



**Euro-BiImaging**  
**European Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences**

**WP 2 Legal, Governance and Ethical Issues**

**Task 2.2**

Establish an appropriate organizational and governance model

**Deliverable 2.3**

Report on governance and legal issues including ethical issues and IPR

**Task leader**

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**Updated DRAFT based on consensus recommendation by Steering Committee and feedback by Intergovernmental Working Group: Governance Structure for Euro-Biolmaging – 17 September 2013**

## **1 Explanatory Notes**

This document proposes a governance structure, which takes into account the complexity of two (and probably more in the future) imaging communities working together under a single umbrella of an ESFRI RI. Please note the following:

- The current governance structure deliberately concentrates on general principles since the details and final structure will be decided by the Euro-Biolmaging Member States on the occasion of the negotiation of the legal framework document (e.g. statutes, article of association or consortium agreement);
- The governance structure will be laid down in the founding documents of the infrastructure, which will be signed by the Euro-Biolmaging Member States;
- Please note that most of the suggestions relate to the time when the infrastructure is in place and running;
- The governance structure was drafted taking into consideration experience from other ESFRI projects such as ELIXIR, EATRIS and LifeWatch.
- The following DRAFT governance structure is based on the consensus recommendation forwarded by the Euro-Biolmaging Steering Committee, which had approved this Governance Structure unanimously on 4 July 2013 (two abstentions) and forwarded it to the Intergovernmental Working Group (IWG). The IWG made suggestions on simplifying the Governance Structure, in particular regarding the number of advisory committees, which is reflected in this updated DRAFT.

## **2 Introduction to Euro-Biolmaging infrastructure model--HUB and Nodes**

Euro-Biolmaging will become a pan-European research infrastructure for imaging technologies of international significance with a distributed “Hub-and-Nodes” structure. The Hub will become the newly created international organisation and be the heart of the infrastructure. It is foreseen to be established, financed and governed by an international consortium of Member States and intergovernmental organizations (IGOs), such as for example EMBL. The Hub’s governance structure will comprise a decision making, an executive and an independent scientific advisory body, as described in section 2 and graphically outlined in the Figure below.

A User and Stakeholder Forum comprising various stakeholder committees will ensure constant feedback from stakeholders and thereby guarantee an infrastructure that meets the needs of the scientific community. Imaging facilities in ESFRI countries that are evaluated by the SAB, supported by their national authorities and approved by the Euro-Biolmaging Board, will enter into collaboration agreements with the Hub and thereby acquire the status of Nodes, which will offer biological, molecular and medical imaging services for researchers at the European level.

The distribution of tasks among the Hub and the Nodes follows the subsidiarity principle i.e. the Euro-Biolmaging Hub will perform those tasks that cannot be performed effectively at the national and local (Node) level or that will benefit from European-level coordination.

Decisions concerning the management and operation of the Nodes will be taken at the level of each Node. Hub and Nodes will complement each other and in some cases their tasks will be closely interlinked and synergistic. Responsibilities of the Hub and Nodes are described in detail in the Annex (Euro-Biolmaging topology: Hub- and-Node model). The actual size of the Euro-Biolmaging Hub will be driven by the user demand for access.

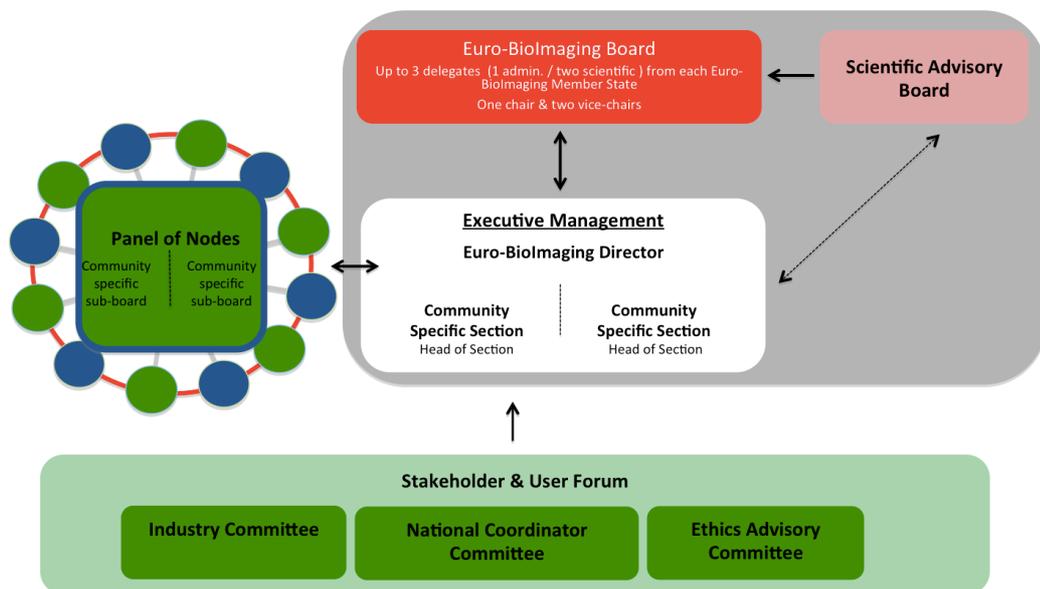
### 3 Governance Structure of Euro-Biolmaging

