



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. Rationale: ACGT Risk Exposure

The challenging and interdisciplinary nature of the ACGT workplan implies that there is inherently a substantial amount of risks, both internal and external, that could affect the project. Beyond this inherent risk exposure, the risk assessment strategy described in this document presents the ACGT policy to **forecast and address potential threats** to the projects, while minimising their respective impacts.

In order to avoid the unexpected emergence of additional issues in carrying out the project, the ACGT's risk management policy will be **permanent throughout the entire project duration**. Moreover, these Risks management procedures are closely linked to the "Definition and Guidelines for the Quality Assurance Process" presented in deliverable D1.2. This document should be referred to for an in depth description of ACGT's quality assurance procedures.

Yet, in spite of the general quality assurance scheme implemented within ACGT, the project is potentially exposed to different risks that could hamper completion of some deliverable, hence putting the entire project in jeopardy.

In order to ensure that ACGT will deliver its expected results, the project coordination has defined a particular scheme to address major risks that could arise.

The following sections of this document:

- 1) Define precisely the risk assessment and risk management mechanisms implemented in the project
- 2) Depict structural and organisational threats inherent to the project, while proposing adapted solutions
- 3) Identify potential risks within and across the Project Workpackages, along with corresponding contingency plans

2. Introduction

2.1. Purpose of this document

ACGT is a dynamic project, based on a life cycle, organs and managerial bodies. As such, the potential risks to which the project is exposed change as the project evolves and moves on along its 4 year work plan.

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

In this perspective, the consortium has designed and deployed a **permanent process** to **identify, manage and overcome risks** that may affect the project as a whole and/ or the work packages.

There are several threats the project could be facing, ranking from the human factors to political changes. Below is as short list of the different types of threats that could affect ACGT:

- **Human** - from individuals or organizations, illness, death, etc.
- **Operational** - from disruption to operations, loss of access to essential assets, failures in implementation, etc.
- **Reputational** - from loss of partner confidence, or damage to reputation in the field
- **Procedural** - from failures of internal systems and controls, organization,
- **Project** - risks of cost over-runs, jobs taking too long, of insufficient quality.
- **Financial** – from limited resources, over-spending, under-spending,
- **Technical** - from advances in technology, technical failure, etc.
- **Natural** - natural disaster, accident, disease
- **Political** - from changes in rules and policies,
- **Others**

To cover these threats efficiently, they have be organised into 3 main risk categories:

1. *Consortium management risks*
2. *Workplan Implementation risks, covering technological risks, and legal or regulatory risks*
3. *Resources and Financial risks*

Under the supervision of the ACGT Management, the project will periodically review each of these risk categories to perform a continuous risk watch and regularly update contingency plans.

3. Permanent Risk Management Activity

The present document outlines the general risks that can potentially endanger the project not only from a global perspective, but also at the level of individual Workpackages.

Yet, as the project progresses along its 4 year work plan, additional threats are likely to emerge and such risk assessment and monitoring must be an **on-going activity during the entire project duration**. Indeed, based on the Quality Assurance scheme that is also continuous throughout the project, the risk assessment will follow the same pattern.

Relying on **regular audio conferencing** (every 2 week) and **periodic Management Board meetings**, the Coordination will ensure that the Risk analysis is addressed in every agenda, to allow **regular updates** and entry of fresh information to improve the risk assessment plan. The Meeting (or audio conference) chair will launch a roundtable discussion to identify new risks or to reconsider proposed contingency plans for improvement.

Following the risks review scheme described in the following section, the project will have a **pro-active** approach trying, in the earliest stages, to identify and forecast potential risks likely to affect the project.

For each potential risk identified, a specific contingency plan will be proposed. The contingency plans will be also be periodically **reviewed, revised and improved**.

Headed by the Coordinator and the Technical Director, the risk assessment sessions will invite all ACGT actors to present what they consider are potential threats (in terms of *Management, Technological, Application, Legal or Regulatory risks*) in accomplishing the project. For each risk identified, a responsible will be appointed to define more accurately the risk and to propose a corresponding contingency plan.

Every new contribution to enrich the present Risk Assessment document will be **reviewed by the Management Board** to ensure that all aspect of the risk have been identified and covered, and to ensure that the proposed contingency plan is both **adequate and realisable**.

All efforts will be made to address the issues before they arise, implementing **pre-emptive measures**. The Management Board should be able to identify potential issues soon enough, thanks to the **internal communication and monitoring system** (either technical, administrative and financial) **established within the Quality Assurance Plan**.

However, should a situation arise that had not been foreseen or for which no contingency plan has been outlined, it is the **responsibility of all ACGT actors** to inform the consortium of the issue. Any critical information should first circulate to the **Project coordinator and the Technical director**, as lay out in the consortium agreement.

