



Risk Analysis of ACGT

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ABSTRACT:

This deliverable defines the risk analysis scheme within the ACGT project. In addition to describing the risk analysis methodology, this deliverables identifies the main potential risks across all the Workpackages and outlines a contingency plan for every risk identified.

KEYWORD LIST: Risk assessment, monitoring, contingency planning

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1. Executive Summary

1.1. ACGT Risk Exposure

The challenging nature of the ACGT workplan implies that there is inherently a substantial amount of risks in the projects that could affect the project. This is referred to as “Inherent Risk Exposure”. The risk assessment strategy described in this document represents the ACGT policy on risk.

In order to avoid the emergence of additional in carrying out the project, the ACGT’s risk management policy and procedures are closely linked to the “Definition and Guidelines for the Quality Assurance Process” deliverable (D1.2). This following sections document should be referred to for an in depth description of ACGT’s quality assurance procedures. It is available on the BSCW server at: <https://bscw.ercim.org/bscw/bscw.cgi/99044>

Yet, ACGT and its stakeholders are potentially exposed to different risks throughout then project lifetime. In order to ensure that ACGT will deliver its expected results, the project coordination both scientific and administrative have defined a particular scheme to:

- 1) identify potential risks
- 2) propose contingency plans to address the corresponding related issues

The identification of risk in a project should not be regarded as a sign of weakness in the proposal. The methodology presented will; help the ACGT team prioritise tasks and the deployment of resources, assist the management team in providing political and financial support, and give early warning to release contingency plans for appropriate tasks.

2. Introduction

2.1. Purpose of this document

It is essential ACGT to identify the possible risks that could affect the project, as well as the methods to overcome or to prevent them throughout the duration of the project.

In this perspective, the consortium has developed and deployed a process to identify, manage and overcome risks that may occur within the activities of all the work packages.

In addition, for each potential risk identified, the present deliverable will outline a specific contingency plan to drive ACGT towards completion.

The consortium in this stage has identified four main risk categories: Management of the consortium, Human resources, Financial, Sustainability, Technological Risks, Human Factor and Application Risks as well as Regulatory Risks

The different risks identified in this internal risks assessment have therefore been organised in the following categories:

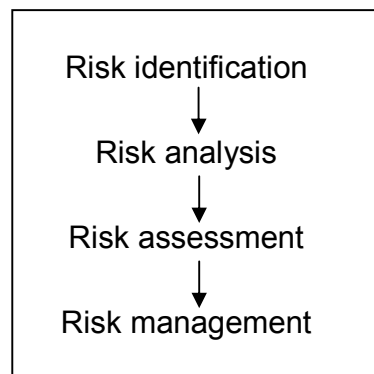
1. *Management risks*
2. *Technological risks*
3. *Application risks*
4. *Legal and Regulatory risks.*

The following section describes the scheme implemented to identify and address the different risk categories.

3. Risks Analysis Scheme

This document will present how this risk is managed, either organisational, legal, scientific or operational. The ACGT management Board has responsibility of overseeing stakeholder's risks and risk management.

Addressing project risk can be dealt with in several separate steps. The first is to identify and analyse the risks pertinent to the project. Then the risks must be actively managed so that the risks that can be mitigated. The fundamental steps of the risks analysis can be represented as follows.



As more information becomes available, the risks should become better defined and their understanding will change. Consequently, risks should be reassessed at regular intervals to reflect any changes in level or introduction of new risks.

3.1. Risk Identification

Risk identification should begin with a statement of the desired outcome of the project. Risk identification determines the potential risks that could be faced by ACGT and should address the issues which threaten the achievement of the project goals. The main types of risk are financial, operational and risk to reputation. All potential sources of risk should be considered.

3.2. Risk analysis

When a specific risk has been identified and is recognised to be significant, the likelihood of the event occurring should be estimated along with the impact that the event would have.

Each risk should then be scored in terms of likelihood and impact. The guidelines describing how the likelihood and impact can be scored are described hereafter. The overall risk score can be found by plotting the scores on the following risk matrix. This risk analysis should be maintained and included in future progress reports.

