBE during Interim Phase Stage 2. The start of Stage 2 is marked by the appointment of the founding director, who takes responsibility for building the research infrastructure.

6.2 Interim Phase Stage 1 (2015-2016)

6.2.1 Objectives

The major objectives of Stage 1 are (i) to continue activities on the national and European level, initiated during the Preparatory Phase, and (ii) secure Stage 2 budget, and (iii) start delivering ISBE-light services.

This comprises the following processes:

- establish an interim governance structure
- formally involve at least three national funding organisations on the basis of a MoU
- identify and pursue further European funding opportunities
- negotiate with national funders and key stakeholders to establish the budget for Stage 2
- select a founding director as soon as the Stage 2 budget is secured
- identify the host country for the Central ISBE Office (CIO) and the coordinating Systems Biology Centre (cSBC)
- start the procedure to identify and select nSBCs that will be formally established in Stage 2
- commence delivery of a portfolio of web-based services and resources called 'ISBE-light'
- operate ISBE-branded activities through the CORBEL, RItrain H2020 projects and FAIRDOM, with continuing partnership with other ESFRI research infrastructures and national infrastructural programmes

6.2.2 Stage 1 management

The management at the outset of the Interim Phase will reflect the commencement of the operations of 'ISBE-light' web-based services and resources with the formation of the **ISBE Interim Committee (IC)** body

The ISBE Interim Committee (IC) will (i) ensure inclusive negotiations with both national funders and key stakeholders that are required to establish the budget for Stage 2, (ii) select the founding director, and (iii) start the procedure to identify and select nSBCs that will be formally established in

Stage 2. The IC will consist of all Management Team and Intergovernmental Working Group members and draw on members of the Preparatory Phase Steering Committee who have expressed their interest in further engagement.

This IC will identify further European funding opportunities for ISBE, as well as coordinate strategic interactions with other ESFRIs. In addition, steps will be taken to form user community forums and an Industry Liaison Board.

The Interim Committee and the Management Team will be chaired by a full time Interim Coordinator, who will be responsible for the development of ISBE during Stage 1.

The Management Team (MT) is a sub-committee of the IC, which will consist of those involved in the delivery of ISBE-light's portfolio of services, and coordination across ISBE-branded activities through the CORBEL and Rltrain H2020 projects and FAIRDOM.

The Intergovernmental Working Group (IWG) is another sub-committee of the IC, which will draw together representatives of national funding organisations who have expressed an interest in supporting ISBE.

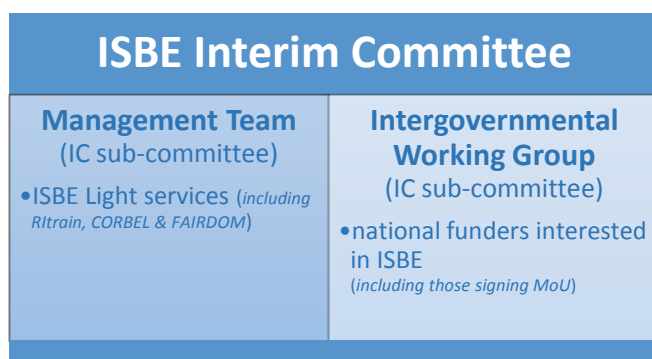


Figure 6.2 Relationship of the three initial governance bodies at the start of Stage 1

6.2.3 Stage 1 budget

The costs of Stage 1 are estimated to be minimally € 250k for 12 months (see Table 6.1 and Appendix 9, Table 1). Contributions are expected via financial and in-kind contributions through ISBE stakeholders and national funders.

6.2.4 Securing the budget for Interim Phase Stage 2

Negotiations with national funding agencies should result in the signing of a MoU and associated financial support, or another type of agreement, in which they declare interest in participating in building ISBE and contribute to a budget for Stage 2.

