Euro-BioImaging

European Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences

WP12
User Access

Task 12.2
Develop Framework

Deliverable 12.7
Preliminary Access Policies

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1 Preliminary User Access Policies

User access is one core topic of Euro-BioImaging and final mandatory regulations will have to be in place by the end of the preparatory phase at the latest. Preferably access regulations should be in place earlier, yet the diversity of opinions and interests of the involved stakeholders makes consideration and alignment a complicated multidimensional process. The present update is therefore the subjective image WP12 has drawn from the proof-of-concept studies and from surveying the steering committee members, notwithstanding any objections from the Intergovernmental working group who ought to discuss the Euro-BioImaging User Access Policies to achieve unequivocal agreement.

2 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.
- Specifically, a two stage review procedure was applied during the PCS, with (a) a scientific review, which was organized by central Euro-BioImaging structures and (b) a consecutive 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.

3 Levels of access

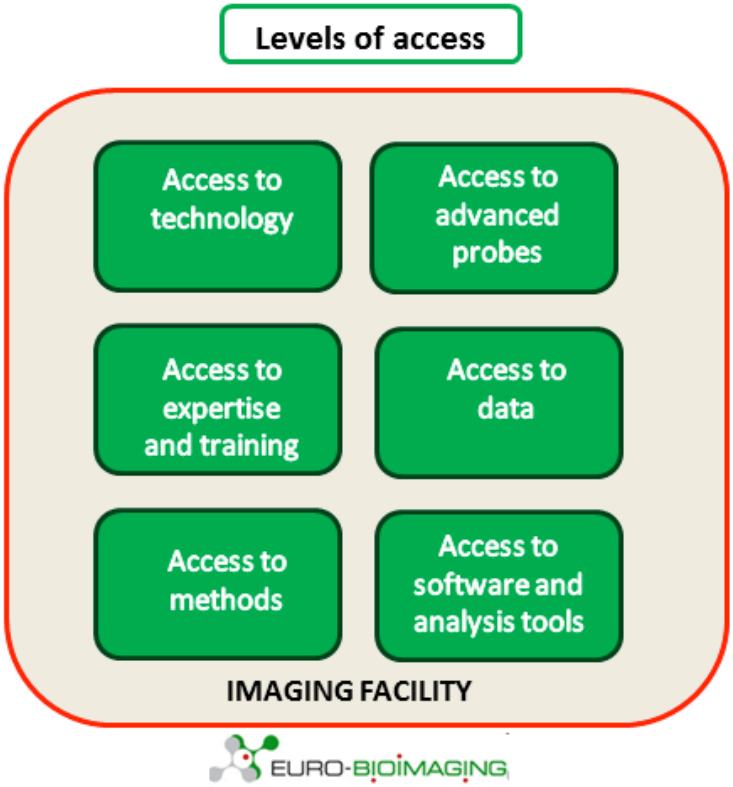

Figure 1: Levels of access.

Figure 1 illustrates examples of the different levels of access within an imaging facility. 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 project will in general be granted access to all resources provided by the Euro-BioImaging imaging node. The access includes, for example, technology, 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 are developed by WPs 11 and 13, respectively.

4 Cost models

Three cost models were discussed within Euro-BioImaging (see).

- 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
…			

Different types or subgroups of users may be charged applying different models (e.g. academic users vs. industry users). Work package 4 is discussing funding models with national funding agencies. These discussions will feed into the Euro-BioImaging user access cost models, which the steering committee of Euro-BioImaging will have to approve.

5 Procedures for User Access

5.1 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
- 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.

5.2 Processing the Applications: Evaluation and Commenting

Evaluation, grading and commenting will also be done online. Evaluation of the submitted applications is a two-step process, consisting of the scientific review which is made by independent reviewers, and the technical review made by the receiving node. The whole evaluation process should be rapid, not lasting longer than 4-5 weeks altogether.

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 EuBI 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.).

During the review process, the identity of the applicant remains anonymous. If the application requires modification or specifications, the reviewers have a possibility to ask for more information. After receiving the notification for further details the applicant can log in to the system and add the supplementary information.

The *first review decision* is done in the EuBI Hub. The applicant receives information about the decision by e-mail including the quantitative assessments. If the decision is positive, the application is forwarded to the node for the second review. If the application is rejected, the decision is justified in detail and suggestions given for improving the application.

In the **second review** decision step, the node managers receive the applications for evaluation. The evaluation procedure is similar to the previously described, i.e. the nodes have rights to ask further information if needed. The node adds an assessment only with respect to feasibility of the project. It takes the final decision whether the project can be carried out at the selected node. A negative decision deviating from the quantitative assessments has to be justified towards both the

central EuBI Hub 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.

