



Report on the proposed organisation, governance and legal structure of ISBE

Deliverable D11.2

Work package 11

Funding Governance and Legal

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Executive summary

ISBE published its business plan at the end of July 2015, which sets out the long term proposed organisation, governance and legal structure of ISBE to be implemented as it establishes itself as a legal entity from 2018 onwards. This report of WP11 deliverable D11.2, sets out the steps taken to develop this proposed structure and determine its suitability for providing the most appropriate framework for ISBE to operate as a sustainable transnational research infrastructure. In developing this structure, ISBE WP11 consulted with a broad range of representatives from national ministries and funding agencies.

The first step in establishing the long term structure was to develop a set of guiding principles that were endorsed by the ISBE steering committee. WP11 then drew on best practice from across the ESFRI Research Infrastructures, both planned and in place, to develop the structure presented.

We believe that the resultant model provides a viable mechanism for ensuring suitable overview by member states supporting it, together with involvement of researchers providing the resources, services and activities for the community. The structure also provides a robust way of ensuring independent advice, most notably in assessing and monitoring institutions that will deliver the operational activities for ISBE.

Finally, the model sets out a modest but efficient executive function that can ensure coordination of operations, development of strategic direction and most crucially, the outreach needed to expand the breadth of provision being set out for ISBE.

Introduction and Background

1. WP11 aimed to deliver several key objectives for ISBE preparatory phase including “*To deliver a long-term funding and governance strategy that supports the objectives and priorities of funding organisations participating in ISBE.*” The key deliverables for the WP were therefore to identify a model that:
 - responds to the strategic and financial expectations of funding organisations;
 - allows bi/multilateral agreements between potential infrastructure elements; and
 - provides concrete recommendations for establishing a sustainable funding model for ISBE.
2. Key to achieving this objective was the establishment of a WP11 Funding Governance and Legal Advisory Committee (FGLAC) to consider possible organisation, governance and legal structures of ISBE. Membership was drawn from:
 - representatives from relevant ministries and funding agencies including the four full participants (ministries and funding agencies) receiving funding from the ISBE grant agreement; four associate members (ministries and funding agencies) not formally receiving funds; and other funding organisations identified by existing members, for:
 - consultation on the viability of the proposed model,
 - to aid negotiations relating to the resulting International Legal Agreements for ISBE, together with consideration of associated commitments and obligations.
 - ISBE project partners, notably in WP1 (Project Management and Co-ordination); WP3 (Overall Infrastructure, Eligibility and Accessibility); and WP7 (Strategy, Vision and Advocacy) to ensure mutual understanding of the challenges and outputs of those work packages;
3. WP11 officers sought additional advice from national funders not on the FGLAC, on related developments in coordinating systems biology infrastructures, and in reviewing the suitability of the ISBE model for providing strategic advice.

Country	Organisation
Austria	FFG
Czech Republic	MSMT
Denmark	DASTI
Germany	PtJ/BMBF
Italy	University of Milan, representing MIUR
Netherlands	NWO
Netherlands	ZonMw
Norway	RCN
Slovenia	MIZS
Sweden	Guttenberg University, representing VR
Switzerland	SystemsX/SNSF
UK	BBSRC

Table 1: National ministries and funding agencies advising WP11 funding committee meetings

Establishing central principles for ISBE Governance

4. As a first step, in December 2012 WP11 FGLAC agreed a set of principles by which ISBE should operate in the long term, once fully established. These principles set out the intention to build efficiently on existing investments and interactions whilst recognising the need for diversity in national approaches.

“Principles of ISBE Funding and Governance”

- ISBE should build on, rather than replace, current national efforts as much as possible.
- ISBE should be designed to allow and support the diversity of national approaches and priorities.
 - *Thereby striving to maximum synergy between national efforts.*
- ISBE should have a governance structure which ensures the overall direction of the infrastructure in the hands of the national or funding agencies which support it.
 - *The more it was able to accommodate and operate within existing national procedures, processes and frameworks the easier it would be to get ISBE established.*
- Coordination should be centralised only where it enhances efficiency.
 - *The subsidiarity principle should apply to the structure; with central coordination being no larger than necessary to improve effective delivery of coordination across the distributed structure, and involving appropriate engagement and consultation with all relevant ISBE centres.*
- Centralised Funding should be minimised.
 - *The funding structure needs to minimise the extent to which funders lose control of their own funds, and minimise the extent to which funds cross borders.*

Developing ISBE Governance structure

5. WP11 identified that in setting up ISBE's governance, it was important to ensure that the appropriate bodies are established to enable the infrastructure to:-
 - consider and reach agreements;
 - agree budgets;
 - seek advice; and
 - assess and review progress.

6. Further, the candidate governance structure needed to be appropriate for ensuring the timely and effective communication, monitoring and reporting of coordinated activities, as well as identification and development of novel activities for support through candidate structure of ISBE centres.

First iteration of ISBE candidate Governance Structure - May 2013

7. The WP11 FGLAC reviewed a candidate governance structure that sought to establish a high level strategic 'coordinating board' with representation by national funders plus scientific experts, together with a 'Heads of centres' committee, responsible for operational activities of the centres that reported to the board. Advice would be drawn from Scientific Advisory and Industrial Liaison Boards. Finally all groups would be supported by a modest executive that was able to provide coherence and advice across centres. (see figure 1 for structure and table 1 for roles below)