Risk Analysis – ‘Scoring’ Guidelines

Likelihood Categories

1. Rare (eg <1 in 20 years; probability <0.1)
2. Possible (eg 1 in 5 to 10 years; probability ~ 0.2 – 0.5)
3. Likely (e.g. 1 in 2 to 5 years; probability ~ 0.6 to 0.9)
4. Frequent (eg 1 per year; probability >0.95)

Impact Categories

1. Insignificant/Minor (undesirable to no threat to objectives. No injury, minor impact on reputation)
2. Moderate (Injuries requiring medical attention, impact on ‘local’ budgets and reputation)
3. Major (Extensive injury, major impact on ‘local’ budgets, reputation and objectives; significant impact on ACGT budgets, reputations and objectives)
4. Catastrophic (Loss of life, fail to meet local objectives, major threat to ACGT objectives and ongoing viability)

Risk Matrix

Impact	4	4	8	12	16
	3	3	6	9	12
	2	2	4	6	8
	1	1	2	3	4
		1	2	3	4
		Likelihood			

Significance

1-2 = Low Risk

3-8 = Medium Risk

>8 = High Risk

3.3. Risk assessment

A thorough risk assessment should be carried out for all significant risks. These risks should then be recorded in the risk register table hereafter. An assessment then must be made as to whether this is an acceptable level of risk. If the risk is deemed to be unacceptable, risk improvement measures must be implemented. All areas of risk should be identified and risk mitigation scenarios identified in each case.

<p>WP Number:</p> <p>WP Name:</p> <p>Risk Owner (WP Leader):</p>

Risk Identified	Proposed Contingency plan
<p>Risk SCORE: _ _ _</p>	

This will enable the project team to make an assessment of the most important areas of risk and what is proposed to minimise the possible effects on the programme. As the project proceeds, the level of risk in each category might be expected to decrease, but this will not always be the case and new areas of risk may be identified and added to the table. There may also be more than one item of risk to report in each work package.

To this, the ACGT project has launched an internal risk assessment consultation across all WP leaders. A dedicated template has been prepared and all WP leaders have been invited to fill it in. The risk assessment template is the single page hereafter:



ACGT - Risk Assessment Template

In the ACGT technical Annex (workplan), we had identified overall risks that had to be taken into consideration, in order to drive the project towards completion.

Example:

Risk Identified	Proposed Contingency plan
<p><i>The ACGT Architectural model is too complex to develop</i></p>	<p><i>This is perhaps the main risk of the project, especially since the entire project hinges on a successful development of the concept architecture. The only feasible mitigation approaches, beyond ensuring that the task is handled by qualified competence, are allocation of sufficient resources, close follow-up, and a broad participation in the task within the consortium.</i></p>

In this respect, we invite **ALL WP Leaders** to identify the possible risks and issues that could affect your Workpackage throughout the project’s lifetime.

This concerns any **foreseeable scientific, technical or legal bottlenecks** that could arise and prevent your WP from achieving its objective. Please be pragmatic in identifying the risk and in proposing a contingency plan or solution to the potential situation.

Please use the table below to provide your input (*try to identify 2 to 3 potential risks to your WP*), and send your contribution to remi.ronchaud@ercim.org and florence.pesce@ercim.org

WP Number:	WP Name:
Risk Owner (WP Leader):	

Risk Identified	Proposed Contingency plan
<div style="border: 1px solid black; padding: 2px; display: inline-block; color: red; font-weight: bold;">Risk SCORE: _ _ _ _</div>	
<div style="border: 1px solid black; padding: 2px; display: inline-block; color: red; font-weight: bold;">Risk SCORE: _ _ _ _</div>	

In accordance with the management board, the contributions from the different WP leaders have been integrated. The risks identified by the WP leaders along with the proposed contingency plans have been listed in the following section.

The Management Board will go through this list at least annually to assess the risk score and revise contingency plans if the current proposals are not considered optimal.

Moreover, the Management board will invite WP leaders to update their list of potential risk during the project life time to make sure that all potential deviation of threats are identified and accounted for. The idea is to maintain a permanent risk watch. Indeed, other instruments and developments on which the project is dependent should be identified as well as the facilities and services essential to the success of the project (European legal environment, partner participation, GRID technology layer, etc...).

3.4. Risk Management

In order to reduce the likelihood of the risk occurring risk management action should be implemented. The action should be given an "owner" who has responsibility for managing and implementing the action. The management action plan should be fully documented and should include milestones to enable implementation.