#### 3.1 Overview

The governance structure of Euro-Biolmaging will comprise

- the Euro-Biolmaging Board representing the Euro-Biolmaging Member States
- the Euro-Biolmaging Director who heads the Executive Management Body including the Community-Specific Sections
- the Scientific Advisory Board (SAB)
- the Panel of Nodes composed of Heads of Nodes
- Other advisory bodies upon request by the Euro-Biolmaging Board
- The Stakeholder & User Forum that provides a platform for interest groups such as users, industry, national coordinators or ethics experts.

Figure: Overview of Euro-Biolmaging Governance (grey box) and advisory bodies (Panel of Nodes and Stakeholder Forum).



#### 3.2 Euro-Biolmaging Board

The Euro-Biolmaging Board will be the decision-making body for the overall strategy and policy for integrated operation and further development of Euro-Biolmaging. The Board will be composed of Delegates of the Euro-Biolmaging Members (countries and IGOs). Delegates will be appointed by each Member.

### *Terminology*

**Member** = country or IGO,

**Delegate** = representative for the country or IGO (up to three)

The Euro-Biolmaging Board will make strategic decisions such as:

- Adopt strategic plan (technological, scientific and administrative), based on advice from the SAB,
- Adopt budget,
- Approve provisional estimates of expenditure for the following year,
- Approve audited annual accounts,
- Approve the annual report presented by the Euro-Biolmaging Director,
- Approve application conditions and criteria for Nodes, based on advice from the SAB,
- Approve inclusion of new and exclusion of existing Nodes, based on advice from the SAB,
- Oversee the performance of the Hub and Nodes' activities based on advice from the SAB and the report by the Euro-Biolmaging Director,
- Appoint the Euro-Biolmaging Director,
- Approve the appointment of Heads of Sections,
- Establish advisory bodies (e.g. Industry Committee, National Coordinator Committee, Ethics Committee) as deemed necessary,
- Adopt rules of procedure for the Hub.

Decisions to be taken by the Board will be prepared and proposed by the Euro-Biolmaging Director, as outlined in section 2c below. Each Member nominates one administrative and up to two scientific Delegates, however each Member will have only one vote. The scientific Delegates will be imaging experts that ideally represent a broad scope of imaging technologies.

### **3.3 *Euro-Biolmaging Executive Management***

The Euro-Biolmaging Executive Management Body is headed by the Euro-Bioimaging Director and comprises the Director's office and the Community Specific Sections led by the Heads of Sections.

#### *Euro-Biolmaging Director*

The Euro-Bioimaging Director will be appointed by the Euro-Biolmaging Board for a term of 5 years. The renewal of the term is possible. The Euro-Biolmaging Director will prepare, propose and execute the Board's decisions, will be the legal representative of Euro-Biolmaging and the central figure representing Euro-Biolmaging and promoting the Research Infrastructure at national and international level. The Euro-Bioimaging Director will be responsible for the development of Euro-Biolmaging's strategy and involve the SAB, as well as the Executive Management including the Community-Specific Sections. In addition the governance structure will comprise the Panel of Nodes, which needs to be consulted by the EuBI Director regarding defined issues. The Board may decide to establish other advisory bodies, which would advise the EuBI Director. The Director will be supported by a Director's Office.

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The Director will

- Implement the strategy as adopted by the Board in accordance with the budget,
- Prepare a budget with detailed estimates of income and expenditure for consideration and approval of the Board,
- Report to the Board on Euro-Biolmaging's activities,
- After consultation with the Panel of Nodes report to the Board on Node specific issues and developments,
- Coordinate the assessment by the SAB of the existing Nodes' activities on the basis of their reporting,
- Execution of decisions regarding quality assurance and coordination of evaluation of Nodes and Hub activities,
- Present applications and funding status for candidate and for renewal of existing Nodes to the Board,
- Coordinate application procedure for new Nodes,
- Negotiate the collaboration agreements with the Nodes,
- Represent Euro-Biolmaging externally, including towards Member States, Funders, EC, ESFRI RIs, Stakeholders in the European as well as global landscape of imaging research infrastructures,
- Identify additional external funding opportunities,
- Involve other Advisory Bodies established by the Board where necessary for the above tasks.