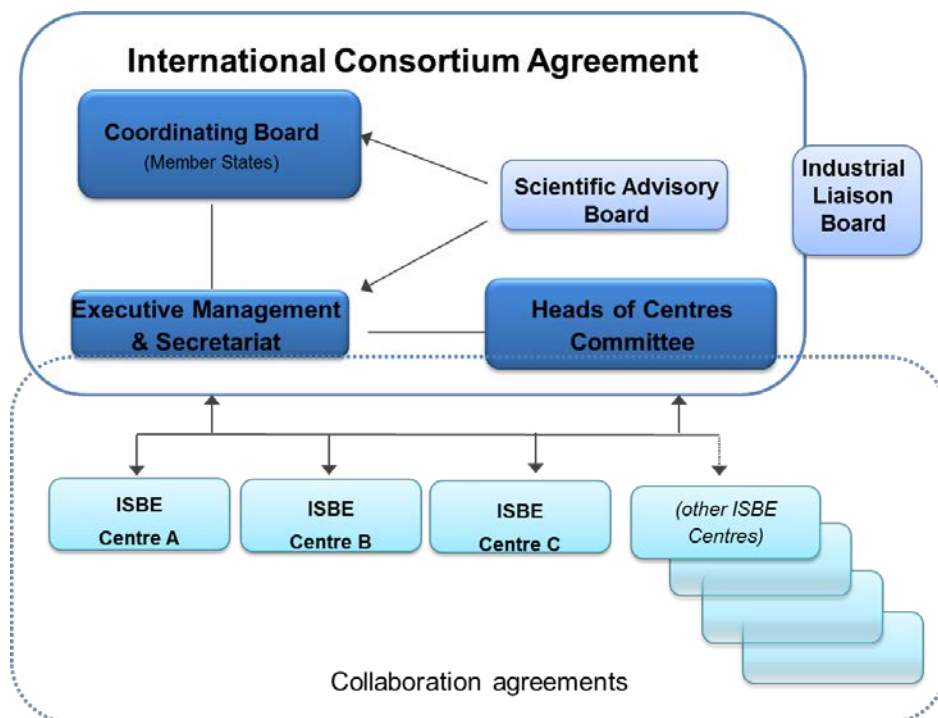


Figure 1: Candidate Governance model for ISBE as of May 2013

Name	Role
Coordination Board	<ul style="list-style-type: none"> • High level oversight • Approval of Strategy and Budgets • Approves Centre's participation in ISBE • Representatives of national funders plus scientific experts
Executive Management and Secretariat	<ul style="list-style-type: none"> • Reports to Coordination Board • Headed by ISBE director • Executes decisions of Coordination Board • Manages 'central budget' • Organises Scientific Evaluation • Manages Collaboration agreements between centres • Considers human resources issues & related issues for entry of Centres (Hires secretariat staff etc.) • Subject to independent audit
Scientific Advisory Board	<ul style="list-style-type: none"> • Scientific Evaluation on new centres • Scientific review of existing centres • Advises Coordination board of wider scientific issues, developments etc. • Consider Social & Ethical issues
Head of Centres Committee	<ul style="list-style-type: none"> • Reports to Coordination Board • Includes all Heads of Centres • Considers operation aspects across centres • Develops and reviews strategic advice to Coordination Board • Arbitrates issues/decisions between centres • Develops and reviews collaboration agreements
Industrial Liaison Board	<ul style="list-style-type: none"> • Liaise with significant commercial interests • Advises on Industrial needs, notably for training • Considers opportunities of joint funding

Table 2: Roles of ISBE potential governing bodies

8. It was agreed that this should form the basis for further elaboration, whilst noting that scientific expertise captured within ISBE would be at the level by 'Heads of Centres Committee' and that the Coordination Board should draw in scientific expertise as required. Also, a clear explanation would be needed as to how the ISBE office would provide coherence and advice across centres, whilst avoiding unnecessary 'middle management'.

Second iteration of ISBE candidate Governance Structure - November 2013

9. In September 2013, the ESFRI Assessment Expert Group reviewed all ESFRI Projects¹, including ISBE, which made 3 recommendations with specific relevance to the Governance model, being:-

¹ <http://ec.europa.eu/research/infrastructures/pdf/jd-final-aegreport-23sept13.pdf>

- *an overarching Ethical Board should be envisaged, and not only at national level. This is important because it, among other things, puts emphasis on the notion of an integrated research infrastructure.”*
- *transparent and clear procedures for the nomination and election of Science Advisory Board members should be included in future documents.*
- *if industry is seen as a demand-pull partner, then their involvement should be organised via an Industrial Advisory Board.*

10. In November 2013, WP11 FGLAC therefore further iterated the governance structure following discussion at the ISBE steering committee, and taking into account the feedback of the high level ESFRI Assessment Expert Group (AEG) report. At this meeting the following amendments to the structure were agreed:-

- the change of name for the “*Coordination Board*” to “*Governing Board*” to emphasise its central decision making role as the body that supervises the activities of the ISBE Executive Management and Secretariat (at the ISBE Central Office) and coordination across the nodes on behalf of the member states.
- identification of the need for relevant ‘technical panels’ and working groups associated with the Governing Board and the Heads of Centres Committee to foster strategic deliberations and ensure operational effectiveness.
- explicit identification of both the Scientific Advisory Board and the Industrial liaison boards as the two main sources of coordinated external advice for both the Governing Board and the Executive Management and Secretariat.
- the inclusion of the Ethics Board, whose function is to be captured within the main ISBE structure covering the following aspects:
 - i. use of animals and humans in experimentation
 - ii. data security and access (including patient data confidentiality)
 - iii. societal and environmental impact.
 - iv. legal issues