6.2.5 Selection process of nSBCs and the host country for the Central European Office (CIO)

The selection of nSBCs in Interim Phase Stage 2 requires an open and transparent procedure, which will be agreed with national funding organisations and research communities. The same holds for the host country of the CIO.

6.2.6 ISBE-light services

To expand awareness of ISBE in the scientific communities and maintain the momentum and interest developed during the Preparatory Phase, ISBE will offer in Stage 1 and Stage 2 a portfolio of four types of web-based services and resources.

Most ISBE-light services will be available free of charge to users. They will be operated and supervised by systems biology centres of excellence that have an interest in continued involvement in ISBE. ISBE-light will commence as soon as possible after the start of Interim Phase Stage 1. Services will continue in Stage 2, forming a solid basis for a complete portfolio in ISBE's Legal Phase.

ISBE-light will offer three types of services:

a. Modelling services and resources

ISBE's modelling services aim to lower the threshold for biologists to incorporate computational modelling in their research. In this early stage of ISBE development, clients will be directed to a ready-to-use web-based modelling platform, linked to relevant model resources. Target communities for these services are researchers in academia and industry with varying levels of training in mathematics and statistics and in computer and information science.

For the initial ISBE-light services, ISBE will focus first on modelling frameworks that have (i) a large potential user base, and (ii) standardised ways of asking research questions. By doing so, one can span a large space of questions with a well-defined set of query parameters. In addition, users can pose a wide range of questions by filling in a form and uploading their own data or models, similar to what is already common place in bioinformatics.

b. Access to tools, standards and model-compliant data and maps

For ISBE-light, ISBE will engage with the existing FAIRDOM initiative¹, a joint action of the ERANet ERASysApp with ISBE. FAIRDOM aims to establish a data and model management service facility for systems biology. This is intended to operate under the ISBE-light umbrella. ISBE-light services will aim for web-based access to tools, archives, model-compliant data and maps which will focus on:

- making software available with user guides that support and improve research asset management from instrument to publication



¹ <http://fair-dom.org/>

- supporting the establishment of research asset management planning for grants
- developing an online 'knowledge hub' which
 - identifies and characterises different tools and standards that can be used within projects
 - identifies public repositories and characterises them according to the type of data that they contain, and what standards are used in conjunction with the repository
 - identifies and categorises minimum information models for different research-asset types
 - providing data-templates that are semantically capable for a range of different data-assay types

c. Education and training

Services will aim at dissemination of information on training and education in systems biology and will include:

- dissemination of information on training and postgraduate education in systems biology (in collaboration with ERASysApp), through the ISBE community portal
- dissemination and implementation of a core curriculum through the ISBE website, publication, Erasmus+ and low cost networking meetings
- dissemination of courses (summer and winter schools, workshops, advanced training) that ISBE partners are involved in

d. Liaise with scientific journals

ISBE is currently exploring a synergistic role between ISBE and scientific journals on

- ISBE being a rich source of multidisciplinary expertise in systems biology, spanning a broad range of biological fields, disciplines and skills
- ISBE taking initiatives in developing and disseminating community standards and standard operation procedures (SOPs) in the systems biology field

6.2.7 Embedding of ISBE in the European research landscape during the Interim Phase

In Interim Phase Stage 1 ISBE will be embedded in European-level systems biology initiatives and national systems biology communities and it will actively contribute to the harmonisation of ESFRI research infrastructures in the life sciences field. Figure 6.3 schematically maps the various interactions and how they relate to interim governance structure

6.3 Interim Phase Stage 2 (2016-2018)

Stage 2 commences with the appointment of the founding director and ends with establishment of ISBE as a legal entity. The major responsibility of the founding director is therefore to develop ISBE's legal identity and operational processes.

