Euro-BioImaging

European Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences

WP12

User Access

Task 12.2

Develop Framework

Deliverable 12.8

List of final policies, including website and supportive info listings

Task leaders

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Background

The project "Euro-BioImaging" is driven by the vision and long term goal of providing open access to a complete range of essential and new emerging imaging technologies for every biologist and medical scientist in Europe taking into account the different needs of the various fields of research.

Euro-BioImaging will provide access to a complete range of state-of-the-art imaging technologies stretching from basic biological imaging in cells and tissues to in vivo molecular imaging in animal models and medical imaging of human patients.

Researchers at any stage of their career will be able to request access to Euro-BioImaging by submitting their application. This report describes the recommendation of the Euro-BioImaging Consortium on the user access policy that will allow for a coordinated, transparent and instant access to the Euro-BioImaging technologies and services.

1 Proof of Concept Studies

During the Euro-BioImaging Proof of Concept Studies (PCS), access procedures to different types and scales of imaging facilities were tested and retrospectively evaluated from the perspectives of users and providers. The evaluation is presented comprehensively in the report D12.6 and in a dossier published by Euro-BioImaging. Yet, selected striking outcomes of the PCS with respect to access policies are:

- 97% of the providers indicate they intended to offer user access in the future. One third of them indicate that this would require upgrades to different aspects of their facilities. Similarly, 99% of the users report they would make use of access to Euro-BioImaging facilities in the future. This **strongly demonstrates potential supply and demand for access imaging facilities**, endorses the general concept of Euro-BioImaging, and provides evidence of the overall encouraging experience both users and providers made during in the PCS. By October 2013, from 110 conducted PSC user projects, 22 publications were already published in peer-review journals and another 20 manuscripts were in preparation for submission.
- Specifically, a two stage review procedure was applied during the PCS, with (a) a scientific review, which was run by independent scientific experts and administered by the Euro-BioImaging project management team and (b) a consecutive technical feasibility evaluation that was performed at the individual sites. This **two-step strategy was strongly endorsed in retrospect by both users and providers**. The concept is reflected in the present document in section 4 where a general access procedure as well as the outline for the future web access tool is presented.
- The aspect of quality assurance (regarding the provided services and infrastructure) and quality control (regarding the evaluation of the project success) was not regulated in the PCS. Interestingly, retrospective evaluation shows that while 89% of users are not aware of any quality assurance / assessment efforts by the providers, 80% of the latter have systems in place to ensure proper function of equipment, 44% of them monitor publication of results generated at their facility, and a vast majority of the providers assess user satisfaction by verbal interviews

only. This indicates a need for additional efforts of Euro-BioImaging **to promote and increase visibility of quality management structures**, either externally or at the accessible sites. This aspect is discussed in section 5.

2 Aspects of access

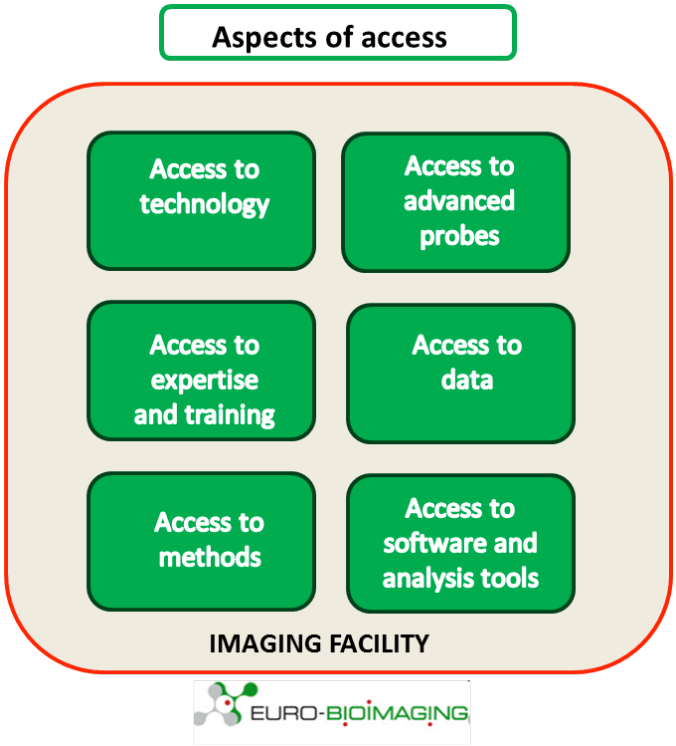


Figure 1: Aspects of access.