11. The following diagram shows this revised structure:-

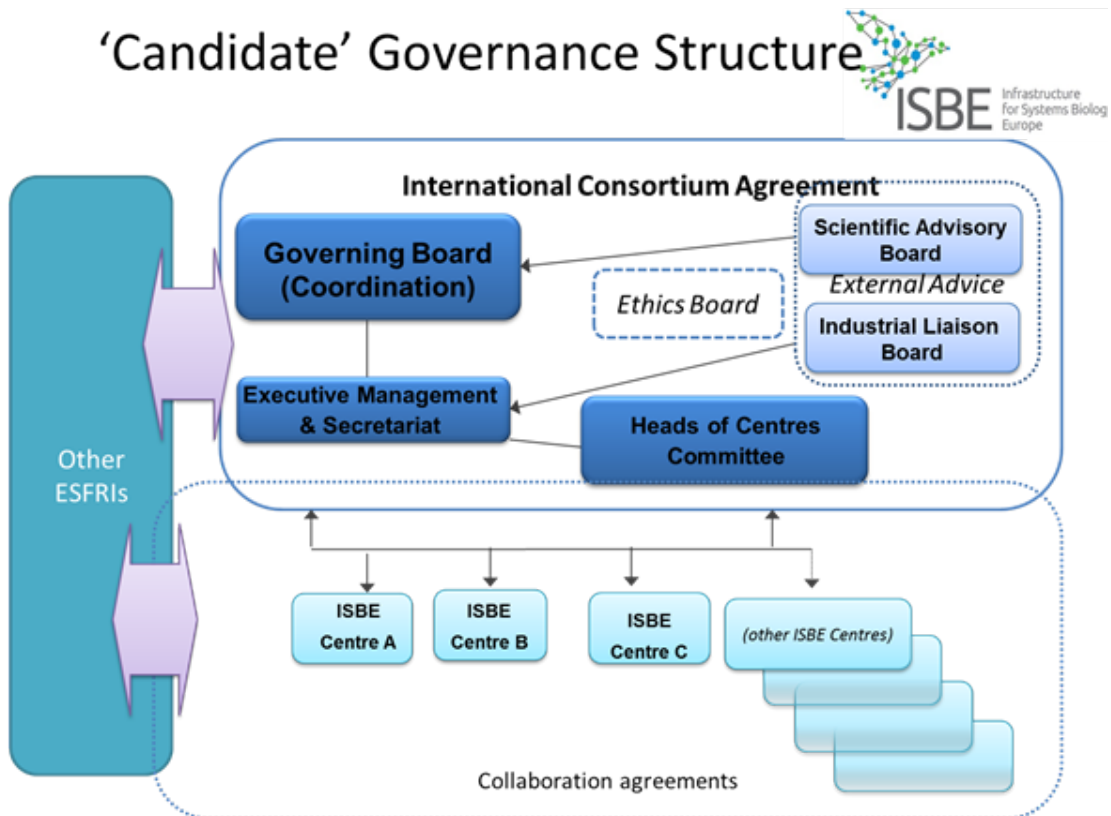


Figure 1: Candidate Governance model for ISBE as of November 2013

Identifying appropriate legal model for ISBE

12. It was anticipated that the ISBE collaboration agreement would identify the main standing bodies responsible for these decision making and executive functions for ISBE. This should set out the nature and operation of the main governing body, how executive operations would be delivered (via a director, and associated staff), and describe appropriate internal management bodies and advisory committees. Finally ISBE must be able to operate effectively with other institutions, including other ESFRIs in order to avoid overlap, improve synergies and provide added value to existing investments.
13. However, this agreement would not be expected to capture every aspect of the operations, such as detailed terms of reference for standing bodies. In addition, there would be separate service level agreements (SLAs) between centres.

Segmentation of ISBE support – The ISBE Dual support model

14. In determining the most appropriate legal model for ISBE, WP11 considered that the legal structure's key characteristics would be to facilitate and enable the sustainability of ISBE as a long-term infrastructure (as distinct from either a fixed-term project or network), whilst enabling suitable flexibility for the inclusion and possible departure of both Member States and institutions providing services, activities and resources through ISBE. The diagram below illustrates the broad segmentation for ISBE according to this 'dual model' approach.

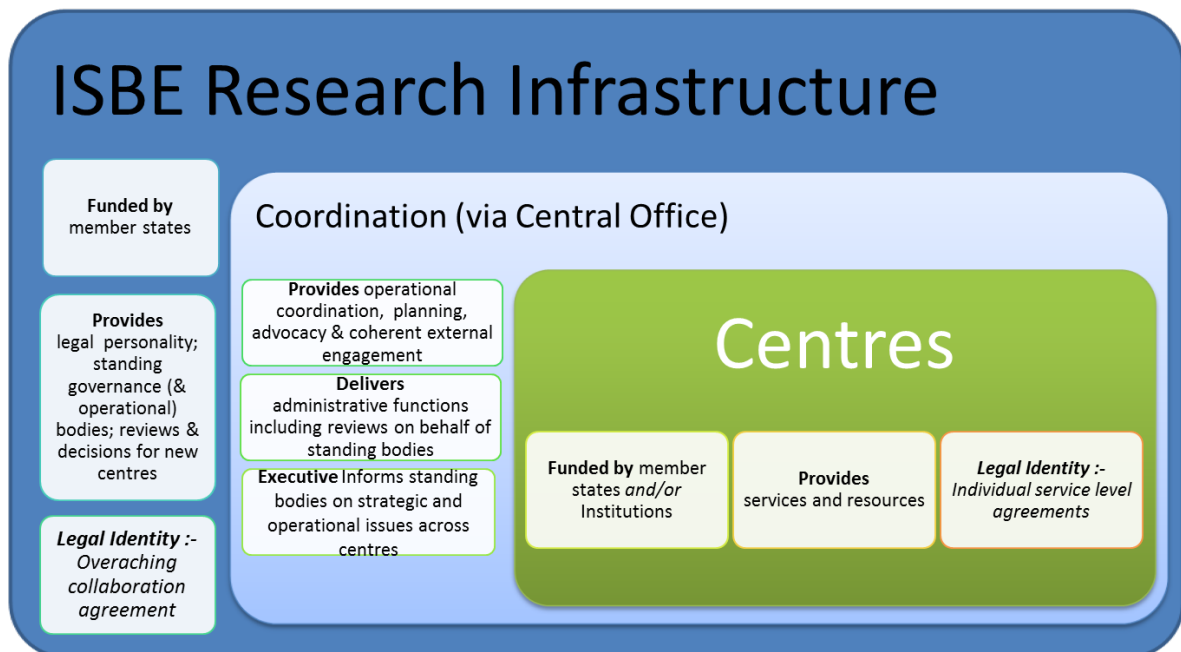


Figure 3: Anticipated aspects of the ISBE as a legal entity, with central coordination, and distributed national centres (as of November 2013)

15. The proposed approach mirrors many other ESFRIs in that it presumes the establishment of a headquarters to administer activities across the infrastructure. This could include support for:

- operation of standing bodies;
- external facing services and representation activities, including web interfaces, publicity/advocacy, fund raising and engagement with EC, national ministries and other funders;
- industrial engagement;
- coordination of communications across centres;
- delivery of coordinated access to services and facilities; and
- coordination of calls for usage of resources and training activities

16. The usage of a system broadly similar to other ESFRIs was endorsed through consultation with national ministries and funding agencies as being both suitable for an infrastructure like ISBE and preferable to allow representation of their interests.

Consideration of the most suitable legal model for ISBE

17. Review in early 2013, of the most appropriate legal model favoured the ERIC mechanism, in principle, subject to review as the ISBE model developed. WP11 funding committee particularly noted the key interface between ELIXIR and ISBE activities, WP11 FGLAC's subsequent review drew on the best practice seen in other existing and planned ESFRIs. It was noted, several other ESFRI projects had recently opted to develop ERIC as legal model of choice for the long-term phase (post-interim phase).

18. In November 2013, a more detailed analysis of several legal models was presented to the WP11 FGLAC. The six models considered are:-

- Memorandum of Understanding (MOU)
- International Consortium Agreement (ICA)
- Association
- Non-profit making Company
- European Economic Interest Grouping
- European Research Infrastructures Consortium (ERIC)

19. The table at **annex 1** briefly summarises the advantages and disadvantages of various types of agreements as considered by WP11 FGLAC that might be applicable and most potentially most suitable to ISBE.

20. WP11 FGLAC concluded that the ERIC mechanism still appeared as the most appropriate fit for the ISBE structure. All subsequent discussions continued to confirm the suitability of an ERIC mechanism as being the most suitable potential model for ISBE.

Legal agreements between individual ISBE centres

21. Consideration by other work packages proposed that Individual centres would provide specific technical expertise and advice to external users, and stakeholder, as well as advise other centres and ISBE standing bodies, on current operations and future needs.
22. While the services, activities and resources that could be administered and delivered by individual centres were expected to vary, it was important to establish links and communication between each component for coordination of technical support and advice between centres as well as commissioning of services resources and activities.
23. The ISBE model proposes that any centre can offer a broad range of technical and administrative services to be defined upon application to become an ISBE centre, WP11 FGLAC advised that each centre should therefore operate through an individual Service Level Agreement (SLA), within a pre-agreed framework that addressed the commissioning of services and resources in a fair, transparent and legally acceptable manner. This would be signed between each centre and the central office upon a centre joining ISBE
24. Each SLA would set out issues such as the delivery of services, financial provisions, quality control, IP and liability for the duration of the agreement. Individual centres would also be expected to share specific technical expertise and advice to other centres to be provided.
25. It was acknowledged that existing coordination of Systems Biology resources often occurred across a number of different institutes within the same Country. It was therefore possible that several legal entities could combine together in providing an integrated service package in some countries, while in others a single ISBE centre could also be single legal entity providing the complete service package. Indeed, in other BMS ESFRIs, several institutions had combined together to form a single 'node', often centred around existing national collaborations. The collaboration agreement would therefore require that one identifiable accountable entity represent that suite of activities.