They will in turn pass on the information to the **Management Board**, who will address the situation, involving all the Workpackage Leaders.

If necessary, the Management Board can require advice from an **External Advisory Panel**, organise a **General Assembly meeting**, or request the creation of a **dedicated Task Force** to address the issue it is up against.

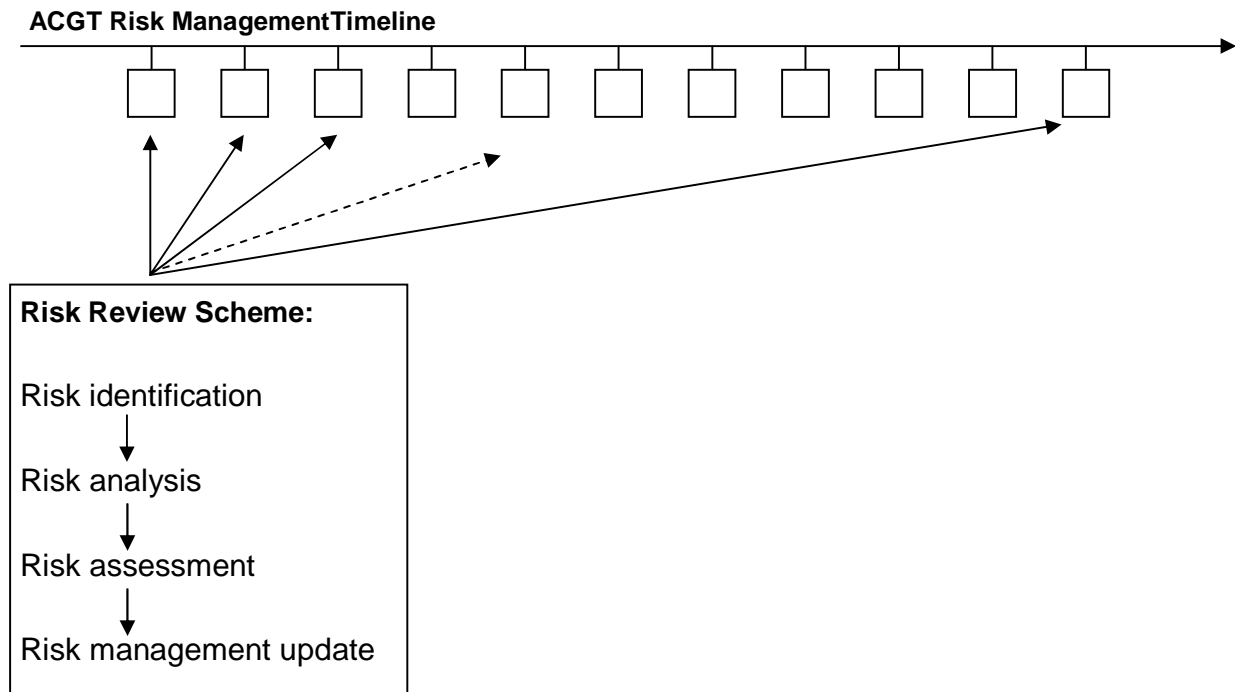
Altogether, the project implement the **Risk Review Scheme** described hereafter periodically; involving all project stakeholders, ranking from participants to Workpackages Leaders and Management Board members.

4. Risk Review Scheme

The Risk Review scheme is an overall assessment of the risks likely to affect ACGT, of their magnitude and their optimal management. ACGT Risk review will be addressed in every management meeting and in every periodic audio conference. It can in principle be held at any stage in the life of the project, with each review building on the results of previous ones. Risk reviews generate information for inclusion in the risk mitigation strategy and risk response plan. The results of a risk review are set out in the updating of the present deliverable.

The overall **Risk management** is conducted continually between risk reviews.

To be efficient, the ACGT risk review is 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. These fundamental steps compose the Risk analysis Scheme, which is implemented periodically throughout the entire project duration:



The risk review scheme - An iterative process:

As more information becomes available, the risk definition will become more accurate and its understanding will increase, allowing the identification of suitable contingency plans.

Therefore, risks should be **reassessed at regular intervals** to reflect any changes in threat level or to monitor the emergence of risks unforeseen as the project moves towards completion.

4.1. Risk Identification

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 risk identification should be both **pro-active and continuous**. The audio conferences and periodic meetings will dedicate a specific session in their agenda to allow all partners to present new risks and/or to update/improve the risk management scheme.

In this regard, the project coordination will launch a **regular risk investigation** activity and prepare contingency plans for any risk identified. There is a wide scope of potential risk likely to affect the ACGT Project: technical, operational, organisational, financial... All potential sources of risk should be considered.