6.3.1 Objectives

The objective of Stage 2 is to develop a legally-based and fully functional ISBE. This includes the following:

- establish the Central ISBE office (CIO), the coordinating SBC (cSBC) and ISBE's governance structure

- continue empowering ISBE-light and organise the transition of ISBE-light towards a fully operational ISBE by developing a broad portfolio of services, resources, community activities and training and education programmes together with the nSBCs and in dialogue with user communities
- establish a collaborative federation of nSBCs that will be fully operational in the Legal Phase
- negotiate the operational budget of ISBE Legal Phase
- develop the legal basis for ISBE, preferentially an ERIC
- continue developing partnerships with other European research infrastructures, primarily through the CORBEL and Rltrain projects

6.3.2 Stage 2 management and budget

The management structure from Stage 1 for the ISBE Interim Committee and the ISBE-light Management Team will be modified at the start of Stage 2 as part of the stepwise migration of the Interim Phase governance structure towards that described for the Legal Phase (in section 4).

Stage 2 requires a budget of approximately € 1.6 M for two years (2016-2018; see Table 6.1 and Appendix 9, Table II), comprising:

- salary of the founding director and CIO staff
- operation costs of the Central ISBE Office (CIO)
- activities to develop and coordinate the European matrix of collaborating nSBCs and ISBE's portfolio of services and resources

ISBE will negotiate with national funding agencies that are MoU signatories, as well as other national funders, to agree on conditions for sustainable funding of ISBE in its Legal Phase. ISBE will seek their contribution to the central budget to support the CIO and coordinating and community activities. In parallel, agreement should be reached about national funding of the individual nSBCs and the coordinating SBC.

6.3.3 Selection of nSBCs

The open and transparent nomination and selection process for nSBCs will be executed along the lines agreed on in Stage 1. Provisions will be made to give users in European countries without an nSBC access to ISBE's resources and services.

6.3.4 Central ISBE office (CIO), coordinating SBC and governance structure

Negotiations in Stage 1 will identify the host country of the interim CIO. The founding director will head the interim CIO and establish the governance structure for the legal phase (see Section 4 for further details).

6.3.5 Adapting the Governance structure towards the legal phase

Modification of the governance structure for Stage 2 will be fully defined in Stage 1. At present it is anticipated that the IC sub-committees will be fully integrated into the Interim Committee, in anticipation of migration the full ESFRI bodies in the Legal Phase. Finally groups expecting to form

nSBCs will be invited to form a “Candidate nSBC working group” (anticipated to grow into the legal phase ‘Heads of Centres Committee’).

6.3.6 Central ISBE office (CIO), coordinating SBC and governance structure

Negotiations in Stage 1 will identify the host country of the interim CIO. The founding director will head the interim CIO and establish the governance structure for the legal phase (see Section 4 for further details).

6.3.7 Legal basis for ISBE

An important aim of Stage 2 is to agree on the legal status of ISBE. The current preference is an ERIC. However, we expect that the development of the ISBE structure for the legal phase will continue and therefore the suitability of ERIC, including the potential for a transitional legal structure to facilitate to foundation of ISBE will be kept under dynamic review. Decisions will be made based on discussions with national funding organisations and governments. Establishing ISBE’s legal status marks the transition of the Interim Phase to the Legal Phase.

6.3.6 Portfolio of services, resources, community activities and training and education programmes

Together with the nSBCs and relevant research communities, ISBE will develop and establish its portfolio of services, resources and community activities within the framework outlined in this Business Plan. This will build on the activities of ISBE-light that started in Stage 1. The portfolio will grow steadily in Stage 2 and in the subsequent Legal Phase, constantly adapting to the developing needs of ISBE’s users.

6.3.7 Engagement with the user-base in academia, hospitals/clinics and industry

A major task of the founding director will be expanding relationships with different user communities, including academia, hospitals/clinics and industry/SMEs. This will build on the expertise in translational research for those centres providing ISBE activities to enhance translation and create a coherence forward look for systems approaches from a joint academia-industry perspective. A vital part of this will involve establishing user committees and advisory boards.