Negotiation of the overall legal instrument

26. WP11 FGLAC funders committee identified the considerations for negotiation with organisations representing potential member states:-
- a. **Distributed Infrastructure:** The host location of the ISBE central office must be identified, and would be governed by the national laws of the host member state.
 - b. **Effectiveness, Entry into force, and Duration:** The agreement should state the conditions for its entry into force - defining the conditions for ISBE to start. It is anticipated that the Agreement would continue in full force and effect for an undefined term. The conditions for termination of the agreement and process and body entrusted with the liquidation of the assets and property allocated to ISBE, should be defined.
 - c. **Access:** It is assumed that ISBE will adopt an open access model for all data and technical services enabling access and support of the data shall be provided on an open access and/or open source basis, and shall be put into the public domain (under the applicable licenses). However, it may also wish to consider using a broader 'open-access ecosystem' that recognises the need for partial and/or delayed release of some data (especially commercial data).
 - d. **Intellectual Property:** As ISBE is not expected to conduct research itself, no Intellectual Property would be developed directly from its activities or operation. However, it should promote the creation of Intellectual Property by researchers using ISBE infrastructure. For any access framework, specific considerations will need to be made for data issues and Intellectual Property (applicable law, data access, attribution, specific data, validity, technology transfer, etc.) via the Ethics Committee.
 - e. **VAT exemption:** A key benefit intended by the creation of European Research Infrastructure Consortium (ERIC) framework was the freedom from taxation derived from the agreement on costs relating to goods and services associated with the management and services of the infrastructure, and in delivering its aims and activities.
 - f. **Confidentiality:** Confidentiality would be dealt with via the separate service level agreements between centres, within the legal framework set out under the main legal agreement
 - g. **Financial contributions and management:** A key consideration should be the overall stability and viability of core operations required to deliver ISBE's mission. The model should be able to receive external funding such as grants, loans and donations. Income from commercial sectors may be obtained for use of services training and resources, and for collaborative funding.

Each level of agreement would identify relevant funding routes and their management. The basis for contributions should be agreed for several years at a time, with a mechanism for annual review (to enable consideration of additional contributions; expansion in the number of centres and/or resources, training and

- services being provided). Dates and timings of payments would also be laid out. The consequences of delayed (or early) payment would also need to be addressed
- h. **Liability:** It is probable that some Member States would not accept unlimited liability, so there will need to be a 'formula' to establish liability levels.
 - i. **Observers and associate members** How observers and associate members should be included. This is especially important in providing representation for states considering membership in advance of signing the official legal agreement.
 - j. **Ethical guidelines** ISBE, or its host organisation, should ensure that activities required as part of the ISBE's mission will be executed in line with relevant laws and regulations and where applicable ethical guidelines. This would be overseen by the Ethics Board who would be responsible for reviewing how ISBE ensures that its centres are made aware of their obligations.

Developing the finance plan for ISBE

- 27. WP11 proposed that the financial plan should be established for 4-5 years in the first instance in order to support resourcing of the infrastructure in the legal phase. Consequently, in 2014, members of WP11 and WP3 worked together to develop a viable model for ISBE based on the costs of establishing the executive and activities likely to be take place at each national Systems Biology Centre contributing resources, services and activities. This was developed in anticipation of the identification of these centres, expected to take place in the interim phase.
- 28. During the development of the finance plan, it was not certain what level of resource would be required for any specific candidate centre. Therefore the finance plan developed made assumptions about the scale of contributions from countries likely to be interested in the legal phase, and the varying size of their current activities and investments, together with their likely level of their growth during the first few years of operation under ISBE. In addition, feedback from partners was used to validate the assumptions made.

Setting out a public statement on proposed Governance and Legal Mechanisms

29. 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 out 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.
30. The conclusion of all considerations for establishing the long term legal and governance structure, together with its funding requirements was provided publically in November 2014 within the ISBE Business Case². This was subsequently revised in the current business plan (sections 4 & 5) that follows. 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.
31. WP11 FGLAC consulted with representative from national ministries and funding agencies in 11 countries (shown in table 2 below) over the course of the preparatory phase in:-
- Development of the ISBE governance structure
 - Identification of an appropriate legal model for ISBE structure
 - Development of a draft MoU
 - Viability of the finance plan

² section 8, pp53-58

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

1 4. Legal and governance from 2018 onwards

◦ 4.1 Legal structure – European Research Infrastructure Consortium (ERIC)

ISBE requires its own legal personality in order to obtain funding, manage budgets and establish legal agreements with the national Systems Biology Centres (nSBCs). This legal entity can coherently engage with users, providers, national ministries, funding agencies and the European Commission. The Preparatory Phase has identified the European Research

Infrastructure Consortium (ERIC) mechanism as being the most appropriate legal model for ISBE. This allows ISBE to become a legal entity with a European identity and to benefit from tax exemptions. The ERIC framework has already been ratified by many EU member states and allows membership for countries outside the EU.

Table 4.1 summarises how the ERIC structure is suitable for ISBE.

ERIC legal document describes:	Advantages of the ERIC structure:
Legal structure	Utilises the existing ERIC framework mechanism that allows for rapid agreement by countries who have already agreed to the framework
Support of the organisational structure	Will allow for funding of the Central ISBE Office coordination functions for periods longer than 5 years
Eligibility to apply for EU funding	Can apply for EU funding in its own right as an 'international partner'
Ability to engage with multinational research programmes	Presents a single European entity able to engage directly with large multinational consortia on behalf of the national Systems Biology Centres (nSBCs)
Establishment and operation of strategic and financial framework, and work programmes	Can provide support for standing bodies tasked with strategy development and financial planning that shares good practice between centres, together with obtaining independent external advice, notably on ethical issues
Effectiveness of collaboration with other European RIs	Provides a single European entity able to formalise strategic and operational links to other RIs
Liability and Intellectual Property administration	CIO is able to establish collaboration agreements with nSBCs
Duration	Sets out period of effectiveness, dates for entry into force, conditions for accession of new members, obligations and conditions for possible termination and consequences

Table 4.1: The ERIC legal document and its advantages

- 4.2 Legal agreements for individual national Systems Biology Centres

While the nature and mechanisms for coordination of nSBCs would be outlined in the ERIC, direct agreements between ISBE and the nSBC will be required to ensure efficient coordination of services across centres. All nSBCs will be established by entering into a pre-agreed Service Level Agreements (SLA) with ISBE that will define in a fair and transparent manner, the commissioning of services, resources and other activities that will be offered. The SLAs will formally define those services and resources that are to be offered through ISBE and define the levels of services expected by users, as well

as the obligations for the nSBCs in maintaining their availability. An nSBC may be a single institution or a single institution may act in a capacity to represent several other nationally-located institutions responsible for providing aspects of the nSBC services.

