



Grant Agreement no. 644956

RAIS

Scalable, point-of-care and label free microarray platform for rapid detection of Sepsis

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1. Introduction

The RAIS Risk Assessment Procedure is a controlling document that incorporates the goals, strategies and methods for performing risk management on the project. It describes all aspects of the risk identification, estimation, evaluation and control processes. The purpose of developing such a plan is to allow risk management on the project to be performed in a cost-effective manner.

Every project has an overall goal, which is usually split into a number of well-specified sub-goals and associated deadlines by when the various goals should be reached. Every goal carries a risk that it will not be reached as specified and/or within the required deadline. This risk has to be managed so as to minimise the probability that the end goal of the project will not be reached. The Risk Assessment document formalises a procedure for the identification, assessment and mitigation of risk within the RAIS project.

Risks are assessed against probability of occurrence and the severity of any impact. These are then ranked into three classes depending on whether the assessments are low, medium or high. A list of risks will be held by the project as shown in Appendix A. Each risk will also have a log which details any mitigation actions and changes to the risk status, as shown in Appendix B.

2. Roles and Responsibilities

The Project Manager is responsible for the implementation of the Risk Assessments and for maintaining an audit log of the identified risks and associated actions. The WP leaders are responsible for identifying the risk factors associated with their Workpackage, for assessing the severity of the risks, for proposing mitigation actions where relevant, and for identifying the key partners to be involved. This can be done through reference to the deliverable and milestone requirements in the DoA together with their own knowledge of the project, or through a formal risk assessment workshop or brainstorming session.

3. Risk Management Steps

The following risk management steps have to be carried out at the overall project level and at the Workpackage level:

1. Define detailed project goals
2. Identify risks that might endanger successful completion of the project goals
3. Assess and rank the risks according to classes
4. Define risk mitigation measures for (at least) the highest class risks
5. Introduce mitigation measures in the project plan, implement and monitor them

3.1. Define detailed project goals

While the DoA defines the overall objectives of the project, it does not cover in sufficient detail the various goals and specifications required to be met along the way. However, the DoA does require that these goals and specifications are defined early in the project and reported in the Annual Action Plans and in various deliverables. This task is therefore already being addressed, and will continue to be so.

3.2. Identify risks that might endanger successful completion of the project goals

An essential requirement for the risk management process is that each individual working on any of the Workpackages of the project should contribute to this step. All existing risks should be recorded, even if they seem unlikely to happen and even if a risk mitigation measure seems quite

obvious or is already being implemented. The ownership of the risk (Workpackage and partner) should also be identified.

3.3. Assess and rank the risks according to classes

The risks identified in the previous step should be ranked according to the likelihood and severity of the risk, as described below. The results of this task are recorded in a risk assessment table, provided in Appendix A. Risks should be numbered according to the WP they relate to, e.g. R2.1 for the first risk identified related to WP2.

3.3.1. Likelihood of Risk

The likelihood or probability that a potential risk will occur will be classified into one of three categories:

Low	Low probability
Medium	Medium probability
High	High probability

3.3.2. Impact of Risk

The estimated severity or level of impact of the risk, if it were to occur, will be classified into one of three categories:

Low	Less than 2 months expected delay on project planning; AND Less than 2 person-months expected additional effort required; AND Less than 20 k€ expected additional project cost.
Medium	More than 2 months expected delay on project planning; OR More than 2 person-months expected additional effort required; OR More than 20 k€ expected additional project cost; AND Back-up solutions can readily be identified and are or can be made available.
High	The concerned aspect of the project cannot be completed as planned; AND Alternative technical solutions do not exist or are not economically feasible.

3.3.3. Risk Categories

Based on the above rankings, risks will be classified into one of three risk classes as follows:

		PROBABILITY		
		Low	Medium	High
SEVERITY	Low	Class I	Class II	Class II
	Medium	Class II	Class II	Class III
	High	Class III	Class III	Class III

Project risk management at the overall project level and at the WP level will mainly focus on Risk Class III, with some attention to Risk Class II also.

Note: this simplified risk assessment and management scheme is deemed to be appropriate for the RAIS project.

3.4. Define risk mitigation measures for (at least) the highest class risks

Risk mitigation measures and back-up solutions will be defined for at least the highest class risks.

3.5. Introduce mitigation measures in project plan and implement

Plans for dealing with identified risks including mitigation measures will be recorded and monitored through the Risk Management Audit Log, shown in Appendix B. Where relevant, these plans will also be incorporated into revised versions of the annual WP action plans.

4. Conclusions

The risk assessment process described will be run at the Workpackage level, coordinated by the WP leaders, and at the project level by the project management team.

A Risk Management Plan will be established for each WP and the overall project. This will be reviewed and approved by the Project Manager and Steering Committee.

WP leaders will be requested to review the risk assessments and the Risk Management Audit Log in their quarterly reports, and update as appropriate.

Appendix A – Risk Assessment Table

No.	WP / Topic	Risk	Probability			Impact	Severity			Risk Class*
			L	M	H		L	M	H	
R1.1										
R1.2										
R2.1										

* – From table on page 6.

Appendix B – Risk Management Audit Log

No.	Risk	Ownership	Potential Risk Mitigation	Actions
R1.1				1.
R1.2				1.
R2.1				1.