

MEDICAL IMAGING

TECHNOLOGY SPECIFIC REVIEW CRITERIA FOR EURO-BIOIMAGING NODES

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Introduction

Based on the PCS studies conducted in Euro-Bioimaging in relation to Innovative Medical Imaging Technologies, i.e. Ultrahigh-Field MR, Phase Contrast Imaging and MR-PET, the following criteria, in addition to the general eligibility criteria, have been identified to be critical for providing efficient access to the technology. Applications for the Euro-Bioimaging Nodes will be evaluated based on the general and technology specific review criteria.

Technology Specific Criteria and Resources:

Technology specific review criteria refer to the resources that are either required or desirable to enable user access to medical imaging technologies in Euro-Bioimaging Nodes.

At the time of the expression of interest to become a Euro-Bioimaging Node, resources described here can be already provided by the institution or consortium, or are planned to be established as part of Euro-Bioimaging Node construction. In order to assist evaluation of the expression of interest, each Node applicant is invited to provide as many of the mentioned resources as possible. However, Eols of technology providers who plan to only offer a selection of these resources will also be considered.

In addition to the individual resources listed here, future Nodes are expected to have capacities available to handle the often complex administrative matters associated, in particular, with radiotracers, animal facilities, and model organisms where required.

In the framework of Euro-Bioimaging, it is expected to have considerable diversity between medical imaging users, depending on their expertise and availability of certain technology at their home institution. In order to successfully host all users, a node should provide an infrastructure together with **specially trained and experienced staff** who will support the user in project planning, protocol optimization, patient or subject recruitment, data acquisition & storage, data processing, analysis & interpretation and who will enable users to utilize the facility in the best possible way. This mandatory comprehensive support will also ensure that data is recorded under optimal technical conditions.

Types of Nodes:

Technology provider can express their interest to become a “Multi-Modal Technology Node” or “Single Technology Flagship” Euro-Bioimaging Node.

Single Technology Flagship Nodes would offer an innovative technology at European leading level. Following innovative medical imaging technologies can be offered by the future flagship Nodes in the first call for Node applications in 2013:

- Ultrahigh-Field MR
- Phase Contrast Imaging
- MR-PET

If a Node-applicant wants to offer more than one innovative technology as flagship capabilities, it may submit a single expression of interest, which contains detailed documentation for each technology to allow evaluation of each technology by the suitable expert groups of the Independent Evaluation Board.

Multi-Modal Technology Nodes would provide excellence by the integration of multiple imaging technologies at one site. A Multi-modal node can include one of the Flagship technologies, in which case the applicant has two options to apply: a) flagship technology is included under the multi-modal umbrella (flagship technology service is not at European leading level) or b) the applicant submits a separate application for the Flagship node for this technology (flagship technology service is at European leading level). Multi-modal technology nodes can include all Euro-Bioimaging technologies including biological, molecular or medical imaging.

Technology Review Criteria for Medical Imaging Euro-BioImaging Nodes

Ultra High Field- MR

1. The infrastructure should be able to **support users at all levels of Ultra High Field-MR (UHF-MR)-based projects**. These are: measurement sequences suitable and optimized for the addressed field of application, RF coils and other pertinent hardware, data management and handling, tools for image analysis, processing and evaluation (e.g. for statistical analyses and presentation of results or correction of systematic errors during image acquisition). **Experienced staff to support users** in all these activities will be necessary.
2. High impact UHF-MR projects typically last several months and sometimes even beyond one year. This may require repeated visits of the users to the infrastructure at different stages of the project. At early stages the feasibility of large-scale projects needs to be evaluated and if necessary terminated or postponed. Therefore, it is essential to have in place a **project management and planning procedure and experienced staff able to over-see the project at all stages to support users**.
3. Infrastructures need to be able to support multiple users over extended periods and need **dedicated staff to support projects with different aims**. A node should provide a friendly and expert environment that helps to run the experiment, helps in the interpretation, hosts and trains its users and teaches them to use the facility in the best possible way. **Staff at the infrastructures needs to be knowledgeable about pertinent fields of application of UHF-MR** as well as their range of imaging techniques in order to be able to judge commitment expertize and required support level of potential users.
4. With open access, the application of new instruments to new applications may be common and there could be a difficult learning curve for users as well as node staff. Nodes need to be **able to support users over extended periods and to have appropriate staff**, who have the time and resources to learn new skills or knowledge for specific projects. Staff will not be leading the user projects, however, and so must get appropriate recognition and career development in these support roles that will take up much of their time.

Phase Contrast Imaging (PCI)

1. The infrastructure must be able to **support the users in all aspects during** an entire PCI based project, including:

- method selection,
- preparation of sample or experimental animals,
- experimental data collection,
- data processing and image calculation
- mathematical evaluation of the data.