- 4.3 Governance and management

The ISBE governance structure will provide for effective and timely management and monitoring of operations across the nSBCs. It will provide suitable external scientific and technical advice and operate with transparency and clarity in its procedures, including the nomination and election of members (figure 4.1).

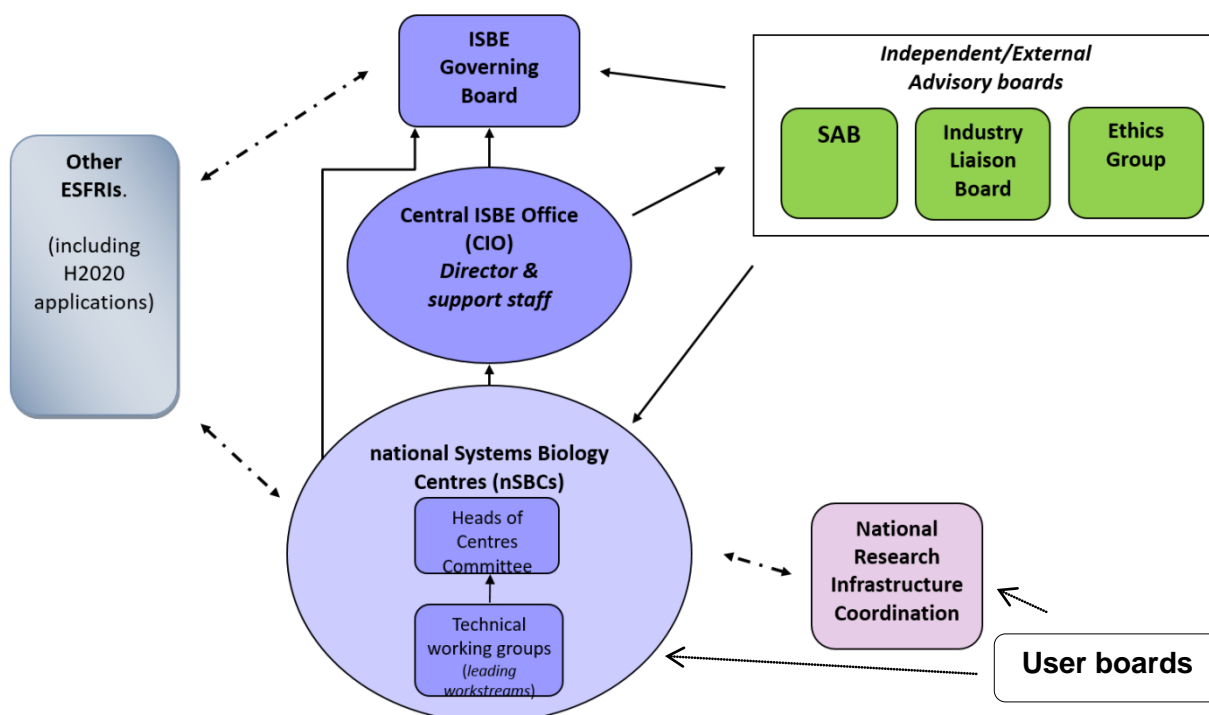


Figure 4.1: Organisational diagram of the main standing bodies of ISBE and key areas of interaction during the legal phase from 2018 onwards

- [4.3.1 Procedure for identification of Central ISBE Office and nSBCs](#)

The location of the host institution for the CIO for the Legal Phase has yet to be identified. The host country will be identified during the Interim Phase (2015-2018).

The procedure and eligibility criteria for approving further nSBCs will also be developed in the Interim Phase, with evaluation processes set out in the ERIC. While the CIO may be situated at the same institution as an nSBC, there will be clear mechanisms that separated their responsibility and functions to allow independent operation and avoid conflict of interest.

- [4.3.2 Governing Board](#)

The *Governing Board* will be the central decision making body with high-level oversight, supervising the CIO on behalf of the member states. It will be responsible for ISBE's strategy and budgets, as well as approval of prospective nSBCs. Representatives will be drawn from and nominated by national funding bodies, together with scientific experts identified by the national funder and tasked with representing the interests of their national communities.

- [4.3.3 Heads of national Systems Biology Centres](#)

The *Heads of Centres Committee* will provide operational coordination across the nSBCs and will be responsible for maintaining effective operations across the nSBCs and developing strategic plans, for agreement by the Governing Board. Members will be the directors of the nSBCs, together with the director of ISBE.

- [4.3.4 Executive management and technical working groups](#)

The ISBE director is expected to have significant experience coordinating collaborative programmes, notably those with significant elements community outreach and industrial involvement. As head of the CIO, the Director will be appointed by the Governing Board. The Director will be responsible for executing the Governing Board's decisions, and management of the central budget. The CIO will organise the scientific evaluation and monitoring of nSBCs, as well as managing SLAs and the interface with other ESFRIs. The CIO will also coordinate internal communications and outreach aspects on behalf of the centres.

In support of this, cross-centre *Technical Working Groups* will lead the delivery of the specific technical and training work streams. These boards will coordinate the delivery of community-led activities.

- [4.3.5 External feedback and input – advisory boards](#)

Understanding user needs is crucial to the success of ISBE. ISBE will draw from the widest possible international expertise to gain insight in how best to meet emerging community needs and opportunities across all sectors, combined with ensuring the continued delivery of cutting edge technologies.

ISBE will establish three main advisory panels, described below, giving independent external advice to enable:

- effective and efficient operations
- suitable oversight and monitoring
- independent audit
- prioritisation of ethical considerations
- a flexibly managed portfolio of expanding resources services by adapting activities

within nSBCs as well as bringing in new nSBCs, including the amendment and termination of existing activities at nSBCs, and proposals for novel services to address emerging challenges.

Scientific Advisory Board (SAB)

The *Scientific Advisory Board (SAB)* will be the main sources of external advice from academia for both the Governing Board and executive. A key role is SAB's evaluation of nSBC applications against a pre-agreed evaluation process, and their subsequent monitoring to advise the Governing Board on decisions such as to renew or terminate nSBCs.