Different aspects of access within an imaging facility are illustrated in **Figure 1**. The access levels have been defined and discussed in Euro-BioImaging Stakeholder and Steering Committee meetings. Based on the implementation model presented by WP12 in D12.1, the accepted Euro-BioImaging user project will in general be granted access to all resources provided by the Euro-BioImaging Node. The access includes, for example, instrumentation, expertise, training, methods, probes, data, software and analysis. Some special cases may require a further evaluation process, to assess access to parts of the infrastructure. This will most likely be the case with the more demanding biological and medical technologies, where each individual user is not expected to acquire the required training to operate the instruments himself.

Access policies to data and training have been developed by WPs 11 and 13, respectively.

3 Cost models

A number of generic cost model principles might be eligible for users within Euro-BioImaging (see also D12.3), for example:

- Under **Free Access,** users do not pay for any of the costs related to the services, instruments, consumables or expertise they make use of. Users only have to cover their travel and accommodation expenses from other sources.
- Under a **Shared Cost** model, users will be charged specific percentages of costs for instrumentation, services and consumables and expertise they make use of, plus their expenses for travel and accommodation.
- Under a **Full Cost** model, users are charged the entire costs of the instruments, services, materials and expertise they make use of, plus their expenses for travel and accommodation.

Table 1: 3 Cost models for user access to imaging facilities.

	Free Access	**Shared Cost**	**Full Cost**
Travel	User	User	User
Housing	User	User	User
Living	User	User	User
Instrument hours	Provider	Shared	User
Support & Training personnel hours	Provider	Shared	User
Know-how	Provider	Shared	User
Consumables	Provider	Shared	User
Electricity	Provider	Shared	User
…			

For Euro-BioImaging user access, Euro-BioImaging strongly advocates a "fund the user" concept, which would recover operational costs through the actual usage of a Node. This will guarantee that the services remain of the cutting edge quality that scientists need and provides the incentive for a national institution to host a Euro-BioImaging Node. Different types or subgroups of users may be charged applying different cost models (e.g. academic users vs. industry users). To establish this system, Euro-BioImaging plans a start-up funding mechanism that underwrites the initially required up-front investment into the Node capacity until the steady state level of users has been reached. After this initial phase, Node operational funding should be user access driven.

See also deliverable D4.4 *Recommendations for the long term funding strategy and model.*

Further decisions on procedural and funding models will be taken during the interim phase by the Euro-BioImaging Interim Board.

4 Procedures for User Access

4.1 Application Procedure

The submission of applications is based on the Web access portal tool, which has been presented in detail in WP12 Deliverable D12.5. The entire procedure is illustrated in **Figure 2**.

An applicant without previous knowledge of the availability of the services/techniques starts the application procedure with the **Site Finder** function. The finder guides the applicant to find the closest suitable Nodes where the desired technique is provided. If the applicant does not know the best technique for the proposed research, he/she can use the technology finder tool and consult imaging experts using the **'Ask an expert'** function before using the site finder. If the applicant already knows which Nodes he/she prefers, the site finder option can be omitted and the application will be submitted, including a listing of the top 3 preferred Nodes. An experienced applicant can also contact the preferred site(s) or use the 'Ask an expert' tool before submitting an application in order to confirm the feasibility of his/her project and make it more competitive for the review process.

Next, the applicant creates a user name and a password and logs in to the online application system in order to be able to fill in the project ***submission form***, with the following details and steps:

- creation of a user account
- basic information about the applicant/s including a competence profile
- basic information about the project
- research proposal with the detailed description of the project
- the level of previous expertise for the applied technique and the requirements for a training from the node
- biological safety level
- possible appendices: CV, references, publication list etc.
- top 3 listing of the nodes where the applicant wants to perform the research.