In risk management there are typically four courses of action available:

- *Risk Elimination* - This may be the preferred option but may not always be possible
- *Risk Control* – This attempts to reduce the likelihood of the risk occurring and to minimise the impact of any undesirable event.
- *Risk Retention* – Potential impacts are dealt with appropriately
- *Risk Transfer* – The impact is transferred to a 3rd party.

ACGT's risk management scheme will be periodically revised during the project lifetime, as any partner or Workpackage leader can call for a dedicated session in the Management Board meetings. As such the risk assessment will be regularly updated. This document will be revised to take these changes into account.

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It is the responsibility of the Project Coordinator, the Scientific Coordinator and the Quality Manager together with the Management Board to ensure that the overall risk analysis and Management scheme is regularly followed in order to anticipate and manage problematic situations that may arise in the course of the project.

4. List of Identified Risks and proposed Contingency Plans

The following table summarises the main risks that the project has originally foreseen following the consultation launched across WP to produce this deliverable. For every risk identified and every corresponding Risk assessment from provided, the Management Board is to discuss and validate the proposed contingency plans.

Risk	Contingency plan
The user requirements identified for the scenarios are not feasible within the scope of the project.	The project will manage the user requirements process in order to ensure that expectations are realistic. It will also clearly prioritise those functions that will be essential for piloting and identify any longer term priority requirements, which could be incorporated at a later date into potential products brought to market.
The <i>ACGT</i> Architectural model is too complex to develop	This is perhaps the main risk of the project, especially since the entire project hinges on a successful development of the concept architecture. The only feasible mitigation approaches, beyond ensuring that the task is handled by qualified competence, are allocation of sufficient resources, close follow-up, and a broad participation in the task within the consortium.
Conflicting expectations with regard to the <i>ACGT</i> Concept within the consortium	In the proposal phase, it is possible that some partners have a clearer understanding of what the <i>ACGT</i> concept is than others. As the development of <i>ACGT</i> must be a joint effort, conflicting perceptions on this important aspect is a risk element. We have addressed this through close discussions at the proposal stage, and will further address the issue through the project management

	mechanisms led by the Technical Manager.
The required applications and services cannot be developed within the time and resource constraints of the project.	While complexity is the main issue regarding the <i>ACGT</i> architectural model development, the amount of resources/funding is the most likely challenge when it comes to the physical design and implementation of the <i>ACGT</i> envisaged platform. Being aware of this, the consortium and task leaders will emphasize efficient resource utilization when executing work. Another mitigation approach is to keep open an option for transferring resources from other work packages or task activities.
The pilot process fails to produce consistent evaluation feedback.	Both the evaluation criteria and testing and validation plan will be rigorously specified before the pilot implementations commence. This means that any variations in the feedback received should provide valuable information about real differences in the potential of <i>ACGT</i> within each of the scenario arenas.
Difficulties in exploiting the project's results in an "open source" and "open access" environment	This is "always" a challenge in research projects of this nature, a fact the Consortium is acutely aware of. It is particularly an issue in <i>ACGT</i> , due to <i>ACGT</i> 's vision of creating a Virtual Organisation of producers and consumers of tools and services based the principles of 'Open Source" and "Open Access". This will require "new models" of exploitation to evolve. Our strategy in responding to such risks is to take exploitation very seriously from the very start of the project and make sure that the task is coordinated by an organisation with related experience (i.e. Biovista) with significant contributions from all industrial partners of the project and the project Coordinator.
Conflicts within the consortium	There is always a risk that minor or more serious conflicts might arise inside a consortium of independent partners. Some early-phase mitigation elements include careful partner selection, signing of a comprehensive consortium agreement, and the development of clear conflict resolution mechanisms. During the start-up of the project, we will also emphasize team-building and clarification of goals and responsibilities. Throughout the project, monitoring of partner relations and project climate will be important, and any "brewing conflicts" will be addressed at the appropriate level of the project governance structure.
Delays and administrative oversights	From experience, one can spend very much time on eliciting the required reporting, cost statements, and other administrative deliverables from project partners, costing both time, money, and not in the least energy. This can damage the project climate and ultimately have more severe consequences. Reducing the risk of this occurring will be done by establishing clear administrative procedures as early as possible, appointing one person from each

	partner responsible for administrative reporting (a person that does not hold work package responsibility), and implementing agreed actions against partners that fail to comply with procedures.
The consortium experiences disruption, e.g. a partner resigns or fails.	There will be strong management of the project by experienced coordinators and senior management within each partner organisation has provided full assurance of their commitment to the project. In case of partner resignation or failure to deliver management will take swift actions for reassignment of work to existing or new partners.