Industry Liaison Board (ILB)

The *Industry Liaison Board (ILB)* will be the main source for wider coordinated consultation of stakeholders within the commercial sector. Its separate identity from the SAB underlines the importance of addressing industrial interest in working collaboratively with academic systems biology researchers. The SAB also will draw from the ILB membership.

Ethical Board (EB)

The *Ethical Board (EB)* will consider the ethical implications of ISBE's activities such as managing information from plant, animal and human experimentation, together with the related issues of data security and access. It will draw expertise from the nSBCs as well as the SAB and ILB. ISBE will build on links being established within the CORBEL project across ESFRIs for the consideration of legal and ethical issues for data exchange and protection in transnational research collaborations.

This will include ensuring appropriate collection and storage of patient samples; regulations on working with genetically modified organisms, and guidelines for accommodation and care of lab animals.

User Boards

ISBE *User Boards* will engage representatives from different user sectors to ensure effective feedback on services and activities, and their involvement in developing novel targeted activities.

◦ 4.3.6 Liaison with other research infrastructures

ISBE will work closely with other research infrastructures building on existing activities, such as those currently supported through CORBEL and RItrain (see Appendix 7), to deliver joint activities and avoid redundancy of operations. Representatives of other research infrastructures will also be invited to attend meetings of standing and advisory bodies. Where longer term agreements are needed, ISBE will work with other research infrastructures to develop appropriate Memoranda of Understanding.

◦ 5. Finance model for the Legal Phase: 2018 and beyond

This section describes the proposed cost model of the ISBE Legal Phase from 2018 onwards. This model is similar to that implemented by or proposed for other European research infrastructures, including BBMRI, ECRIN and ELIXIR. The proposal is provided as guidance for negotiations with national funding agencies and governments, recognising that it makes certain assumptions that will be subject to ongoing review.

The proposed cost model of ISBE has five main components:

- national Systems Biology Centres (nSBCs)
- the Central ISBE Office (CIO)
- further expansion of ISBE
- services and community activities
- funding through third parties

Full details of these models are provided in Appendix 9, with a summary of the main aspects described below.

◦ 5.1 Cost model for the national level: nSBCs

When considering how contributions to ISBE will add value, it is important to understand the overall costs across all the nSBCs. The operational costs of each nSBCs will be covered at the national level, with many of these services and resources often already receiving national support. Further national support in the context of ISBE will enhance national investments and uptake by their growing national user base. ISBE will make national investments more cost-effective by providing access to a

broader user and provider base at the European level.

Table 5.1 summarises three potential scenarios presenting a range of services that nSBCs may provide in the first five years of ISBE's Legal Phase, starting 2018. These estimates are based on existing operational and staff costs for research institutions in the UK and the Netherlands and therefore need modification for costs in other European countries. Estimates include staff costs, running costs and overheads.

Table 5.1: three possible scenarios for three possible sizes of nSBC at the start of ISBE’s Legal Phase (2018 – 2022)

	Annual operational costs (k€)					Total (5 yrs)
	2018	2019	2020	2021	2022	
small nSBC	200	300	400	450	500	1850
medium nSBC	350	600	700	800	900	3350
large nSBC	600	700	1250	1500	1700	5750

◦ **5.2 Cost model for European operations: CIO**

The CIO, headed by the ISBE director, will coordinate the development and maintenance of the portfolios of services, resources and community activities and takes responsibility for ISBE’s finance, governance and outreach. It is estimated that in total six full time equivalent staff (FTEs) will be the optimal to monitor and coordinate overall operations and oversee ISBE strategy development all services and resources. Table 5.2 summarises the expected costs of the CIO for the first three years of ISBE’s Legal Phase (2018-2022). A detailed overview of anticipated support staff, expertise and operational costs is presented in Appendix 9.

In practice, levels of national member state contributions should reflect their relative size. To support the CIO, ISBE therefore proposes to use a similar Gross Domestic Product (GDP) based

subscription model to that currently employed by other ESFRIs. It is anticipated that additional contributions such as ‘in-kind’ support of indirect costs may come from the country that hosts the CIO.

◦ **5.3 Further expansion of ISBE**

ISBE will expand its budget in two ways, i.e. through stepwise increased national budgets of its nSBCs and by acquiring funding at the European level through the CIO.

◦ **5.3.1 Stepwise increase of national budgets**

Once established, ISBE is designed to grow with expanding user demand, as well as new countries joining over time. The ISBE infrastructure model allows for its subsequent expansion over time, in a manner that can respond to evolving user demands by developing the scope of services and resources it supplies (see tables 5.3 and 5.4).

Table 5.2: expected costs for the Central ISBE Office (assuming 6FTEs)

	Annual operational costs (k€)					Total
	2018	2019	2020	2021	2022	
CIO	625	675	710	765	785	3560

Table 5.3: projected growth in number and value of commitment of the differing sizes of nSBCs in the first five years of the Legal Phase (2018-2022)

Construction of ISBE nSBCs	2018	2019	2020	2021	2022
small nSBCs	2 (400 €k)	2 (600 €k)	4 (1600 €k)	6 (2700 €k)	8 (4000 €k)
medium nSBCs	2 (726 €k)	3 (1614 €k)	3 (2160 €k)	4 (3276 €k)	5 (4550 €k)
large nSBCs	1 (600 €k)	2 (1410 €k)	3 (37870 €k)	4 (6180 €k)	5 (8200 €k)
Total number of nSBCs	5	7	10	14	18

- [5.3.2 European level funding](#)

There are increasing opportunities in the Horizon 2020 scheme for developing European research infrastructures. Examples are the recently awarded grants for the CORBEL (harmonizing activities of life sciences research infrastructures) and RItrain (training research infrastructure personnel) programmes in which ISBE participates. Another example is the transnationally funded FAIRDOM programme, which will be integrated in the ISBE activities. Together, this presently represents a European level budget for ISBE of ~€4.6M. The CIO will, together with the nSBCs, make a continuous effort in expanding European funding of ISBE.

- [5.4 Services and community activities](#)

A detailed cost model for ISBE services for all user types will be developed in conjunction with nSBCs and relevant national funders based more exactly on the specific services a centre will provide.

- [5.5 Reviewing legal agreements](#)

As ISBE develops in the legal phase, the CIO will develop legal documentation for concluding agreements with nSBCs and collaborative agreements with other ESFRIs for ISBE services. This would also require legal advice, and further iterations of the financial plan will need to properly cost this element.