4.2 Processing the Applications: Evaluation and Commenting

Evaluation, grading and commenting will also be done online. In general, the two-step procedure of I) scientific evaluation by independent experts and II) technical and feasibility evaluation by the Node staff, as executed and tested during the Proof-of-Concept studies, was well accepted among the majority of PCS providers and users.

The evaluation process as practiced during the proof-of-concept studies is described in detail below:

After submission, the portal administrator uses the ***keyword search*** function to direct the application to the most suitable ***reviewers***. The reviewers (2-3) should be experts in (at least one of) the desired technique(s) and should have no attachments with the applicant or the selected nodes to make sure that the review process is objective and transparent. They will be selected through the keyword search from the database of experts who have been nominated to evaluate Euro-BioImaging applications. The reviewers will be provided with precise review guidelines, specifying quantitative assessments of several categories. This review guideline will be public (see 4.3).

If the application requires modification or specifications, the reviewers have a possibility to ask the user for more information. After receiving the notification for further details the applicant can log in to the system and add the supplementary information.

The ***scientific review decision (1st step)*** is taken by independent reviewers administratively supported by the Euro-BioImaging Hub staff. The applicant receives information about the decision by e-mail. If the decision is positive, the application is forwarded to the Node staff for the technical evaluation. If

the application is rejected, the decision is justified in detail and suggestions given for improving the application.

In the ***technical and feasibility review decision (2nd step)***, the Node managers receive the applications for their technical and feasibility evaluation. The evaluation procedure is similar to the previously described, i.e. the Nodes have rights to ask further information if needed. They take the final decision whether the project can be carried out at their selected Node. A negative decision deviating from the scientific assessment has to be justified towards both the reviewers and the applicant. In case the Node cannot accept the applied project, it will be automatically forwarded to the next preferred site. If the project is accepted at the Node, the Node manager contacts the applicant, details are agreed and the project can begin. At this stage it is important to check that the quality control of the user meets the site requirements, e.g. there is no risk of contamination of the site facilities by the user samples.

The whole evaluation process is supposed to be rapid, lasting ideally less than 4 weeks.

4.3 Evaluation Criteria

Evaluation procedures for user access proposals to sites are given below. The standard criteria for scientific EU-funded project proposals should be valid also for Euro-BioImaging procedures:
After a formal review of eligibility criteria, the scientific expert evaluation may cover 3 evaluation criteria, each rated from 1=poor to 5=excellent.

1. Scientific / Technical quality (1-5)
    - Soundness of concept & quality of objectives
    - Progress beyond state-of-the-art
    - Quality & effectiveness of the S&T methodology & associated work plan
2. Implementation (1-5)
    - Individual participants (quality, experience, expertise)
    - Resources to be committed, appropriateness, justification of resources
3. Impact (1-5)
    - on applicants work,
    - on field of science,
    - on economy/society

4.4 Safety Training Requirements

The Euro-BioImaging Nodes will follow their own safety training procedures when training the visiting users.