4.1. Updated list of identified Risks and proposed Contingency Plans

An internal consultation of the Workpackage Leaders has delivered the identification of the following risks and the definition of the proposed contingency plan.

These risk tables will be reviewed annually and revised if necessary to avoid the emergence of unexpected issues or situations.

4.2. WP2

WP Number: 2
WP Name: User Needs Analysis & Specifications
Risk Owner (WP Leader): N Graf

Risk Identified	Proposed Contingency plan
Missing input from WPs to inquiries, questionnaires and homepage Risk SCORE: 4	<ul style="list-style-type: none"> - Direct contact with all WP-leaders to address this point again. This should also be done at each Management Board meeting. - Concrete naming of a contact Person in each WP, who is responsible for providing such data or input
Input of WPs regarding the development of new scenarios	<ul style="list-style-type: none"> - Page on the Wiki (already done) http://wiki.healthgrid.org/index.php/ACGT:Scenarios/Development - Direct contact with all WP-leaders to address this point again. This should also be done at each Management Board meeting.

<p>Risk SCORE: 4</p>	<p>– Concrete naming of a contact Person in each WP, who is responsible for the scenario development in that WP</p>
<p>Policy of ACGT regarding the scientific community outside of ACGT</p> <p>Risk SCORE: 3</p>	<p>Roles and rights have to be defined. This point is addressed and part of the security system for ACGT.</p> <p>This point is very important for the communication with the world outside of ACGT. It has to be defined: who outside of ACGT is allowed to get access to the ACGT platform to use data or tools. There should be a common language. People start to ask this question. If there is not a common policy this will be negative for the spread of ACGT in the scientific community.</p> <p>During the next Management Board Meeting this point has to be addressed and clarified.</p>
<p>Cohesion and coordination of work</p> <p>Risk SCORE: 1</p>	<p>As a result of the WIKI this is a minor risk factor now.</p>
<p>Tool for pseudonymisation of data</p> <p>Risk SCORE: 3</p>	<p>This point was in extensively discussed in all Management board meetings. The importance is already understood by everyone. Work has started to develop such a tool. The risk is very low, that such a tool will not be available soon. Without such a tool, no data transfer will happen.</p>

4.3. WP3

<p>WP Number: WP3</p> <p>WP Name: Architecture</p> <p>Risk Owner (WP Leader): J Nabrzyski</p>
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Risk Identified	Proposed Contingency plan
<p>The architecture is too closed to allow future use cases</p> <p>Risk SCORE: 3</p>	<p>The architecture has to be revised on the main milestones of the project, allowing for extensions and modifications, taking into account new use cases and user scenarios that might appear as project evolves.</p>
<p>The architecture does not allow for certain</p>	<p>If the architecture is based on the layered architecture make sure</p>

<p>operations between various layers of the architecture</p> <p>Risk SCORE: 2</p>	<p>that layer violations are possible in specific, approved situations.</p>
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4.4. WP4

<p>WP Number: WP4</p> <p>WP Name: Grid Technology Layer</p> <p>Risk Owner (WP Leader): J Nabrzyski</p>

Risk Identified	Proposed Contingency plan
<p>Grid is about sharing of data and infrastructure. There is a risk, however, based on some cultural barriers, but also legal, that people do not want to lose a full ownership and control over their data and resources.</p> <p>Risk SCORE: 2</p>	<p>To deal with this problem it is needed to educate people (end users, data owners, resource owners and providers). Series of Grid-related training is needed. This will be provided by PSNC team.</p>
<p>Grid vision does not solve all the problems faced in the project</p> <p>Risk SCORE: 4</p>	<p>Of course this is very probable. It is very important that the project is opened for other technologies as well.</p>
<p>There is a software being used in the projects that is based on the per processor utilization license scheme, which stops this software from being used on the Grid.</p>	<p>One of the solutions is to try to use open software wherever possible. If this is not possible, the negotiations with the software vendor need to be conducted.</p>