4.2. Risk analysis

When a specific risk has been identified the next step is to work out the likelihood of the threat being realized and to assess its impact. If the Risk is clearly recognised to be significant, the **likelihood** of the event occurring should be estimated along with the **impact** that the event would have.

One approach to this is to multiply this by the impact scale if it happens. This provides a general rating, representing a value for each risk.

A dedicated matrix has been established in order for each risk should then be scored in terms of likelihood and impact. **The Management Board will review periodically the different risk identified and validate the ranking** (in terms of likelihood and impact) assigned to each and every risk.

As presented before, the Management Board will then assign a person to each risk identified to propose an effective contingency plans. **Every contingency plans will be reviewed by the Management Board** during the next Risk Assessment session. A new ranking is set every time to keep each risk under close surveillance.

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 (probability <0.1)
2. Possible (probability ~ 0.2 – 0.5)
3. Likely (probability ~ 0.6 to 0.9)
4. Frequent (probability >0.95)

Impact Categories

1. Insignificant/Minor (no threat to objectives, minor impact)
2. Moderate (slight impact on effectiveness and delivery)
3. Major (Significant risk, significant impact on ACGT objectives)
4. Catastrophic (failure to meet objectives, major threat to objectives and to ACGT viability)

Risk Matrix

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

Significance:

- 1-2 = Low Risk
 3-8 = Medium Risk
 >8 = High Risk

4.3. Risk assessment

Following the risk analysis (ranking in term of likeliness and impact), for every risk identified, the Management Board will assign a person to described the threat and outline a contingency plan. This information will be presented and recorded in the dedicated table hereafter.

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

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

All areas of risk should be identified and risk mitigation scenarios identified in each case. A **contingency plan** must be proposed to minimise the likeliness and/or impact of the threat to the project.

The assessment then must be made as to whether this is an acceptable level of risk. 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 end, the ACGT project has launched:

- An overall ACGT risk analysis addressing **inherent and structural threats** to the projects (contractual , financial, participation, organisational issues)
- An internal **risk assessment across all Workpackages**. A dedicated template has been prepared for WP leaders to provide updated information periodically. 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>The ACGT Architectural model is too complex to develop</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
<p>Risk SCORE: _ _ _</p>	
<p>Risk SCORE: _ _ _</p>	

The contributions from the different WP leaders will be regularly integrated and will periodically enrich the overall ACGT risk analysis.

The Management Board will go through this list at during its periodic meetings to **assess the risk** and **revise contingency plans** if the current proposals are not considered optimal.

Moreover, the Management board will invited WP leaders to updates 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, any key instrument or development on which ACGT is relying 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...). The periodic review of the risks (both at a general and Workpackage level) will ensure a **broad coverage and monitoring of the project's cornerstones exposure to risks**.

4.4. Risk Management

In order to reduce the likelihood of the risk occurring risk management action should be implemented. The action will be assigned by the Management board to 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, and 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 can be regularly revised to take these changes into account.

To update the risk analysis document, or to signal a new potential threat, all ACGT actors are invited to contact directly by e-mail:

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Remi Ronchaud remi.ronchaud@ercim.org

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.

5. Identified Risks and proposed Contingency Plans

The ACGT Management will i) identify **general and structural risks** likely to affect the project as a whole and ii) launch a **risk identification at the Workpackage level** in order to obtain both a “*top-down*” and a “*bottom-up*” vision of the potential threats ACGT could have to address.

General and Structural Risks

Indeed, the project has already identified several general risks inherent to a research project, and in particular to a project like ACGT with strong inter-disciplinary activities.

To reach its objectives, the ACGT Project is relying on a **Consortium**, a **Workplan**, and **Resources**. Should any of these pillars be affected by a threat, the entire project could be in jeopardy. The Management of the project, both administrative and Technical, is to ensure that the project reaches completion and that the consortium has all the necessary resources and support to achieve its objectives.

We expect that, in an Integrated Project such as ACGT, every member of the consortium will take its responsibilities and carry out its tasks as per the workplan, in cooperation with other ACGT partners and within the resources it has been assigned. From experience, it is usually the case, in particular when the consortium, the workplan and the resources are closely monitored through periodic managerial and risks assessment meetings.

In the following section, we will outline the general structural risks likely to affect:

- **Consortium Management risks**
- **Workplan Implementation risks**
- **Resources and Financial risks**

Consortium

Several risks can affect the Consortium, hence the ACGT Project: Institute withdrawal for multiple reasons, researcher leaving position or company, need to involve a new partner, conflict between two Parties or more, non –respect for internal rules and procedures ...