6.4 Summary of costs of the Interim Phase and current funding

2020 CORBEL and €185k for the Rltrain project consortia that aim at harmonisation and collaboration with other ESFRI life sciences research infrastructures (see Appendix 7). In addition the FAIRDOM project that intends to interact with ISBE under the ISBE-light umbrella of activities has received €2.7M. ISBE will continue to build on the success of the recent CORBEL and Rltrain awards, by seeking additional funding through the Horizon 2020 programme, as well as from other parties.

ISBE Interim phase		
	FTEs	Cost (k€)
Interim phase stage 1 (2015 - 2016)	1	250
Interim phase stage 2 (2016 - 2018)	4	1500
Total (k€)		1650

Table 6.1 Summary expected costs for ISBEs Interim phase

6.5 Coordination with ELIXIR on ensuring synergies to address community needs

In developing its portfolio ISBE recognises the key links it has already forged with ELIXIR as part of developing the CORBEL and Rltrain proposals. In addition the FAIRDOM project addresses the overlapping data standards requirement across both Research Infrastructures. ISBE and ELIXIR will continue to work closely in ensuring a common strategic framework for delivery of services and resources that avoids duplication and redundancy of provision. As a first stage both RIs are committed to formalising their relationship and further defining their interface, by developing a common strategic document on joint working early in 2016.

6.6. Key Performance Indicators for the ISBE Interim Phase (2015-2018)

ISBE has identified three areas where it will monitor and review of its activities until the end of the Interim Phase to determine if the project has been successful. Analysis of the 11 key performance indicators (KPIs) will show what aspects of the research infrastructure need special attention at the beginning of the Legal Phase. The areas are summarised in Figure 6.4. which lists 11 KPIs that allow an objective and quantitative assessment of ISBE's activities. Their assessment is explained in table 6.2. The KPIs create a clear compass for the process of developing ISBE during the Interim Phase. The first integral evaluation is foreseen at the end of the Interim Phase and should help to decide whether ISBE is ready to enter its Legal Phase in 2018. In a later stage of ISBE's development these KPIs can be adapted for assessment of ISBE's performance during its Legal Phase.

As a key part of developing a robust risk mitigation strategy, ISBE will make full use of independent advice from its advisory boards to draw in industry and other major stakeholders, together with engaging other ESFRIs to understand and implement best practice for auditing outputs developed across the ESFRI family.



Figure 6.4: Key performance indicators are grouped according to the 3 main pillars of ISBE operations.

Table 6.2: KPIs to be assessed at the end of the Interim Phase

Category	Component	Quantity/quality measured	Assessment criteria
services	1. modelling services	number of users with positive user satisfaction and submitted publication acknowledging ISBE essential support	number of support requests and user evaluation forms)
	2. resources	number of users and user satisfaction with acknowledgement in publications	through evaluation forms
	3. stewardship	number of users and user satisfaction with acknowledgement in publications of help in stewardship	through user evaluation forms
	4. teaching and training	number of users of training courses and user satisfaction number of hits on education and training database uptake of core curriculum	through user evaluation forms through website analytics report based on meetings/survey

Category	Component	Quantity/quality measured	Assessment criteria(date/number/success threshold)
community activities	5. assume responsibility for ongoing and new community activities	impact of collaboration with communities (e.g. VPH, ERASysApp, CASyM, repositories, ELIXIR, journals)	reports of evaluation meetings with communities and report
	6. make results re-usable	contribution to FAIRDOM programme	report summarising activities and achievements
	7. engagement with other research infrastructures	activities in context of CORBEL and Rltrain	reports summarising activities and achievements
governance and management	8. legal structure	establishment of a legal identity (e.g. ERIC)	5 or more countries sign
	9. management and coordination	demonstrate effective functioning of CIO and coordinating SBC	evaluations of Supervisory Board and Board of heads of nSBC
	10. matrix of cooperating interim nSBCs	demonstrate synergistic and coordinated matrix of nSBCs	overview of coordinated activities and collaborative actions in matrix by CIO
	11. governance	demonstrate an effective governance structure; show effective exchange with the different Advisory Boards (SAB, Industry Liaison Board and Ethics Board); show satisfaction of nSBCs and funders with ISBE	annual reports of Supervisory Board; annual reports of Supervisory Board and Board of heads of interim nSBC; annual reports by individual boards