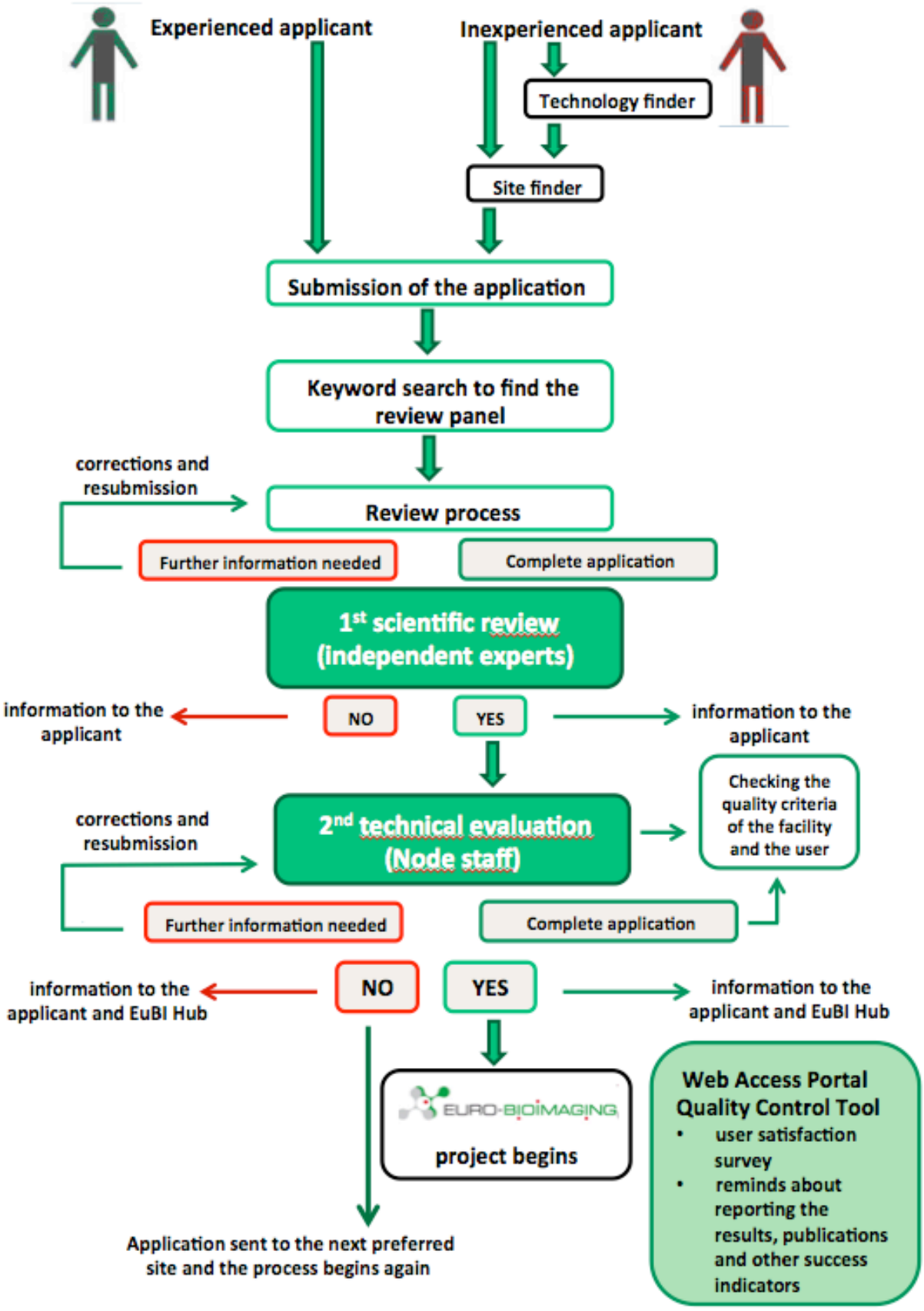
4.5 Web Access Portal – Integrated Quality Control Tool

One very important feature in the Euro-BioImaging web access portal will be the quality control tool, implemented in the future by the Euro-BioImaging Hub. It will be absolutely essential to measure user satisfaction, amount of publications and other potential success indicators such as research

grants where the Node facility/Euro-BioImaging is mentioned. A user satisfaction survey is done on-line after the project is performed. This will comprise a question on specific funding users gathered to cover their costs of external access. Thereby identified funding sources will be fed into a database, which will be made accessible as a list of possible user funding sources country by country on the Euro-BioImaging website (see also D 12.3). The Quality control tool will also remind the user via e-mail repeatedly as long he/she will fill in the required information. Nodes will receive feedback anonymously which helps them to develop their services.

The quality tool will provide template for acknowledging Euro-BioImaging and also automatically remind the users about notifying Euro-BioImaging when the performed work has been published.

Figure 2: Flowchart illustrating the access procedures from application to project evaluation, independent of review models. The scientific content could be reviewed either on the hub or node level.