<p>Risk SCORE: 3</p>	
<p>There is a risk that using the Grid is not allowed for some companies. They are not legally allowed to use the Grid.</p> <p>Risk SCORE: 3</p>	<p>In this case it is needed to make sure, that all the operations that are available on the Grid have their local equivalent. This is, however, very often impossible, due to the need of accessing data that resides on the grid.</p>
<p>Grid technology is delivered by one partner only, i.e. PSNC. What if the partner does not deliver the promised technology?</p> <p>Risk SCORE: 3</p>	<p>A contingency plan here would be to stay in touch with several other partners, such as EGEE for example. Also, training of all the IT partners on the PSNC's Grid technology is important, so always one of the partners may try to continue the work of PSCN.</p>

4.5. WP5

<p>WP Number: 5</p> <p>WP Name: Distributed Data Access, Tools and Applications</p> <p>Risk Owner (WP Leader): A Bucur</p>

<p>Risk Identified</p>	<p>Proposed Contingency plan</p>
<p>Different and even conflicting requirements among the potential users of the data access services.</p> <p>Risk SCORE: 4</p>	<p>The phase of collecting requirements has to be thorough and to focus on each distinct group of users. The key and secondary drivers should be properly identified before starting to implement the data access services.</p>
<p>Evolving requirements, the user requirements are developed incrementally.</p> <p>Risk SCORE: 3</p>	<p>The data access services should take into account the fact that requirements evolve, and consider flexibility and adaptability as essential requirements.</p>

<p>Complexity of the ACGT scenarios can result in a system complexity that cannot be managed.</p> <p>Risk SCORE: 4</p>	<p>Insightful decisions to trade-off features and complexity. Address the real, practical needs of the users and avoid excessive generalization.</p>
<p>Complex interdependencies among the different WPs in the project may affect the coherence and the validity of the project's results.</p> <p>Risk SCORE: 2</p>	<p>Good communication among workpackages to avoid ignoring relevant dependencies.</p> <p>Coordinate decisions that may affect other parts of the work. The integration WP could keep track of the activities and signal inconsistencies.</p>

4.6. WP6

<p>WP Number: 6</p> <p>WP Name: Data Mining and Knowledge Discovery Tools</p> <p>Risk Owner (WP Leader): S Kiefer</p>
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Risk Identified	Proposed Contingency plan
<p>Analysis results and data mining models violate ethical or legal rules, in particular about privacy-protection.</p> <p>Risk SCORE: 5</p>	<p>Methods from the field of privacy-preserving data mining may be used to protect the privacy of patients. However, as privacy-preserving data mining is still a developing field and the legal and ethical constraints could be complex, novel methods would have to be developed. Sufficient resources, both from the data mining and the legal and ethical perspective, would need to be allocated.</p>
<p>The available data is not rich enough to test and evaluate the applicability of the analysis environment in the envisioned usage scenarios (or such data is not available soon enough to be incorporated in the development and</p>	<p>Simulation experiments and experiments with publicly available data sets will have to be designed and conducted to demonstrate the usefulness of the ACGT approach. This would mean a much higher involvement of clinicians and application scientists to ensure that the conducted experiments and tests are realistic and practically useful.</p>

evaluation process) Risk SCORE: 4	
The requirements for analysis methods and operators are too diverse to be implemented in a single end-user-friendly and error-tolerant software system. Risk SCORE: 2	Should the integrated system prove to be a too complex solution to be used by non-technical users, thus limiting the usefulness and practical impact of the project, significant effort will need to be diverted to the development of a simpler interface, assistants, wizards, or a recommendation system to reduce the complexity of using the system. Training effort would have to be adjusted accordingly.