For PCI, data analysis is complex and methods are not yet standardized. Special attention should be paid to this circumstance by allowing extra time and resources for user support in this aspect. Nevertheless, specially trained and experienced staff in the facility should warrant all aspects of support.

2. Since PCI is an innovative technique users may often be inexperienced. Therefore, proper discussion of projects ahead of start maybe necessary. For one project there should often be multiple **visits planned**: A first short visit to make preliminary tests of the applicability of methods and targeted samples or sample animals, followed by more elaborately planned visits for data collection. The latter visits should host the detailed set of measurements to complete the entire set of experimental data needed. The infrastructure should provide a clear project plan for a mandatory and structured preparation phase existing before the first visit of the user. This is to accommodate them with the different assessment and analysis technologies available and to assess which of these methods is the best in order to tackle the given questions. For example, images with reference methods such as CT and MRI should, if applicable, have been recorded upfront to show the limitations of the conventional techniques. This requires sufficiently **trained and experienced staff for project management and project planning**.

3. With open access, the application of new instruments to new applications may be common and there could be a difficult learning curve for users as well as node staff. Nodes need to be **able to support users over extended periods and to have appropriate staff**, who have the time and resources to learn new skills or knowledge for specific projects. Staff will not be leading the user projects, however, and so must get appropriate recognition and career development in these support roles that will take up much of their time.

1. The infrastructure should be able to support users at all levels of an MR-PET-based project. These are: definition and setup of bimodal protocols, selection of the radiotracer appropriate for the specific question to be studied, application for legal approval of studies using radiotracers in human research, selection and optimization of adequate MR sequences, optional equipment for blood sampling, optional equipment for metabolite correction, data management and handling, tools for image analysis, framework for quantitation and kinetic analysis of PET data, processing and evaluation (e.g. for statistical analyses and presentation of results or correction of systematic errors during image acquisition). **Experienced staff to support users in all these activities will be necessary.**

2. With the involvement of PET in MR-PET one has to take into account that the feasibility of an MR-PET project might depend heavily on the availability of PET-radiotracers adequate for the specific question to be studied. Infrastructures can either rely on commercially available tracers or develop and produce tracers. Therefore, only those studies can be realized in an infrastructure in which the demanded radiotracer is already available or can be made available in short time. Furthermore, the time to obtain the legal approval of studies using ionizing radiation and radiotracers in human research may be dependent on the specific national and/or regional situation. The infrastructure should be able to take responsibility for these applications. Thus, the preparation phase of MR-PET projects may last even beyond one year if non-standard radiotracers are required. Repeated visits of the users to the infrastructure at different stages of the project are necessary. At early stages the feasibility of such large-scale projects needs to be evaluated and if necessary terminated or postponed. Therefore, it is essential to have in place a **project management and planning procedure and experienced staff able to oversee the project at all stages to support users.**

3. Infrastructures need to be able to support multiple users over extended periods and need **dedicated staff to support projects with different aims.** A node should provide a friendly and expert environment that helps to run the experiment, assists in the analysis and interpretation, hosts and trains its users and teaches them to use the facility in the best possible way. **Staff at the infrastructures needs to be knowledgeable about pertinent fields of application of MR-PET** as well as their range of imaging techniques in order to be able to judge commitment of potential users.

4. With open access, the suggestions for new applications may be common and there could be a difficult learning curve for users as well as node staff. Nodes need to be **able to support users over extended periods and to have appropriate staff,** who have the time and resources to learn new skills or knowledge for specific projects. Staff will not be leading the user projects, however, and so must get appropriate recognition and career development in these support roles that will take up much of their time.

Overview of Technology Review Criteria for MI Euro-BioImaging Nodes

Type of Node		Technology	Facilities									Training					
Multi-modal	Flagship		1. Probes	2. Animal Facility	3. Biobanking	4. High Biological Safety Level	5. Workstations - Desk, ICT access	6. Data Storage - images	7. Accommodation	8. Mechanical Shop	9. Patient / Subject recruitment	10. Methodological set up	11. Facility Induction	12. Technical assistance to run instrument	13. Image acquisition	14. Image processing and analysis	15. Project planning
			Priority														
	Yes	Phase Contrast Imaging	N.A.	High	Med.	Med.	High	High	Med.	Med.	Med.	High	High	High*	High	High	High
	Yes	Ultra High Field MRI	N.A.	Med.	N.A.	N.A.	High	High	Med.	Med.	Med.	High	High	High*	High	High	High
Yes	Yes	MR-PET	High**	N.A.	N.A.	N.A.	High	High	Med.	Med.	Med.	High	High	High*	High	High	High

*Remark: for medical imaging it is unlikely that the external users will actually run the instrument

**Radiotracers are considered Probes for MR-PET