Experienced applicant
Inexperienced applicant
Technology finder
Site finder
Submission of the application
Keyword search to find the review panel
corrections and resubmission
Review process
Further information needed
Complete application
1st scientific review (independent experts)
information to the applicant
NO
YES
information to the applicant
corrections and resubmission
2nd technical evaluation (Node staff)
Checking the quality criteria of the facility and the user
Further information needed
Complete application
information to the applicant and EuBI Hub
NO
YES
information to the applicant and EuBI Hub
EURO-BIOIMAGING
project begins
Application sent to the next preferred site and the process begins again
Web Access Portal Quality Control Tool
• user satisfaction survey
• reminds about reporting the results, publications and other success indicators

5 Quality Management

Quality Management (QM) systems aim at optimizing and standardizing the quality of the entire range of services of an access-providing facility. Euro-BioImaging aims at becoming a high-class quality label for imaging infrastructure. Thus, for facilities of different kinds and in different environments, this can only be achieved by defined quality standards and formalized quality management procedures.

Surveys conducted after the PCS indicated that the importance of formalized QM systems is underestimated in the scientific community: while the majority of providers indicate having quality assurance and monitoring tools in place, the vast majority of users did not notice any QM measures. The proclaimed quality measures applied by providers at present are rather informal.

On the other hand, QM aspects are for accessible facilities at the very centre of funders' attention. It is therefore suggested that QM matters must become a prominent aspect within the Euro-BioImaging strategy. It is proposed to stress a QM system in place as an important review criterion for potential Nodes. It is further suggested including the existence of a formal QM system in the Node eligibility criteria.

QM is defined here as

- Quality assurance (QA): measures related to the quality of the provided instruments & services in the responsibility of Nodes
- and Quality Control (QC): measures to monitor user satisfaction and publishing of project results in the responsibility of Euro-BioImaging to warrant objectivity.

5.1 Quality Assurance

Quality assurance (QA) comprises measures to provide and maintain excellent instrumentation, materials and services. Measures include calibration, supply control, service personnel certification etc.

- All Node applicants apply formalized documented quality assurance (QA) measures. (Minimum requirement and node eligibility criterion)
- Node applicants document their QA system in detail (node review criteria)
- QA system of the nodes is published on the web (node review criteria)
- Responsibility lies with a dedicated position (not with a specific person) to warrant continuity (node review criteria)
- Nodes assess QA measures comprehensively covering the full range of provided access features (node review criteria):
    - central items like instrumentation, services and training etc.
    - peripheral items such as housing etc.

- Nodes make quantitative and/or qualitative assessments of equipment and services provided unrelated to visits at defined, regular "downtimes" of equipment and services (node review criteria)
- Nodes maintain QA documentation in a way that allows monitoring visits within 2 days notice (node review criteria)
- Nodes deliver annual QA reports (node review criteria)

5.2 Quality Control & Monitoring

Quality control (QC) comprises the assessment of external access projects in terms of

- Publications, successful grant applications and acknowledgements of any kind.
- User satisfaction with respect to instrumentation, service etc.

Both may be assessed automatically using the web-access tool as described in section 4.5.
In addition, monitoring of Nodes should be implemented (at random choice and upon indications of poor quality) to assess and improve implementation of QA measures at nodes. This may involve physical site visits and remote interviews with personnel and users.

5.3 Implementation

WP12 suggests to include QC and monitoring in future central Euro-BioImaging structures and QA into the criteria for nodes as described above, to increase the visibility of the important aspects of QA towards all Euro-BioImaging peer groups: Providers, Users and Funders.

6 Approval, Maintenance & Updating of Access Policies

While in previous discussions the implementation of a dedicated Access Policy board had been supported, it is now consensus to avoid the inauguration of further formal administrative structures apart from the committees proposed in the Euro-BioImaging Governance Structure (see D2.3). The Euro-BioImaging Consortium has now forwarded its recommendation on the user access policy to the Intergovernmental Working Group as outlined in this deliverable D12.8. During Interim Phase, the Euro-BioImaging Interim Board will assess and approve the final user access framework and policies. When Euro-BioImaging is operational, user access procedures may require the advice from the scientific advisory board (SAB), which may also be responsible to re-evaluate and update the access policies if necessary. Any other administrative entities as defined in the governance structure may be consulted for their subjective view on the access policies.