4.7. WP7

<p>WP Number: 7</p>
<p>WP Name: Ontologies and Semantic Mediation Tools</p>
<p>Risk Owner (WP Leader): V Maojo</p>

Risk Identified	Proposed Contingency plan
Pre-processing of data after integration (due to Pseudo-nomization or Anonymization) could affect the integration process. Risk SCORE: 4	Pseudonomization and Anonymization process cannot be supported by the mediator itself, since data cannot leave original databases without having taken care of data protection. However, in order to approach processes like mapping or instance level cleaning with guarantees, the fact that data have to be changed before reaching integration level must be taken into account.
Ontology updating process cannot be unsupervised. This supervision process might slow down the progression in the ontology development and maintenance.	Define protocols to ask for ontology updates. These protocols must specify approximately how long the updating process would take. This way, both users and ontology responsible people could know about the possibilities of the process itself, and about the implications it could have with the work they are doing.

Risk SCORE: 3	
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4.8. WP8

<p>WP Number: 8</p> <p>WP Name: In Silico Oncology Technologies and Tools</p> <p>Risk Owner (WP Leader): G Stamatakos</p>
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Risk Identified	Proposed Contingency plan
<p>Insufficient clinical data for a reliable validation on a patient specific level</p> <p>Risk SCORE: 4</p>	<p>Although this scenario is considered highly unlikely, should such cases or sub-cases arise, the Oncosimulator is expected to be used as a population mean response to therapy prediction tool or a study platform for parametric explorations.</p>

4.9. WP9

<p>WP Number: 9</p> <p>WP Name: The Integrated ACGT Environment</p> <p>Risk Owner (WP Leader): S. Sfakianakis & M Tsiknakis</p>
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Risk Identified	Proposed Contingency plan
<p>The scenarios cannot be implemented as workflows in a straightforward way that makes them usable and readily available to the users</p> <p>Risk SCORE: 6</p>	<p>The implementation of clinical trials and scenarios and their deployment via the ACGT platform in a secure setting is the most important aspect of the project. It is important that all participants have a clear understanding of the internals of these scenarios, their objectives and requirements, in order to be able to implement them. Cooperation between the domain experts and the technology providers is needed during the course of the project to clear things and establish a common understanding.</p>

<p>Tools and services implemented or reused do not conform to the architectural, syntactic, and semantic constraints of ACGT</p> <p>Risk SCORE: 8</p>	<p>The monitoring of the tools and services that produced throughout the project is the only way to realize the integration vision. This monitoring will also work backwards so that any desirable feature identified will trigger the validation of, and possibly its consolidation to, the ACGT architecture and integration plan. It would be also an option to ignore (i.e. do not integrate) an in-compliant component if time, cost, and other constraints do not permit its integration to the ACGT platform and, additionally, if this component's functionality is considered to be non critical for the project's success.</p>
<p>Unfriendly and inflexible, user interfaces repulse the users</p> <p>Risk SCORE: 2</p>	<p>Special emphasis should be given to the ACGT user interface in order to make it usable and attractive to users. The ACGT participants that are more close to the users' point of view should be present throughout the development process to give their input and guidance regarding these non functional aspects of the software. The build of prototypes, early and often, is therefore needed to assist this effort.</p>

4.10. WP10

<p>WP Number:10</p> <p>WP Name: Ethical, legal and QA issues</p> <p>Risk Owner (WP Leader): N Forgo</p>
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Risk Identified	Proposed Contingency plan
<p>Compliance of all ACGT partners with the designed regulations</p> <p>Risk SCORE: 6</p>	<p>- Raise ACGT-partners awareness of data protection and ethical issues</p> <p>- binding contracts</p>
<p>Designed regulations require complex technical implementations</p> <p>Risk SCORE: 3</p>	<p>Close cooperation with Custodix and WP 11</p>
<p>Possible Change of</p>	<p>Permanent observation of changes in European legislation</p>