#### *Euro-Biolmaging Director's office*

The Director's office will support the Director in his tasks and in the overall coordination and administration of Euro-Biolmaging including:

- Administrative support of the Executive Management,
- Public relations and communication,
- Support and interlink all national imaging initiatives,
- Facilitate and coordinate quality control functions and support quality assurance measures at the Nodes as determined by the Euro-Biolmaging Board,
- Strategic support of upgrade and maintenance of RI,
- Organizational framework for governance (Organization of Euro-Biolmaging Board meetings, support of Board members, preparation of meetings etc.),
- Set-up and maintenance of Euro-Biolmaging website,
- Initiation and maintenance of industry relations,
- Stakeholder management,
- Support and coordination of SAB and other advisory bodies once established,

In addition, the Community-Specific Sections will support the Director in these tasks as far as they require community-specific implementation (see below).

Community specific tasks can be delegated to Community-Specific Sections by the Director.

#### *Community Specific Sections*

If required by the number of Nodes and the user demand for access and to maintain a balanced representation of different imaging communities, *Community Specific Sections* will

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support the Director to execute tasks that require community-specific implementations. Each Community-Specific Section will be chaired by a Head of Section.

The Heads of Section report to the Director and their appointment is approved by the Euro-Biolmaging Board for a term of 5 years. Renewal of the term is possible. The number of FTE's in the Community-Specific Sections will be based on the required effort for supporting user access from the respective community, which will increase with higher number of users.

The Heads of Section support and coordinate the community-specific day to day activities of the infrastructure, manage the distribution of section resources and prepare all necessary section-specific material (community specific strategic plans, reports, guidelines etc.) for consideration and approval by the Director.

In particular the Sections will

- Coordinate and support community-specific training
- Coordinate and support community-specific outreach activities
- Coordinate and support community-specific data management activities
- Support community-specific user access

### **3.4 The Scientific Advisory Board**

The independent **SAB** will be composed of independent and highly qualified, international scientists, that are widely recognized as leading experts in the different imaging technologies and research communities reflecting the Node composition and user demand of the Euro-Biolmaging infrastructure, selected on the basis of their excellence in all aspects of Euro-Biolmaging. Members will be appointed by the Euro-Biolmaging Board based on nominations by the Director. The SAB will directly advise the Euro-Biolmaging Board and the Euro-Biolmaging Director on the quality of the Euro-Biolmaging activities at the coordinating Hub and the Nodes, including the performance assessment of existing Nodes as well as the evaluation of new Nodes.

### **3.5 The Stakeholder & User Forum**

The Stakeholder & User Forum assembles all interest groups linked to Euro-Biolmaging, such as users of the infrastructure, industry, ethical experts, and national coordinators.

Representative user delegations ideally will meet once per year for an update on the infrastructure by the Euro-Biolmaging Management and to provide highlights of successful research outcomes by using the infrastructure and their respective feedback in general. The Euro-Biolmaging Director will provide the Board with regular updates on the stakeholder's suggestions and requirements.

The Stakeholder & User Forum could also provide a platform for **industry representatives** such as major vendors and producers of bio-optics and medical imaging equipment as well as major industrial users of the infrastructure. They would transfer the industry position on imaging technologies and thereby allow the European imaging industry to speak with one voice to emphasize the importance of imaging technologies for European innovation, their competitiveness and the growing bio-economy of the 21st century.

The Stakeholder & User Forum should also provide a platform to National Coordinating Persons who are elected by, and represent, the national biological and medical imaging initiatives in currently 22 European countries.

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They will provide valuable input on the needs and developments in the national imaging communities to guarantee a close communication and collaboration with the European research infrastructure.

Finally international experts regarding ethical questions in the field of the life sciences should be assembled under the Stakeholder & User Forum. Based on the ethical model and compliance with national ethical regulations they will provide advice to the Euro-Biolmaging Director regarding all ethical issues related to Euro-Biolmaging activities.

#### **4 Legal issues including ethical issues and IPR**

Regarding the evaluation of suitable legal structures for Euro-Biolmaging, please see deliverable D2.1. The final decision on the legal model for Euro-Biolmaging will be taken by the Euro-Biolmaging Interim Board in 2014.

Regarding ethical issues please refer to deliverable D2.4 Draft Ethics policy, which still reflects the current status of Euro-Biolmaging ethics policy.

Regarding IPR issues please refer to deliverable D2.5 Draft IPR policy, which still reflects the current status of Euro-Biolmaging IPR policy.

**ANNEX- Euro-Biolmaging topology: Hub- and-Node model.**

Euro-Biolmaging will become a distributed pan-European research infrastructure consisting of a coordinating and supporting Hub and Nodes, which are distributed over its Member States. The Hub serves the Nodes so that they can optimally provide pan-European user access to cutting-edge imaging technologies and related services and expertise. The number and type of Nodes will be driven by user demand, and the size of the Hub will be driven by the number of Nodes and Users it will support.

