



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

WP1 Project Management

Task 1.3
Delivery of milestones; reporting duties

Deliverable 1.1
Quality Assurance and Risk Management Plan

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Introduction

The purpose of the quality and risk management plan is to describe how Quality Assurance and Risk Management will be structured and performed in the Euro-Biolmaging Preparatory Phase project. This document outlines policies and procedures for identifying and handling uncommon causes of project deviations (i.e. risk). In addition this plan outlines a strategy to guarantee that quality aspects of the project are met and regularly monitored.

General aspects of Euro-Biolmaging Quality Assurance and Risk Management

The Euro-Biolmaging project is characterised by its complexity and the **large and diverse consortium** involving 39 Beneficiaries and more than 180 Associated Partners coming from 26 European and Associated Countries. The way the project interfaces with the general public, new stakeholders and the scientific community it is vital for the success of Euro-Biolmaging.

Transparency and a good communication flow within the Project Management Team and between the coordinators and the project members are key to avoid problems and conflicts before they arise. A good communication strategy will favour the cohesion among the participants, while giving a positive image of the project to the outside.

Two major and also interlinked risks are expected at the end of the Preparatory Phase when the planning will lead into the construction phase. At this time point it will be crucial that a significant number of **founding partners** will accept the Euro-Biolmaging business and construction plan and **agree to sign the founding documents** (e.g. memorandum of understanding, international consortium agreement, statutes of governance model). In addition, the required amount of **financial commitment** for Euro-Biolmaging construction has to be allocated by the participating funders timely.

Due to the key role of these potential risks for the overall success of Euro-Biolmaging, the Consortium is establishing and continuing the close interaction with future key partners representing Member States and funders throughout the Preparatory Phase. The Consortium, in particular the Project Management Team and WP4--Finance Planning, have already elaborated and pursued a strategy for communication with high-level stakeholders in close collaboration with the national Euro-Biolmaging coordinating persons in the individual Member States.

Euro-Biolmaging activities have been planned in the most careful way possible in order to achieve the objectives. However, **unexpected activities**, leading to extra costs, might need to be integrated in the original working plan in order to correctly implement the research infrastructure. These involve for example the communication between coordination activities on a national level and Euro-Biolmaging and the preparation, publication and evaluation of the Euro-Biolmaging “Open Call for Nodes of the Infrastructure”.

Some of the **major perceived risks** related to the project work plan and the “transition phase” are listed in table 1, including a classification of their probability as well as a description of contingency measures envisaged by the consortium.

Risk identification will be a continuous activity throughout the life span of the Preparatory Phase, although a majority of the risks should be identified early enough to guarantee proper response planning and monitoring.

Responsibilities for the Quality Assurance and Risk Management Plan

The quality and risk management approach is pro-active in order to identify and manage potential sources of variation at an early stage. The quality assurance and risk management plan applies to every project partner.

Quality and risk management is a task of the Project Management Team that will address, monitor and periodically reassess risks in the individual work packages. The Project Management Team is also responsible for the final decision on risk actions, in co-ordination with the Steering Committee.

This task includes:

- Monitoring of the project to identify any new or changing risks
- Planning and reassessment of assigned resources during various project phases

Quality Assurance

Definition and avoidance of risks assure the quality of single tasks, work packages and deliverables.

Standards and quality criteria for Deliverables

- If a project partner has consistent doubts that problems occur in terms of quality within the Euro-Biolmaging Preparatory Phase project the Project Management Team shall be contacted to discuss the issue and define response strategies
- Steering Committee and External Advisory Board members may be asked for their feedback on deliverables.
- Up-dates for deliverables during project life time will be discussed within a task or work package in order to incorporate improvements.
- Regular communication of such improvements to the entire consortium via face-to-face meetings and/or telephone conferences