6.7. Measuring Wider Impact

In addition to understanding and measuring the direct outputs of ISBE and its services, it is also important to develop appropriate metrics to understand how we have supported the delivery of the research of those communities using ISBE. During the Interim Phase ISBE will consider the needs for longer term monitoring of services and their users, ISBE plans to demonstrate to its funders how its activities and services:

- has influenced the development of a highly skilled work force
- have fostered the usage of data and model standards, and appropriate tools
- have aided in development of collaborations of provider and users at scientific institutions in Europe and worldwide
- has encouraged closer collaboration between academia, the industry to the benefit of the EU bioeconomy.
- has enhanced to application and integration of systems approaches in the biosciences by acting as a ‘knowledge broker’ of choice
- has facilitated the rapid uptake of novel and innovative technologies across all biomedical sectors

(Extract from) appendix 9 Details of the ISBE financial model

STAGE 1 INTERIM PHASE COST MODEL (Aug 15 - Jul 16)

The model for primary activities in stage one, ensures the continuation on discussions established in the preparatory phase by the Steering Committee, whilst expanding deliberations to establishing the interim bodies, beginning activities under ISBE-light, and continuing the programme of outreach.

Table I: Overview of costs for the ISBE Interim Phase stage I (all costs are in k€)

Expenditure		Costs (k€)
Personnel Costs	<i>Project Officer (1 FTE)</i>	70
Investments/facilities	<i>Consumables</i>	4
	<i>Hardware + software</i>	10
	<i>Running costs</i>	1
Portfolio of web-based services		35
Travel and conferences		10
Outreach and coordination		20
Total (k€)		150

STAGE 2 INTERIM PHASE COST MODEL (Aug 16 - July 18)

The model envisages the appointment of the founding director as the beginning of Stage 2 with specific resources to provide defined support for personnel within the interim Central ISBE office to provide secretarial support interim bodies, with staff effort for outreach and community engagement activities as well as providing for the costs of delivering the central portal for ISBE-light.

Table II: Overview of costs for the ISBE Interim Phase stage II (all costs are in k€)

Expenditures		FTE	Costs (k€)
Personnel	<i>Director</i>	1.00	390
	<i>Web manager</i>	0.70	130
	<i>Secretary</i>	0.20	40
	<i>Public relation manager</i>	0.50	95
	<i>Liaison officer (project manager)</i>	1.00	95
	<i>training and education developer</i>	0.60	95
Investments/facilities			
	<i>Consumables</i>		26
	<i>hardware + software</i>		87
	<i>Running costs</i>		30
Portfolio of web-based services			250
Travel and conferences			137
Outreach and coordination			125
Totals (investments and Personnel costs) (k€)			1500

ANNEX 1

TEMPLATE FOR A POTENTIAL MEMORANDUM OF UNDERSTANDING (MoU) CONCERNING THE CONSTRUCTION AND OPERATION OF A EUROPEAN INFRASTRUCTURE FOR SYSTEMS BIOLOGY

Established between the following partners (referred to hereafter as "partners" and their home countries referred as "partner countries"):

- *[List of representative organisations]....*

This document is intended for internal use within ISBE project, and is subject to further amendment through ongoing discussion within the ISBE project, and subsequent negotiation with the potential MoU partners.