5.3 Evaluation Criteria

Evaluation procedures for user access proposals to sites are under discussion. The standard criteria for scientific proposals in FP7 projects may serve as a blueprint 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

5.4 Safety Training Requirements

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

5.5 Web Access Portal – Integrated Quality Control Tool

One very important feature in the Euro-BioImaging web access portal will be the quality control tool. 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. 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. 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.

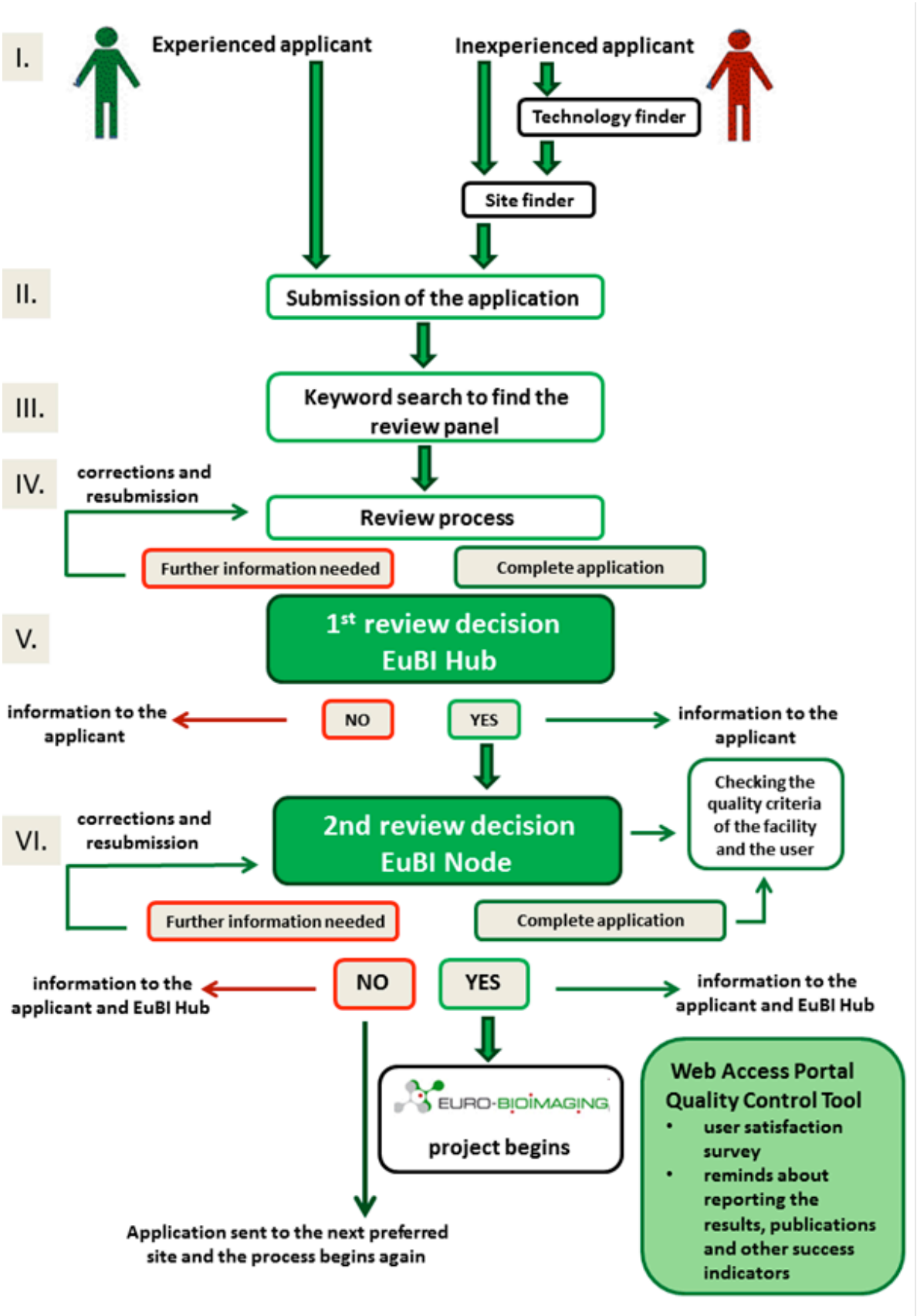

Figure 2: Flowchart illustrating the access procedures from application to project evaluation.

6 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 EuBi 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.

6.1 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. (Minumum 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)

6.2 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 5.5.
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.

6.3 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 EuBi peer groups: Providers, Users and Funders.

7 Approval, Maintenance & Updating of Access Policies

While in previous discussions the implementation of a dedicated Access Policy board had been fancied it is now consensus to avoid the inauguration of further formal instances apart from the steering committee. The latter is entitled to approve the proposed user access framework and policies.

Final procedures may require approval by the scientific advisory board (SAB), which will also be responsible to re-evaluate and update the access policies if necessary (e.g. bi-annually).

The industry board, the head of nodes committee, the ethics advisory committee, and national coordinating persons may be consulted for their subjective view on the access policies.