European legislation	throughout the project
Risk SCORE: 4	

4.11. WP11

<p>Number: 11</p> <p>WP Name: Trust & Security</p> <p>Risk Owner (WP Leader): B Claerhout</p>
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Risk Identified	Proposed Contingency plan
<p>People with a different background approach the data protection issue differently. Some are not used or inclined to follow data protection policies and procedures, especially when this is new to them.</p> <p>Risk SCORE: 3</p>	<p>WP10 and WP11 should spend sufficient effort on creating awareness on best-practices, legal requirements and the data protection strategy to be followed within ACGT. The ACGT management board must make sure that the data protection policy is enforced among all partners.</p>
<p>Security is a “vertical” issue, influencing all (horizontal) layers of an architecture. If the diversity of used technologies within the ACGT platform is too big, it will be impossible to develop all required security modules/additions.</p> <p>Risk SCORE: 6</p>	<p>This risk is already well contained by choosing a main technology platform at the beginning of the ACGT project (the GRIDGE toolkit). However, the issue should be kept in mind during each (technical) management board meeting. Care must be taken that technology choices made within the ACGT consortium strive for uniformity.</p>
<p>The most innovative security solutions will never be used in the</p>	<p>Sufficient attention should be given to updating (upgrading) the “operational” ACGT infrastructure as new tools are developed.</p>

<p>field, as the basic ACGT infrastructure should be available already quite early, and the research for data protection technology continues throughout the full project.</p> <p>Risk SCORE: 4</p>	
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4.12. WP12

<p>WP Number: 12</p> <p>WP Name: Clinical Trials</p> <p>Risk Owner (WP Leader): C Desmedt</p>
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Risk Identified	Proposed Contingency plan
<p>That the complexity of the final ACGT platform would discourage investigators to use it.</p> <p>Risk SCORE: 4</p>	<p>The purpose of ACGT is to provide strong logistics support and to increase the efficiency of running multicentric clinico-genomic trials such as the TOP trial by providing a unified infrastructure for sharing, joining and analyzing biomedical data in agreement with legal and ethical requirements.</p> <p>However due to the different specific fields involved in the development of the ACGT platform, we fear that the final result would be too technical and not “end-user-friendly”.</p> <p>This is why we believe that in order to make the ACGT platform attractive and useful for new clinico-genomic trials, WP2 and WP12 should be in continuous interaction with all the other WP’s, redefining regularly the needs and requirements of clinical investigators and biomedical researchers.</p>

4.13. WP13

<p>WP Number: 13</p> <p>WP Name: Evaluation and Validation</p>
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Risk Owner (WP Leader): M Delorenzi

Risk Identified	Proposed Contingency plan
<p>Lack of commitment of technical WPs in the development of evaluation and validation procedures.</p> <p>Risk SCORE: 3</p>	<p>This is the main risk for WP13. Evaluation and Validation activities may be perceived as a secondary task in the development process. The mitigation approach is to convince the WP leaders that Evaluation and Validation procedures can help staying focused in the development process and can improve the quality of the final product by anticipating potential issues. Some workforce should be dedicated to this task from the very beginning and a person should be officially in charge of the E&V issues in every relevant WP.</p>
<p>Lack of follow-up of the evaluation and validation procedures</p> <p>Risk SCORE: 4</p>	<p>Once E&V procedures have been established there is a need for their follow-up over the whole length of the project. The mitigation approach is similar to that described above.</p>

4.14. WP14**WP Number: 14****WP Name: Training****Risk Owner (WP Leader): L Maioreescu**

Risk Identified	Proposed Contingency plan
<p>Most of the ACGT users are not able to access the training modules</p> <p>Risk SCORE: 4</p>	<p>This risk is related to the moment and place where the training is provided. The right approach of this risk is to provide the training as much as possible in an online form accessible permanently to all registered users of the ACGT system. The provision of the training should not be limited in time or in terms of access rights. This risk should be eliminated through the general ACGT policies and methodology.</p>
<p>Most of the ACGT users are not able to use the online training modules</p> <p>Risk SCORE: 4</p>	<p>This risk is related to the form in which the training is provided. The training modules should be developed according to the actual standards (both technical and pedagogical) in this area. Training modules should be simple to use, relevant and based on creating competencies and transferring knowledge rather than information. Task 14.3 (training modules for clinical and biological investigators</p>

	and students) should provide a model for how the training modules have to be developed.
Most of the ACGT users find the training modules as irrelevant or helpless Risk SCORE: 2	This risk is related to the content of the training. This risk can be approached by defining a methodology for training content development as an integrated part of the ACGT infrastructure development. Each service or content provider that uses the ACGT infrastructure should be encouraged to create and provide online training modules for its own services or resources. Task 14.3 (training modules for clinical and biological investigators and students) should also describe how the training modules have to be integrated in the ACGT system.
Most of the ACGT users are not able or are not happy to use the ACGT portal Risk SCORE: 2	This risk is related to the form in which the information is presented within the portal. It can be reduced by a good analysis of the way users are likely to interfere with the ACGT system through the portal. The analysis is initially made in Task 14.1 (consolidation of requirements analysis for ACGT portal), but it is consolidated during the testing of the ACGT Portal prototype (Task 14.2) and it should be updated constantly together with the development of the ACGT infrastructure.