Avoiding Consortium related issues is part of the general coordination activities and all efforts will be made to make sure that partner changes are notified as early as possible. The coordinator will then initiate the preparation of the corresponding contract amendment. Whether a partner is leaving or entering the consortium, the workplan will have to be amended accordingly, tasks reallocated, along with the corresponding resources (both financially and in terms of person-months).

Any major modification of the ACGT consortium falls under the rules outlines in the project Consortium Agreement (CA). Any leaving member will have to withdraw following the rules of the CA, and any entering member will have to sign the CA to effectively join the project. Moreover, all decisions concerning the ACGT consortium have to be ratified by the General Assembly, as per the Consortium Agreement.

The management will organise an annual General Assembly meeting to address and take decisions on any Consortium related issue. If necessary, the General Assembly can be summoned (meeting, audio conference, or electronic vote) to address a specific issue if the situation requires it. In case on conflict between two parties, a solution will first be sought through consensus, all parties knowing that major turmoil between two parties can put in jeopardy the entire project. Yet, should there no possible agreement between the two Parties, the final decision will be taken by a vote of the ACGT General Assembly, as laid out in the Consortium Agreement.

Consortium related risks will be managed seeking consensus through the coordination and the Management board, and ultimately the General Assembly if no solution is found.

Workplan

Risks related to the workplan are numerous: technological bottlenecks, interoperability issues, regulatory risks, restrictive ontology, low user satisfaction for technology adoption, integration complexity,... Because the scope of these potential threats is wide, the project had already started in its proposal phase to identify potential risks.

However, when the project started, more specific issues have appeared and in accordance with the iterative and continuous Risk Management scheme presented in the sections above, all the Workpackage Leaders have been identifying the potential threats to their Workpackage and to the project from their perspective. This list of risks and proposed contingency plans is presented in the section hereafter. Yet, this list will be evolving in time and will be improved as the periodic risk analysis session will be organised throughout the entire project duration.

One essential point of risk management in the workplan implementation concerns the risk of having poor software quality.

Software reliability is one of a number of aspects of computer software which can be taken into consideration when determining the quality of the software. Software reliability has to be measured using objective criteria. Much of the real work in improving the reliability of software is practical.

The reason is that software development must be manageable, comprehensible and profitable. The last requirement is one of the driving forces as competition in software is getting much stronger, and as users are searching for better functioning software, for they are more and more frustrated by from poorly designed user interfaces or direct programming errors.

The usability of software is a major cornerstone in software development. In the United States, both the Food and Drug Administration (FDA) and Federal Aviation Administration (FAA) have requirements for software development.

The more critical the application of the software to life-science, the more important is the need to assess the software's reliability. In other words, the software should behave in the way it is intended, or even better, in the way it should.

In this respect, the partial risks hereafter will be addressed in the following sections.

1- It is not specified how a software should work

2- The software does not works as expected

3- There is no validation process of a new software implemented

4- The developed software is not needed (or accepted) by the scientific community

1. It is not specified how a software should work

This risk happens, if there are problems with:

- Architecture
- Overall program concept
- Overall program structure
- Data processing

Solution:

Every software that will be developed will be developed according to a scenario. Without a scenario no software will be developed, meaning the first step, before starting programming the scenario has to be developed. This process will omit this risk.

2. The software works not as expected

This risk happens, if

- the developers of the program do not know the program's desired behaviour in advance
- the developers cannot determine its desired behaviour in parallel with the development in sufficient detail.

Solution:

Every software that will be developed will be developed according to a scenario. In building a scenario the purpose of the scenario is defined. The user of the scenario has to define the behaviour of the program in advance. He has to specify the needs and requirements as well as the expected output of the program regarding what and how he wants to get the result.

3. There is no validation process of a new software implemented

Before starting a validation process criteria or quality factors for good software have to be defined: Such criteria are:

- Usability: convenient and practicable to use; most important: GUI
- Security: protection of data and unauthorized access

- Understandability the purpose of the product is clear
- Maintainability: easy updating to satisfy new requirements
- Reliability: performance of intended functions is satisfactorily
- Efficiency: fulfilling its purpose without waste of resources
- Completeness: all parts are fully developed and functioning
- Conciseness: reduction of lines of code to a minimum
- Portability: operation is easy on multiple computer configurations
- Consistency: uniform notation and terminology within itself

It is difficult to measure software quality factors because of their vague description. It is necessary to find measures, or metrics, which can be used to quantify them as non-functional requirements

To evaluate software quality factors different questions should be answered for every characteristic, which are relevant to that characteristic. Some type of scoring formula has to be developed based on the answers to these questions, from which a measure of the characteristic may be obtained.

Most important of these characteristics is the usability. In the setting of ACGT users as clinicians or molecular biologists have to validate the system according to predefined questions, which are listed below.