Information in red is subject to ongoing negotiation with project partners, and/or with potential signatories

Contents:

- 1 Purpose and Nature of this Memorandum of Understanding
- 2 Implementation of a Legal Structure
- 3 Establishment and Tasks of Interim Bodies
- 4 Contributions
- 5 Entry of new partners
- 6 Entry into Effect, Duration and Termination

ANNEX: DESCRIPTION OF THE LEGAL FRAMEWORK “ERIC”

Preamble

Systems biology aims at understanding the dynamic interactions between components of a living system, between living systems and their interaction with the environment. Systems biology is an approach by which biological questions are addressed through integrating experiments in iterative cycles with computational modelling, simulation and theory².

The partners recognise that life-sciences and biomedical research are critical to tackling the European grand challenges of healthcare for an ageing population, food security and environmental protection, and that systems approaches to biological and medical sciences will require support for a European-level infrastructure that can coordinate to delivery of systems approaches to ensure that maximum value is obtained from the current and planned investments.

The success of systems biology approaches depends on the ability to access and integrate a great diversity of (large) data and models generated by the scientific community, as a result of significant investments by funding organisations across Europe. Significant efforts are being undertaken over the last 10 years, including through the ERA-Nets; ERASysBio, ERASysBio+, and ERASysAPP. In addition, preparatory support has been provided by EU under FP7 to explore the establishment of the European research infrastructure project, Infrastructure for Systems Biology – Europe (ISBE). This is intended to enable access to an integrated, distributed infrastructure for state-of-the-art facilities for systems biology.

Most recently under the umbrella of ISBE and ERASysAPP, Germany (BMBF/PtJ) Switzerland (SystemsX.ch), The Netherlands (NWO), and the United Kingdom (BBSRC), agreed to support the Data Management Core Project “FAIRDOM” in order to build on these previous investments and support future services to the scientific community.

Building on these previous investments, the partners desire to further strengthen the position of Europe's Member States in research in the world, and to intensify scientific co-operation across disciplinary and national boundaries to support the construction and operation of a European the infrastructure for systems biology for the European life sciences research Community.

This joint action aims to:

2

www.erasysbio.net/lw_resource/datapool/_pages/pdp_2/ERASysBio_Systems_Biology_Strategy_Paper_25-Mar-2008.pdf

- **support the researcher community funded by the Partners and through associated ERANets in systems biology**, based on criteria of scientific and service provision excellence, whilst exploring how this could improve international competitiveness
- **expand membership** to other countries to participate in these activities in order to extend the support to the European systems biology community in countries not funded represented in this MoU.
- **identify and establish the central Headquarters** to be located at an existing research organisation in one of the partner countries.
- **establish boards and panels** required to enable due consideration and advice for the implementation of a subsequent legal vehicle for the infrastructure, to explore a strategy for financial sustainability, and the mechanism to support collaborative operation of centres;
- **provide financial contributions** for the support of the appointment of a Director to develop advocacy and outreach activities, together with suitable administrative support for the above boards; and
- **explore the potential for pilot studies** that might help test the nature of integrated services and transnational access, and advance the establishment of links and agreements between nationally located centres of excellence, and coordinate with relevant ESFRIs, notably ELIXIR.

1. Purpose and Nature of this Memorandum of Understanding

- 1.1. The purpose of this Memorandum of Understanding (hereinafter referred to as “MoU”) is to summarise the current intent of the partners regarding the following steps to be taken towards the construction and operation of the Infrastructure for Systems Biology, Europe **that incorporates [potential to include any specific identified Data Management resources]**
- 1.2. The Partners agree to explore the suitability of establishing a ‘European Research Infrastructure Consortium’ (ERIC) mechanism and facilitate continued discussions to offer Data Management services, solutions, training and advice to European systems biology community. To this end, the Partners may provide each other with all necessary relevant information towards the implementation of this MoU.
- 1.3. This MoU represents the intentions of the partners, made in good faith, to collaborate in respect of the “European Infrastructure for Systems Biology Project”. Each partner hereto understands and agrees that nothing contained in this MoU is intended to constitute a legally binding obligation, and under international public law, and nothing in this MoU shall be deemed to constitute an agency or any kind of formal grouping or entity between the Partners.