***Euro-Biolmaging Hub***

The Hub will become a newly created international legal entity that will carry out coordinating and supporting activities at the European level. The Hub will host the Euro-Biolmaging Executive Management (Director, Director's Office, and Community-Specific Sections) and represent the single entry point for infrastructure users. If required by user demand from specialized communities, community-specific tasks regarding user access, training and data management can be carried out by Community Specific Sections. Sections could be located at the Statutory Seat or in a different country. The Executive Management shall be flexible in its tasks in order to serve the Nodes and Users optimally.

In particular, the responsibilities of the Euro-Biolmaging Hub Executive Management (Director's office plus Community-Specific Sections) in order to support the user access at the Nodes are:

**Supporting User Access**

- Web portal for submission of user project proposals
- Common first consultation point for users (technical experts support users to identify the most suitable imaging technology, the most suitable Node)
- Administrative framework for transparent scientific evaluation of user projects (*1. Step of user project evaluation of Euro-Biolmaging Access policy*)

**Training**

- Coordination and support of user training activities
- Dissemination and advertisement of Euro-Biolmaging training courses
- Coordination of design and execution of RI facility staff training courses
- Management of and access to common repository for training activities in biological and medical imaging

**Data Management**

- Provision of access to standardized, annotated data repositor(ies) of general relevance for the research community e.g. for Biological Imaging in collaboration with ELIXIR (European Life Sciences Infrastructure for Biological Information)
- Access to common European repository of standardized and quality controlled tools for image data analysis
- Coordination of common European cloud computing services for standardized image processing

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Furthermore, the Hub responsibilities at the Euro-Biolmaging Director's office include the overall coordination and administration of Euro-Biolmaging including administrative support of the Executive Management and the Scientific Advisory Body as well as the external representation of Euro-Biolmaging, as described in the definition of Hub tasks in the governance.

#### b. Euro-Biolmaging Nodes

The Euro-Biolmaging Nodes provide services to enable user access to imaging technologies. Training and data management will be defined through negotiations between the future Euro-Biolmaging Hub and the Node candidate on a case by case basis (see also section c). The tasks will have to become part of bilateral collaboration agreements and comprise:

##### **User access**

- Evaluation of technical feasibility of user proposals (*2. Step of user project evaluation of Euro-Biolmaging Access Policy*)
- Direct and extensive user consultation and management for project realization including support with travel arrangements (*for further user services provided by the Nodes see also Imaging Technology Specific Criteria for Nodes*)
- Provision of access to imaging technologies, required services and expertise

##### **Training**

- User-training: hands-on training for use of instruments
- Performance of regular user training courses (levels based on available instrumentation and expertise)

##### **Data Management**

- Storage and support for data management and quality control of users' data
- Support with image analysis and processing of users' data

##### **Node types**

The Euro-Biolmaging Nodes are based on two distinct characteristics and combinations thereof i.e. the number of sites and the offered modalities of imaging technologies. Based on the number of sites, there are two types of Nodes:

- Single-sited Nodes providing the complete service package in a single geographical location,
- Multi-sited Nodes providing an integrated service package with a single point of entry for the user.

A **single-sited** Node can consist of one or several institutes that can collaborate to jointly offer complementary services to users. A single-sited Node that gives physical access to users can be operated by one or by several institutions, which are in the same location. A Node can also be **multi-sited**, if required to optimally serve the user.

Both types of nodes are represented and coordinated by a single legally responsible contractual partner of Euro-Biolmaging, under whose umbrella combined services are offered to the users.

Based on the offered imaging technologies, there are two types of Nodes envisaged:

**Single Technology Flagship Nodes** would offer an innovative technology at a leading European level.

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**Multimodal Technology Nodes** would provide excellent imaging technology packages by the integration of multiple imaging technologies at one site.

The types of Nodes are described in more detail in the document “*General Criteria for Application for Euro-BiImaging Nodes*”.

c. Relationship between the Euro-BiImaging Hub and Nodes

Nodes will enter into bilateral collaboration agreements with the Hub. The collaboration agreements will define the relationship between the Hub and the respective Node, in particular the respective obligations such as the services that a Node will deliver as part of Euro-BiImaging. Collaboration agreements will ensure open and transparent access to all users.

The model relies on the **subsidiarity principle**, i.e. the Euro-BiImaging Hub performs tasks that cannot be performed effectively at the national or local (Node) level or that will benefit from European-level coordination. It follows that decisions concerning the management and operation of the Nodes will be taken at each Node.

The national institutes hosting the Euro-BiImaging Node will keep their own legal identity and only that part of the imaging facility which provides the services to the Euro-BiImaging users will be accountable for these services to the pan-European research infrastructure Euro-BiImaging.