Usability

- Is a GUI used?
- Is there adequate on-line help?
- Is a user manual provided?
- Is the software well documented?
- Is the user interface self-explanatory/ self-documenting?
- Are meaningful error messages provided?
- Is the user interface intuitive?
- How much teaching is necessary for using the software (hours) without problems
- Is it easy to perform easy operations?
- Is it feasible to perform difficult operations?
- Do widgets behave as expected?
- Is the user interface responsive or too slow?
- What is the availability of (free or paid) support

Regarding the other characteristics the following questions are important to answer. The questions regarding security, understandability, maintainability, reliability and efficiency have to be answered by the enduser, mainly the clinician, whereas the other questions are primarily addressed to the IT-People, developing the software.

Security

- Does the software protect itself and its data against unauthorized access and use?
- Does it allow its operator to enforce security policies?
- Are appropriate security mechanisms in place?
- Are those security mechanisms implemented correctly?
- Can the software withstand attacks that must be expected in its intended environment?

- Is the software free of errors that would make it possible to circumvent its security mechanisms?
- Does the architecture limit the impact of yet unknown errors?

Understandability

- Are variable names descriptive of the physical or functional property represented?
- Do uniquely recognisable functions contain adequate comments so that their purpose is clear?
- Are deviations from forward logical flow adequately commented?
- Are all elements of an array functionally related?

Maintainability

- Has some memory capacity been reserved for future expansion?
- Is the design cohesive, i.e., each module has recognisable functionality?
- Does the software allow for a change in data structures (object-oriented designs are more likely to allow for this)?
- If a functionally-based design (rather than object-oriented), is a change likely to require restructuring the main-program, or just a module?

Reliability

- Are loop indexes range tested?
- Is input data checked for range errors?
- Is divide-by-zero avoided?
- Is exception handling provided?

Efficiency

- Have functions been optimized for speed?
- Have repeatedly used blocks of code been formed into sub-routines?

Completeness

- Does the program contain all referenced subprograms not available in the usual systems library?
- Are all parameters required by the program available?
- Are all inputs required by the program available?

Conciseness

- Is all code reachable?
- Is any code redundant?
- How many statements within loops could be placed outside the loop, thus reducing computation time?
- Are branch decisions too complex?

Portability

- Does the program depend upon system or library routines unique to a particular installation?
- Have machine-dependent statements been flagged and commented?
- Has dependency on internal bit representation of alphanumeric or special characters been avoided?

Consistency

- Is one variable name used to represent different physical entities in the program?
- Does the program contain only one representation for physical or mathematical constants?
- Are functionally similar arithmetic expressions similarly constructed?
- Is a consistent scheme for indentation used?

Solution:

A validation process of new software is implemented. Most important are the endusers, who play a critical role in validating the software. The validation process is standardized for every of the above mentioned different criteria. For every developed tool or software software this process of validation has to be done. Every time a problem is recognized, this problem will be given back to the program developers in a feedback loop.

4. The developed software is not needed or accepted in the scientific community

This risk will reveal if:

- the developers of the program do not know what is needed by the scientific community in advance
- the developers of the program do not know, that the same software is already existing and available
- the developed software is too expensive
- new questions to be answered by the scientific community are coming up faster than the developed software can fit

Solution:

A market analysis is done

The information about ACGT has to be spread to the scientific community

The scientific community is asked to provide ACGT with scenarios

More clinicians have to run clinicogenomic trials in ACGT

In addition to these four points, the risk analysis scheme will periodically come up with new questions that the project will address internally. The Management Board, the Technical Director and the quality Manager coordinate the overall risk assessment scheme through periodic meetings. The internal communication flow allows fast and almost real-time (wiki) exchanges among the different research teams. Every Workpackage Leader can review and update regularly its own list of risk and contingency plans, **in close collaboration with the other Workpackage Leaders**, hence avoiding the emergence of unexpected technical issues.

Resources

The consortium activity within the frame of the ACGT workplan is fuelled by resources. Any risk exposure will therefore affect the project in its integrity. Person-months allocation and financial management are the key elements of the resources monitoring within ACGT.

To avoid the emergence of unexpected problems in this field, the coordination is carrying out periodic assessment of the resources allocated and declared by each and every partner institute. The coordinator has provided clear guidelines to assist the partners in their financial claims. Yet, close monitoring is essential, in particular through the analysis of the person-months efforts declared in the periodic six-monthly reports.

Information on the person-months declaration can help the management forecast potential problems with institutes over-spending or under-spending. For example:

- **Over-spending** in person-months has to be monitored carefully to make sure that the institute will have enough resources left to carry out the remaining tasks.
- **Under-spending** person-months should also to be kept under surveillance as it usually indicates a limited commitment of the corresponding team to the workplan.