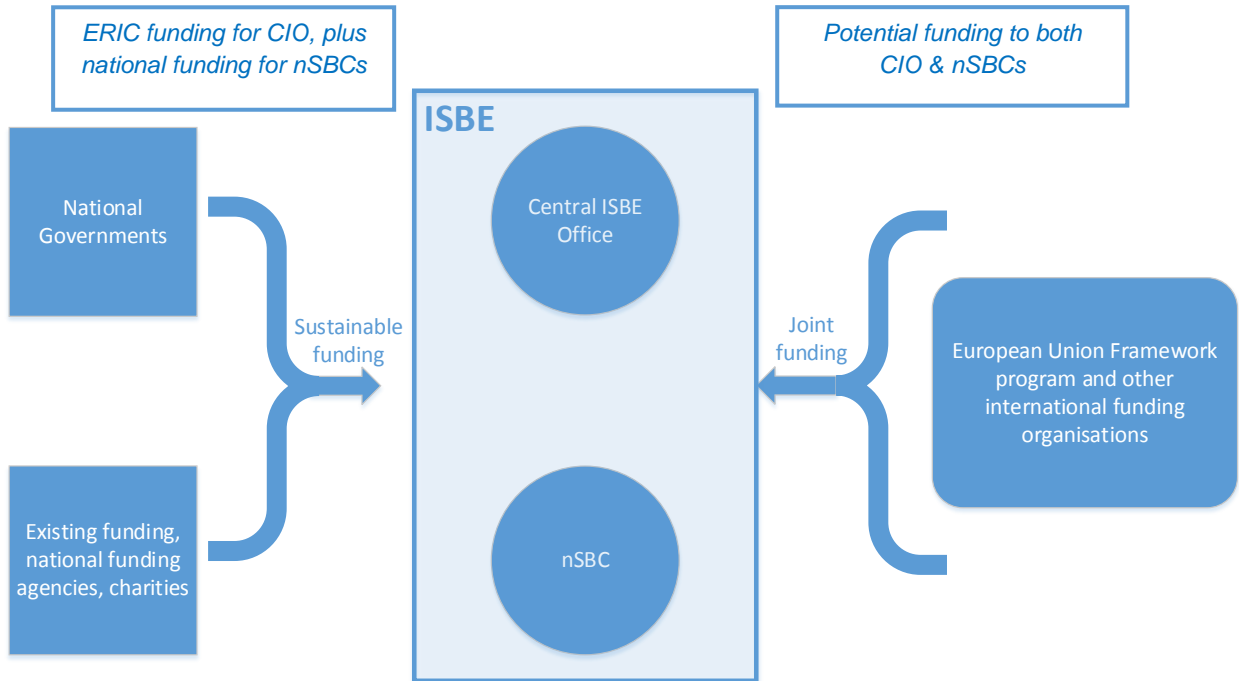


Figure 5.1 ISBE's funding streams

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

LEGAL PHASE COST MODEL - CIO (Aug 2018-2022 onwards)

The model for the legal phase envisages the expansion of personnel at the CIO in order to support the newly agreed national Systems Biology Centres that take over delivery of operations from the ISBE-light organization. This is reflected in the need to support a broader range of standing bodies and support technical and operational coordination working groups across the nSBCs. Support for outreach and community engagement activities is similarly enhanced to deliver the central portal for ISBE as a legal entity.

Table III: summary of personnel and operational costs for the Central ISBE Office for the first 5 years of the legal phase (2018-2022) (all costs are in k€).

	2018	2019	2020	2021	2022
Personnel	495	530	545	560	580
Operational costs	130	145	165	205	205
Total	625	675	710	765	785

Table IV Summary of estimated fulltime equivalents (FTEs) and personnel costs for the Central ISBE Office for the first 5 years of the legal phase (2018-2022) (all costs are in k€)

Expenditures		Legal phase				
		2018	2019	2020	2021	2022
Personnel Costs	<i>Director (1.0 FTE)</i>	165	175	180	180	185
	<i>Web manager (1.0 FTE)</i>	70	70	70	70	75
	<i>Secretary(0.5 FTE)</i>	30	30	35	35	40
	<i>Public relation manager(0.4-0.5 FTE)</i>	30	30	35	35	40
	<i>Liaison officer (project manager) (1.0 FTE)</i>	70	75	75	80	80
	<i>QC officer (0.75-1.0 FTE)</i>	70	75	75	80	80
	<i>training and education developer (0.8-1.0 FTE)</i>	60	75	75	80	80
	Subtotal Personnel FTE	5.45	6.00	6.00	6.00	6.00
Subtotal Personnel costs	495	530	545	560	580	

Table V: Summary non-staff operational costs for coordinating for the Central ISBE Office for the first 5 years of the legal phase (2018-2022) (all costs are in k€)

Investments/ facilities in the legal phase			2018	2019	2020	2021	2022
CIO Office functions	<i>Consumables</i>		5	5	5	10	10
	<i>hardware</i>		10	15	15	20	20
	<i>Software</i>		10	10	15	15	15
	<i>Running costs</i>		5	5	5	10	10
Subtotal		30	35	40	55	55	
Portfolio of web-based services		40	50	60	75	75	
Travel and conferences		10	10	15	15	15	
Outreach and coordination		50	50	50	60	60	
Subtotal		100	110	125	150	150	
Subtotal Investments		130	145	165	205	205	
Totals (investments and Personnel costs) (k€)		625	675	710	765	785	

LEGAL PHASE COST MODEL - nSBCs (Aug 2018-2022 onwards)

The model for estimated that likely cost for the differing sizes (small, medium & large) of national Systems Biology Centres (nSBCs) **NB** that the support for these centres is anticipated to continue to be met through national funding programmes and opportunities and is provided in advance of the more exact modelling of costs for services that would follow the identification of the actual services, activities and resources that a member state would itself propose during the interim phase.

Table VI: Summary of estimated fulltime equivalents (FTEs) and costs for a **small** national Systems Biology Centre for the first 5 years of the legal phase (2018 - 2022) (all costs are in k€)

Expenditures	S	Legal phase				
		2018	2019	2020	2021	2022
Personnel FTE	<i>Administrative; Integration and modelling; Steward & standardisation</i>	2.0	3.0	4.5	5.0	5.0
Subtotal Personnel costs		140	240	320	350	390
Investments/ facilities	<i>Consumables; hardware; Software; Running costs</i>	25	25	35	40	50
Portfolio of web-based services		15	15	20	20	25
Travel and conferences		10	10	10	15	15
Outreach and coordination		10	10	15	15	20
Totals (investments and Personnel costs) (k€)		200	300	400	450	500
						1,850

Table VII: Summary of estimated fulltime equivalents (FTEs) and costs for a **medium** national Systems Biology Centre for the first 5 years of the legal phase (2018 - 2022) (all costs are in k€)