4.15. WP15

WP Number: 15

WP Name: Dissemination

Risk Owner (WP Leader): Y Legre

Risk Identified	Proposed Contingency plan
Lack of Coordination in Dissemination activities Risk SCORE: 3	<p>It is vital that all ACGT partners familiarise themselves with the Dissemination Plan which will be produced and identify the areas within their countries and/or Federations that need to be addressed. Cohesion is essential for the success of the dissemination activities.</p> <p>The technical meeting will be used to coordinate and harmonise the ACGT dissemination effort. Moreover, the Dissemination plan will be circulated to all partners for approval, validation and feedback. If necessary, the dissemination plan can be updated to improve its efficiency in the light of new perspectives or contributions. Finally, to support a good circulation of information in ACGT, several communication channels have been activated. The use of the collaborative tools (BSCW server document repository, periodic</p>

	audio-conferencing, mailing-lists, wiki...) will help avoid the emergence of potential information bottlenecks in this project.
<p>Limited Dissemination Resources</p> <p>Risk SCORE: 4</p>	<p>The dissemination task is huge, yet the corresponding resources (budget) are limited. This means that it the dissemination activities and the use of the resources have to be planned carefully and targeted very accurately. The risk could be to launch inefficient dissemination activities that will reduces the remaining resources accordingly. In this regard, WP15 will monitor is different activities in terms of efficient and costs before starting their implementation. At this stage, validation with the Management Board will be essential to ensure that the resources are optimally allocated. This situation also implies that dissemination targets have to be clearly identified and approved of by the Management Board to focus exclusively on efficient actions. These actions will also be defined in the dissemination plan.</p>
<p>Broadness of the dissemination task</p> <p>Risk SCORE: 3</p>	<p>ACGT an interdisciplinary project, and as such WP15 will be brought to disseminate the project achievements across a wide array of communities: IST and computer scientists, praticians, geneticians, patients, academic institutions, private companies,...</p> <p>To this end, WP15 will only disseminate different specific information to the relevant communities. Timely and progressive release of information will have to be planned carefully, taking into consideration the respective progress made within these different areas.</p>

4.16. WP16

<p>WP Number: 16</p> <p>WP Name: Exploitation</p> <p>Risk Owner (WP Leader): A Persidis</p>
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Risk Identified	Proposed Contingency plan
<p>Results not good – critical mass or mix of services not achieved</p> <p>Risk SCORE: 6</p>	<p>Ensure good technology results and that a sufficient number of services (supporting a clearly specified need) exists early enough in the project</p>
<p>Exploitation activities</p>	<p>Ensure from beginning of project central coordination of activities;</p>

become fragmented Risk SCORE: 4	ensure continuity and adopt a staged approach that reflects the status of the project results.
Low attractiveness because ACGT has not addressed the appropriate stakeholders Risk SCORE: 3	Go 'wide' from the start. Contact and pursue each stakeholder group with appropriate value adding 'services' (e.g. through the web site).

5. Conclusion

The main recommendation of this risk assessment is to monitor closely the following potential critical points and to implement a relevant contingency plan for each and every of the following items:

- Ensure sufficient input to user requirement and harmonise any conflicting requirements
- Ensure ad equation of GRID technologies with i) existing software and ii) with ACGT users IT policies.
- Compliance with ethical or legal rules, in particular about privacy-protection
- Implement efficient Pseudonomization techniques that comply with the other ACGT functionalities
- Collect sufficient clinical data for a reliable patient specific validation
- Ensure that the tools and services implemented conform to the architectural and semantic constraints of ACGT
- Define and implement a secure functionalities at all levels of the ACGT system.
- Design of user friendly interface to facilitate user adoption
- Commitment of all partners to the evaluation of the system
- Careful preparation of Training and dissemination activities
- Deliver an efficient and functional final system to allow the exploitation and uptake of ACGT.