Risk Management

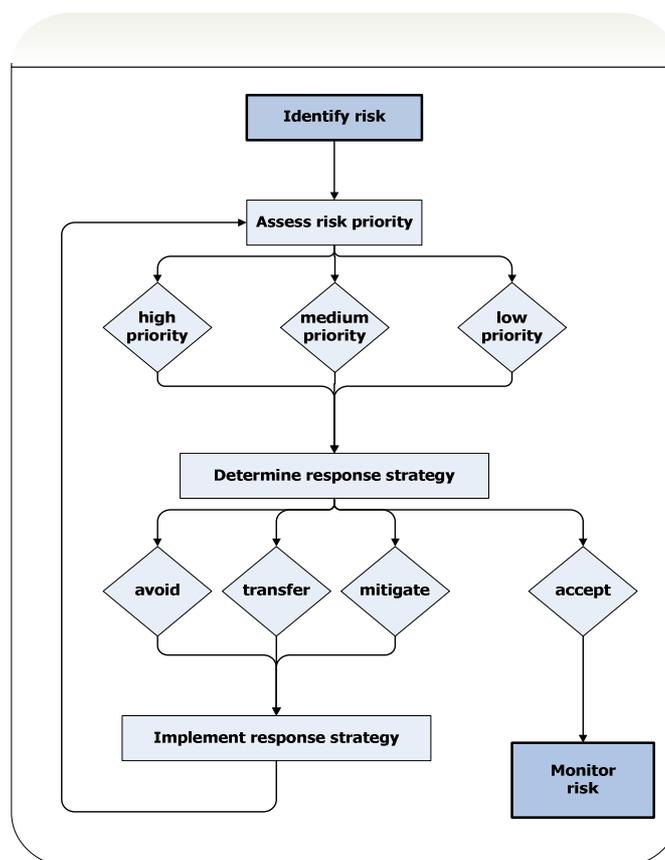
Risk Identification

Risk identification is done throughout the life-cycle of the Euro-Biolmaging Preparatory Phase project.

The following shall be considered as tools and techniques for risk identification:

- Analysis of deliverables status
- Analysis of WP schedules and scopes
- Regular Communication of the PMT

Euro-Biolmaging Preparatory Phase Risk Management Process



Risk Monitoring and Control

Even though the identification, analysis and evaluation of risks have been done well at the beginning of the project (see section “General aspects of Euro-Biolmaging Quality Assurance and Risk Management and table 1) it is important to identify new risks as early as possible. To do so, Euro-Biolmaging implements the following risk management procedure:

1. Every Work Package Leader is responsible for the Risk Management within its WP and shall report to the PMT about newly identified risks.
2. Risk management shall be put on the agenda of Euro-Biolmaging PMT Meetings in order to monitor the process in a consistent way.

Table 1: Description of Risks, Probability and Mitigation Strategy

| WP | Risk no. | Risk description | Probability | Mitigation Strategy |
|-----------|-----------------|--|--------------------|---|
| 1 | 1.1 | Deviations in workplan during the Preparatory Phase due to the size of the project (issues related to delivery of milestones & deliverables) | Medium | Application of Quality and Risk Management Plan; in case of deviations, the Coordinator will contact Project Officer to clarify situation and agree on contingency measures |
| 1 | 1.2 | Weak flow of communication within consortium due to the high number of project partners | Low | Additional efforts will be made to ensure optimal communication |
| 1 | 1.3 | Unexpected and unforeseeable activities leading to a modification of the original plan (national activities) | Medium | Seek close communication with the organizers, monitoring and selection of additional activities, support in finding new funding at the national level. |
| 1 | 1.4 | Loss of a key member of the consortium due to change of position etc. | Medium to high | Seek close interaction with the related working groups |
| 1 | 1.5 | Lack of interest of the national funding providers | Medium | Foster the liaison through national coordinating persons |
| 2 | 2.1 | Unforeseen difficulties in finding suitable governance and legal structure – in particular due to distributed nature of the project | Medium | Seek external expertise and legal advice |
| 2 | 2.3 | Disagreement over IPR policy to be applied | Medium | Seek external IPR advice and expertise |
| 3 | 3.1 | Surveys fail to provide the needed response/outcome to proceed with defining the process plan | Medium | Incorporate existing information from surveys performed by other infrastructure proposals, seek cooperation with experts (if necessary external, industry board) when designing the surveys; risk prevention by applying pilot runs |
| 3 | 3.2 | Diverging views on the vision & mission of Euro-BiImaging | Low | Maximise involvement of all stakeholder groups, seek agreement on vision & mission at Steering Committee Meetings |
| 3 | 3.3 | Failure to establish a Business Plan for Euro-BiImaging | Medium | Apply quality assurance and risk management procedures; seek external advice |
| 3 | 3.4 | Industry reluctant to take on a role in PPP | Low | Integration of biomedical imaging industry into activities of Euro-BiImaging early on; creation of an Industry Board to seek dialogue with industry |
| 4 | 4.1 | Insufficient funding for implementation and operation phase | Medium to High | A finance and risk management plan will be elaborated and included in the business plan to identify and |

