Grant Agreement no. 287596

D-LIVER

ICT-enabled, cellular artificial liver system incorporating personalized patient management and support

INSTRUMENT: Collaborative Project (Integrating Project)

CALL: FP7-ICT-2011-7

OBJECTIVE: ICT-2011.5.1 Personal Health Systems

D10.2 Risk Assessment Procedure

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Lead partner for deliverable: iXscient

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Dissemination Level		
PU	Public	✓
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including Commission Services)	
CO	Confidential, only for members of the consortium (including Commission Services)	

Document History

Issue Date	Version	Changes Made / Reason for this Issue
30th November 2011	v0.1	First draft

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Table of Contents

1. Introduction

The D-LIVER 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 D-LIVER project.

In summary the process is:

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

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 1. Each risk will also have a log which details changes to the risk status.

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 DoW together with their own knowledge of the project, or through a formal risk assessment workshop or brainstorming session. WP leaders will provide a summary of the identified risks and changes to their status in the WP Quarterly Report.

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 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 project plan and implement

3.1. Define detailed project goals

While the DoW 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 DoW 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 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, preferably in a brainstorming session organised for each work package. 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 1.

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 D-LIVER 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

Action plans for dealing with identified risks including mitigation measures will be recorded and monitored through the Risk Management Audit Log, shown in Appendix 2. Where relevant, these action plans will also be incorporated into revised versions of the DoW.

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. These 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 1 – Risk Assessment Table

No.	Topic / Target	Risk	Probability			Impact	Severity			Risk Class
			L	M	H		L	M	H	
R1										
R2										
R3										

Appendix 2 – Risk Management Audit Log

No.	Risk	Ownership	Potential Risk Mitigation	Actions
R1				1.
R2				1.
R3				1.