Expenditures		Legal phase				
		2018	2019	2020	2021	2022
FTE Personnel						
	<i>Administrative</i>	0.4	1.0	1.0	1.0	1.0
	<i>Integration and modelling</i>	1.5	3.0	3.0	4.0	4.0
	<i>Steward & standardisation</i>	1.6	2.0	4.0	4.0	4.0
Subtotal Personnel FTE		3.5	6.0	8.0	9.0	9.0
Personnel Costs						
	<i>Administrative</i>	28	70	70	70	75
	<i>Integration and modelling</i>	105	210	210	280	300
	<i>Steward & standardisation</i>	112	140	280	280	300
Subtotal Personnel costs		245	420	560	630	675
Investments/facilities						
	<i>Consumables</i>	30	30	40	40	50
	<i>hardware</i>	5	5	10	10	15
	<i>Software</i>	10	10	10	20	20
	<i>Running costs</i>	3	3	10	10	15
Portfolio of web-based services		30	30	40	40	50
Travel and conferences		20	20	20	34	45
Outreach and coordination		20	20	30	35	40
Totals (investments and Personnel costs) (k€)		363	538	720	819	910
						3,350

Table VIII: Summary of estimated fulltime equivalents (FTEs) and costs for a **large** national Systems Biology Centre for the first 5 years of the legal phase (2018 - 2022) (all costs are in k€)

Expenditures		Legal phase				
		2018	2019	2020	2021	2022
FTE Personnel	<i>Administrative</i>	1.0	1.0	2.0	2.0	2.0
	<i>Integration and modelling</i>	2.0	3.0	5.0	8.0	8.0
	<i>Steward & standardisation</i>	2.0	2.0	6.0	6.0	6.0
Subtotal Personnel		5.0	6.0	13.0	16.0	16.0
Personnel Costs	<i>Administrative</i>	70	70	140	140	150
	<i>Integration and modelling</i>	140	210	350	560	600
	<i>Steward & standardisation</i>	140	140	420	420	450
Subtotal Personnel costs		350	420	910	1,120	1,200
Investments/facilities						
	<i>Consumables</i>	60	60	80	80	100
	<i>hardware</i>	15	20	25	30	35
	<i>Software</i>	20	20	20	35	35
	<i>Running costs</i>	5	5	15	20	20
Portfolio of web-based services		70	80	100	120	100
Travel and conferences		40	40	40	60	60
Outreach and coordination		40	60	70	80	90
Totals (investments & Personnel costs) (k€)		600	705	1,260	1,545	1,640
						5,750

LEGAL PHASE COST MODEL - SCALABILITY OF ISBE (Aug 2018-2022 onwards)

The ISBE infrastructure model allows for scalability in size and over time, responding to the actual ISBE user numbers it serves and the scope of services and resources requested by the European users. This is an estimate, based on current communication with national funding organisations, of the development of ISBE.

Table IX: projected growth in amount of nSBCs of ISBE in the first 5 years of the legal phase

Construction of ISBE: nSBCs	2018	2019	2020	2021	2022
small nSBCs	2	2	4	6	8
medium nSBCs	2	3	3	4	5
Large nSBCs	1	2	3	4	5
Total number of nSBCs	5	7	10	14	18

Table X: projected growth in relation to amounts of nSBCs and expected costs (k€) of ISBE in the first 5 years of the legal phase

Construction of ISBE	2018	2019	2020	2021	2022
small nSBCs	400	600	1600	2700	4000
medium nSBCs	726	1614	2160	3276	4550
Large nSBCs	600	1410	3780	6180	8200
Total Costs (k€)	1726	3624	7540	12156	16750
					41796

Analysis of legal models

ANNEX 1

Legal Model/Description	Advantages	Disadvantages	Potential suitability for ISBE
<p>Memorandum of Understanding (MOU)</p> <p>Mainly used to express will between the parties</p>	<p>Can avoid obligations under international law</p> <p>Member States may be able to get away with having a lower level of Government approval</p> <p>Allows flexibility</p>	<p>Cannot establish a legal entity under this model</p> <p>Cannot enter into contracts, borrow money, own property or have the ability to employ staff</p>	<p>Could be used as an interim measure while a long-term viable agreement is in development</p>
<p>International Consortium Agreement (ICA)</p> <p>Binding or non-binding agreement</p>	<p>Can be linked to an existing legal entity e.g. ELIXIR</p> <p>Can be linked to a new entity and national legal model i.e. INSTRUCT which is a company limited by guarantee</p> <p>Allows legally binding or non-binding status</p> <p>May allow for privileges such as tax exemption</p> <p>Could be transferred into another model i.e. ERIC at a later stage if needed</p>	<p>May take a lot of time to negotiate</p> <p>There will need to be much consultation between Member States and individual governments</p> <p>May be timely to get approval and authority</p>	<p>Could potentially be a suitable model, as it allows a legal status</p> <p>It would be up to the partners what statutes they would like the ICA to be made up of as well as a governance structure</p> <p>Flexible to allow changes in membership</p>

Legal Model/Description	Advantages	Disadvantages	Potential suitability for ISBE
<p>Association</p> <p>Non-profit organisation where two or more entities share their knowledge or activities but there are no benefits.</p> <p>The seat must be where the Association is registered</p>	<p>Creation is usually simple and fast</p> <p>All kinds of entities could be members i.e. public/private</p> <p>No capital required but loans/subsidiaries are allowed</p>	<p>Must not be used to get round public regulations such as procurements rules</p>	

Legal Model/Description	Advantages	Disadvantages	Potential suitability for ISBE
<p>Non-profit making Company</p> <p>Different types of non-profit making companies depending in Europe</p> <p>Legal entity status open to EU and international members</p>	<p>Many of the ESFRI projects have used this model (X-FEL, FAIR, INSTRCUT)</p> <p>Allows any types of members to join i.e. full/associated</p> <p>Allows flexibility in defining statues and governance</p> <p>The French model -allows operational as well as coordination activities and infrastructure management. Creation is simple and only required a national registration. Contributions from members can contribute via cash or personnel.</p> <p>Loans and subsidies are allowed</p> <p>Adapted to public and private needs</p>	<p>National instrument which may limit commitment from other Members</p>	<p>This type of legal model in conjunction with an ICA would allow flexibility and can even incorporate things like profit etc. where appropriate</p>

Legal Model/Description	Advantages	Disadvantages	Potential suitability for ISBE
<p>European Economic Interest Grouping</p> <p>More to facilitate the economic activities by pooling resources, activities or skills</p>	<p>Flexible in creating a governance structure</p>	<p>Members can only belong to EU Member States</p> <p>Limitations to recruitment</p> <p>Lack of legal personality and limitation of activities</p>	<p>Unclear if this could offer the right mechanism for the needs of ISBE</p>
<p>European Research Infrastructures Consortium (ERIC)</p> <p>Created by the EU to simplify cooperation across Europe and wider for ESFRI projects</p>	<p>Allows non-EU membership</p> <p>Allows a flexible structure</p> <p>Exempt of VAT</p> <p>Requires stronger involvement from Member States that may help national funding</p>	<p>Long application process at European level</p> <p>Large control by the EC but no financing</p> <p>Lack of legal personality in some Member States</p>	<p>Previously stated by WP11 FGLAC as potential preferred option</p> <p>The model is specific to research infrastructure needs</p>