2. Implementation of a Legal Structure

- 2.1. The Partners intend to make their best efforts to diligently undertake all necessary steps required to establish the Research Infrastructure under the mechanism of an ERIC, as described in the ISBE Business Case. It is the intention of the Signatories to establish a European Infrastructure for Systems Biology under this mechanism within the next thirty six (36) months from the date of entry into force of this MoU in accordance with section 6 below.
- 2.2. The Partners agree to negotiate in good faith the terms of an international legal agreement that will form the legal basis of a “European Infrastructure for Systems Biology”.

3. Establishment and Tasks of Interim Bodies

- 3.1. The Partners agree to evaluate the possibility of setting up
 - 3.1.1. An Interim Governing Board for the Research Infrastructure that assembles interested future Member States; whereby each partner would delegate one scientific and one administrative delegate. Each partner will have one vote only. The board may allow observers, and explicitly seeking to encourage participation from other countries who are not partners from the start, as a consultative voice to its meetings. The Interim Governing Board will determine additional groups to get observer status (e.g. charities, industry, the EU).
 - 3.1.2. The main task of the Interim Governing Board will be to carry out the negotiations of a final draft of the ERIC for the construction and operation of the Research Infrastructure that will then require approval by the Partners.

3.1.3. The Interim Governing Board will have a chair and at least one vice-chair elected by and among the delegates

3.1.4. The Interim Governing Board will establish Rules of Procedures, which will consider the

contents of this MoU. An Interim Scientific Advisory Board that will advise the Governing Board on scientific issues and will perform on behalf of the Interim Governing Board the evaluation process of future national centres.

4. Contributions

4.1. The partners aim to secure and earmark a minimum budget to finance for the project for a minimum period of three years. The funds provided by the partners will be used for the operational budget of the Interim ISBE secretariat, including the appointment of an Interim Director and resourcing to support the Tasks of Interim Bodies; and consistent to their respective specific national rules and legal frameworks.

4.2. The funding model is a virtual common pot, where each country funds **[amount €XXk]** toward operation costs.

4.2.1. The final decision on funding will be taken by the Partners.

4.2.2. Funding will be awarded and administered according to the terms and conditions of the respective partners taking into account all applicable national regulations and the respective legal frameworks.

4.3. Each Partner declares its political will to evaluate the possibility:

4.3.1. to identify a host nation for the headquarters of the Research Infrastructure, and to contribute to its operational budget; and

4.3.2. to support financially its relevant national scientific entities ("national centres/etc.") for their participation in the ISBE infrastructure.

5. Entry of new Partners

5.1. The entry of new partners requires the approval of all existing partners at the respective time and the new partner's signature under the existing MoU.

6. Coming into effect, Duration and Termination

6.1. This MoU will come into effect between the Partners by the date of its **number [fifth]** signature. It will then come into effect regarding each additional Partner that signs it after this date as of the date of signature by said Partner.

- 6.2. It shall remain in effect for the entire funding period of 3 years, with any subsequent agreed extension period necessary to ensure that the subsequent legal agreement to establish the Research infrastructure is signed off.
- 6.3. Any one individual partner or group of partners may decide to terminate their accession to this MoU at an earlier stage. In the case of an individual partner deciding to terminate their accession to this MoU, they will inform the other partners in writing subject to a three months prior notification. The remaining partners may decide to maintain the MoU in effect among them for the duration as specified in the present Paragraph.

7. Amendment

Any modification of this MoU requires the written consensus signed by all the partners hereto.

8. Resolution of Conflict

Any conflict that might arise concerning this MoU will be settled amicably. If no amicable solution is possible, any one individual Signatory or group of Signatories may terminate their accession to the MoU as described in Paragraph 6.3.



Date:

Signatures

Signature (including official stamp):

Name:

Position

Etc.