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| | | | | remedy financial risks at an early stage; to avoid duplication, Euro-Biolmaging will join forces with other ESFRI BMS projects |
| 4 | 4.2 | Delay in developing funding model due to lacking input from other strategic WPs (WP2, WP3) | Low | The overall quality and risk management plan will ensure timely delivery of information to other WPs and strengthen communication and interaction of the relevant WPs |
| 5 | 5.1 | Redundancies with other ESFRI projects | Low | Seek close communication and collaboration with the other ESFRI projects from the start |
| 6 | 6.1 | Budget and duration of the PPP are too limited to gather complete know-how for running a national and international imaging facility | Low | Take advantage of the experience of EMBL as a provider of scientific services; a report will be commissioned from the EMBL Advanced Light Microscopy Facility as guidance for running tests at other sites |
| 7 | 7.1 | Assess needs of the ALM imaging community insufficiently | Low | Seek close communication and collaboration with stakeholders and imaging communities (e.g. ELMI); invite for participation in Working Group WP7, Stakeholder Meetings |
| 8 | 8.1 | Assess needs of the Molecular Imaging community insufficiently | Low | Seek close communication and collaboration with stakeholders and imaging communities (invite for participation in Working Group WP8, Stakeholder Meetings) |
| 9 | 9.1 | Assess the needs of the Medical Imaging community insufficiently | Low | Seek close communication and collaboration with stakeholders and imaging communities (e.g. EIBIR; invite for participation in Working Group WP9, Stakeholder Meetings) |
| 10 | 10.1 | Differences in national guidelines regarding the implementation of the infrastructures | Medium | Preparation of the partnership agreements and data exchange |
| 11 | 11.1 | Duplication of efforts with related ESFRI and national infrastructures for computing and data resources | Medium | Seek close communication and collaboration with other ESFRI projects and data management initiatives from the beginning of the PPP |
| 11 | 11.2 | Large variety of user needs of the WP11 infrastructure (biologist, computer scientists, clinical researchers) | Medium | Seek close communication and collaboration with stakeholders and imaging communities (invite for participation in Working Group WP11, Stakeholder Meetings). No single monolithic architecture, but guidance by needs of individual scientific communities, to ensure that final plans will generate tools with real scientific value. |
| 12 | 12.1 | Acceptance of access policies on the different | Medium | Carefully balance site-specific/local regulations, overreaching Euro- |

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| | | levels | | Biolmaging objectives, and potential community-specific user interests; design access policies to minimize administrative burden, to optimize charging policies, to ensure site autonomy, and to mitigate the heterogeneity within the Euro-Biolmaging community. |
| 12 | 12.2 | Different needs for access for the different imaging technologies | Medium | Seek close communication and collaboration with stakeholders and imaging communities (invite for participation in Working Group WP12, Stakeholder Meetings). |
| 13 | 13.1 | Complexity of the training portfolio and the not completely uniform academic regulation across Europe | Medium | Seek close communication and collaboration with stakeholders and imaging communities (invite for participation in Working Group WP13, Stakeholder Meetings). Use experience of Beneficiaries and Associated Partners who run programs alike. |