In both cases, the coordination will ensure that proper justification is given by the corresponding institutes. Failure, for a given institution, to justify the over- or under-spending may results in a budget reallocation of it resources to other partner institutes in the project, in accordance with the general rules defined in the consortium Agreement.

The Coordinator is also to pay regular attention to the request of the ACGT Partners, in order to give them optimal working conditions.

This does not only include monitoring the person-months and allow changes in the effort allocation if necessary to adapt to the technical constraints of the project if necessary, but it also involves counselling the institutes in the way they allocate their resources; for example for the acquisition of durable equipment, or even consumables.

This permanent risk assessment provides a general frame for all partner institutes, and allows the coordination to assess closely the general resources consumption in the project.

In addition, the annual financial statements to be produced for the European Commission are and additional checkpoint to review cost claim, and resources expenditures for each teams and for the project as a whole. It will also be the opportunity to confront the resources spent by every teams against the achievements presented in their annual activity report, and to measure any noticeable discrepancy.

Risk Identification at the Workpackage Level

An internal consultation of the Workpackage Leaders, using risk assessment forms, has delivered the identification of the following risks and the definition of the proposed contingency plan.

For every risk identified and every corresponding risk assessment form provided, the Management Board is to discuss and validate the proposed contingency plans. Each risk will be periodically reviewed during management meeting or dedicated risk assessment sessions that are organised during the technical meetings.

The risks already identified by the WP leaders along with the proposed contingency plans have been listed in the following section. They are addressed:

By using existing assets:

Existing resources can be used to counter risk. This may involve improvements to existing methods and systems, changes in responsibilities, improvements to monitoring and internal controls, etc.

By contingency planning:

If a risk is identified and accepted, plans to minimize its effects if it happens have to be developed. An efficient contingency plan will allow you to take action either before the problem occurs, or immediately when the situation arises. Close monitoring and control is essential to have a strong yield in a crisis management situation.

By investing in new resources:

The risk analysis should give the project the vision for deciding whether to bring in additional resources to counter the risk: allocate more resources to a bottleneck task, bring in additional expertise,...

These risk tables presented hereafter will be reviewed and **updated periodically** to avoid the emergence of unexpected issues or situations.

5.1. WP1

Risk	Contingency plan
<p>Conflicts within the Consortium</p> <p>Risk SCORE: 6</p>	<p>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. The consortium agreement accepted by all Parties will define the internal rules and procedures in case of conflict between two Parties or more.</p>
<p>The consortium experiences disruption, e.g. a partner resigns or fails.</p> <p>Risk SCORE: 4</p>	<p>In case of partner resignation or failure to deliver management will take swift actions for reassignment of work to existing or new partners. The Coordinator will call for a contract amendment to revise the consortium composition and to reallocate the tasks corresponding resources among remaining Parties. Yet, all effort will be made by the experienced co-ordinators to avoid this situation or to avoid last minute management of this situation by maintaining a permanent thread of communication with every partner institute and research team.</p>
<p>Conflicting expectations and role understanding within ACGT</p> <p>Risk SCORE: 6</p>	<p>In the proposal phase, it was possible that some partners had a limited understanding of their role in the project. The organisation of the kick-off meeting was the opportunity to clearly define roles, functions and cooperation. If conflicting perceptions prevail, this important aspect is a risk element. To this end, the internal communication flow is a key mechanism for transparency by allowing close discussions and exchanges. In particular periodic audio conferences allow partners to exchange views, and to confront their vision.</p>
<p>Delays and administrative oversights</p> <p>Risk SCORE: 4</p>	<p>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, defining clear Quality Assurance measures and by appointing a person from each partner responsible for administrative reporting (a person that does not hold work package responsibility). If necessary, actions could be taken</p>

	against the partners that failed to comply with procedures.
<p>The ACGT Architectural model is too complex to develop</p> <p>Risk SCORE: 12</p>	<p>This is perhaps the main risk of the project, especially since the entire project relies 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. The close monitoring of Workpackage activity and resources spent will help assess progress in the workplan, and allow the early identification of potential issues.</p>
<p>The user requirements identified for the scenarios are not feasible within the scope of the project.</p> <p>Risk SCORE: 6</p>	<p>The project will manage the user requirements process in order to ensure that expectations are realistic. First, the ACGT project will rely on existing scenarios to define the scope of its applications. Second, the scenarios will be defined in close collaboration with the ACGT technical teams to ensure that the user expectations are met. 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.</p>
<p>Difficulties in exploiting the project's results in an "open source" and "open access" environment</p> <p>Risk SCORE: 8</p>	<p>It is particularly an issue in ACGT, due to the idea 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. Headed by Biovista, the exploitation will first focus on the first critical step of technology adoption by the potential user community. Our strategy in responding to such risks is to involve stakeholder and users as early as possible in the project and to have them interact with the ACGT system to gather feedback and promote its uptake for exploitation.</p>
<p>The required applications and services cannot be developed within the ACGT time and resource constraints</p> <p>Risk SCORE: 4</p>	<p>While complexity is the main issue regarding the ACGT architectural model development, the amount of resources/funding is the most likely challenge when it comes to the physical design and implementation of the ACGT envisaged platform. Being aware of this, the consortium and task leaders will emphasize efficient resource utilization when executing work. The Coordination will not only monitor the resources consumption and the work progress, but it will also, if necessary, take measures to transfer resources from Workpackages or Parties, to other activities or teams to ensure that the project delivers.</p>
<p>The pilot process fails to produce consistent evaluation feedback.</p> <p>Risk SCORE: 6</p>	<p>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 ACGT within each of the scenario arenas.</p>

<p>Failure to monitor use of resources against the workplan progress</p> <p>Risk SCORE: 4</p>	<p>This is very unlikely to happen, but should it occur, it would have a strong impact on the project. Provided that the periodic review of resources spent by the partners have not been able to identify the situation beforehand, the main contingency plan would be to consider the origin of the overspending (or under spending). Once identified, the Management can propose to reallocate the remaining resources from other partners (with their agreement) to carry out the bottleneck tasks. This decision will have to be taken by the General member Assembly, in accordance with the consortium agreement rules and procedures. If necessary, the project can vote the withdrawal of a partner if the situation requires it and to redistribute the remaining funding from this partner among the remaining participants or to invite a new partner to take up the remaining tasks.</p>
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5.2. 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 will 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 Risk SCORE: 4	<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 will be done at each Management Board meeting. - Concrete naming of a contact Person in each WP, who is responsible for the scenario development in that WP
Policy of ACGT regarding the scientific community outside of ACGT Risk SCORE: 3	<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>
Cohesion and coordination of work Risk SCORE: 1	<p>As a result of the WIKI, regular telephone conferences and the regular Management board meetings this is a minor risk factor now.</p>

<p>Tool for pseudonymisation of data</p> <p>Risk SCORE: 3</p>	<p>This point was 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>
<p>Missing or delayed validation of developed software tools</p> <p>Risk SCORE: 4</p>	<p>A standardized validation process for software tools will be worked out.</p> <p>More clinicians and other endusers have to be recruited for validation</p>

5.3. WP3

WP Number: WP3

WP Name: Architecture

Risk Owner (WP Leader): J Nabrzyski

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 operations between various layers of the architecture</p> <p>Risk SCORE: 2</p>	<p>If the architecture is based on the layered architecture make sure that layer violations are possible in specific, approved situations.</p>

5.4. 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>Risk SCORE: 3</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>There is a risk that using the Grid is not allowed for some companies. They are not legally allowed to</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>use the Grid.</p> <p>Risk SCORE: 3</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>

5.5.

5.6. WP5

WP Number: 5

WP Name: Distributed Data Access, Tools and Applications

Risk Owner (WP Leader): A Bucur

Risk Identified	Proposed Contingency plan
<p>Different and even conflicting requirements among the potential users of the data access services may impact focus and coherence.</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. The key requirements of the users should be addressed first.</p>
<p>Evolving requirements. Not all important requirements of the users of the services and tools developed in WP5 can be defined or are known at this point.</p> <p>Risk SCORE: 3</p>	<p>The user requirements analysis is carried out in an iterative fashion, to allow new requirements to be added at a later stage in the project. 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 ACGT may affect the coherence and the validity of results.</p> <p>Risk SCORE: 5</p>	<p>Good communication among workpackages to identify all dependencies and 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>

<p>The system may trade-off usability for functionality and features. End-users may find the system difficult to use.</p> <p>Risk SCORE: 6</p>	<p>The system should be validated by end-users at different stages during development, and not only in the validation phase. Usability should be emphasized. Users' comments should be taken into account and newly identified requirements incorporated into the next versions.</p>
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5.7.

5.8. WP6

WP Number: 6**WP Name: Data Mining and Knowledge Discovery Tools****Risk Owner (WP Leader): S Kiefer**

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 evaluation process)</p> <p>Risk SCORE: 4</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>
<p>The requirements for analysis methods and operators are too diverse to be implemented in a single end-user-friendly and error-tolerant software system.</p> <p>Risk SCORE: 2</p>	<p>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.</p>

5.9. WP7

WP Number: 7

WP Name: Ontologies and Semantic Mediation Tools

Risk Owner (WP Leader): V Maojo

Risk Identified	Proposed Contingency plan
<p>Ontology updating process cannot be unsupervised. This supervision process might slow down the progression in the ontology development and maintenance.</p> <p>Risk SCORE: 4</p>	<p>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.</p>
<p>The appearance of new data sources after the project completion would require its integration in the mediator. Disparateness in access interface and structure could make this impossible or very difficult.</p> <p>Risk SCORE: 9</p>	<p>Spend enough amounts of resources in the design and development of the Mapping and Unification tools. These must be flexible enough to easily cope with future databases.</p> <p>To tackle with this problem, a study of cases of heterogeneity has been developed. This and other activities to be carried out in the future are directed to speed up mapping process, making it feasible to integrate new sources of information in the system.</p>
<p>Size of the Master Ontology could make it difficult for clinicians to construct appropriate and complex enough queries.</p> <p>Risk SCORE: 3</p>	<p>Appropriate visual query interfaces should be developed. These should feature the ability to guide inexperienced users, such as clinicians, in this process.</p> <p>To this end, an exhaustive analysis of specific user requirements has been performed during first months of work in WP7. This includes interviews and discussions with end-users. Intermediate results of this analysis have been captured in Deliverable 7.1. However, this kind of requirements has an evolving nature, so this kind of task will continue during the entire project life.</p>

<p>The mediator will offer services to very different kinds of users. These will include clinicians (usually lacking an expertise in computer usage) as well as analytical tools. Each will have different needs from the mediator.</p> <p>Risk SCORE: 8</p>	<p>The design and development of different kind of interfaces for different kind of users needs is a well known but difficult problem in software engineering. There exist standard patterns to tackle with these processes that are being and will be taken into account.</p> <p>Intermediate layers offering specific services for each kind of user should be developed. This will cope with the problem, while not adding much complexity to the mediator design.</p>
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5.10. WP8**WP Number: 8****WP Name: In Silico Oncology Technologies and Tools****Risk Owner (WP Leader): G Stamatakos**

Risk Identified	Proposed Contingency plan
<p>Insufficient clinical data available for a reliable validation on a patient specific level.</p> <p>(Data to be provided by WP12)</p> <p>Risk SCORE: 4</p>	<p>Although this scenario is considered rather unlikely, should such cases or sub-cases arise, the Oncosimulator can still become a prediction tool for the population average response to therapy or a study platform for parametric explorations of tumour behaviour.</p> <p>Nevertheless, a more intense exploitation of retrospective data will also be carried out even if this might entail a lower degree of patient specificity.</p>

5.11. WP9

WP Number: 9**WP Name: The Integrated ACGT Environment****Risk Owner (WP Leader): S. Sfakianakis & M Tsiknakis**

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>

5.12. WP10

WP Number:10**WP Name: Ethical, legal and QA issues****Risk Owner (WP Leader): N Forgo**

Risk Identified	Proposed Contingency plan
<p>Compliance of all ACGT partners with the designed data protection and ethical regulations</p> <p>Risk SCORE: 6</p>	<p>ACGT-partners come from very different background, therefore appliance of data protection and ethic regulations might be new and unfamiliar for them. Together with WP11 it will be of high importance to raise ACGT-partners' awareness of data protection and ethical issues and to provide guidelines and Privacy Enhancing Technologies. It will be essential to rule data protection issues by binding contracts between all ACGT partners so that data processing within ACGT complies with current data protection regulation. An ACGT data protection board will be installed that will be capable to control compliance with data protection regulations within the project.</p>
<p>Designed data protection regulations require complex technical implementations by WP11</p> <p>Risk SCORE: 3</p>	<p>The success of the designed data protection and ethic regulations for the most part is depending on the technical implementation done by WP 11. A very close cooperation between WP10 and WP11 regarding the needs of data protection and technical possibilities is of substantial importance.</p>
<p>Possible Change of European legislation throughout the project</p> <p>Risk SCORE: 4</p>	<p>To assure ACGT's enduring accordance with European data protection legislation, a permanent observation of changes in the European legislation throughout the project is of high importance. If data protection regulation is modified by the EU, this modification process should be studied by WP10 in order to guarantee compliance with future European legislation.</p>

5.13. 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: 9</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 field, as the basic ACGT infrastructure should be available already quite early, and the research for data protection technology continues</p>	<p>Sufficient attention should be given to updating (upgrading) the “operational” ACGT infrastructure as new tools are developed.</p>

throughout the full project. Risk SCORE: 4	
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5.14.

5.15. 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>

5.16. WP13**WP Number: 13****WP Name: Evaluation and Validation****Risk Owner (WP Leader): M Delorenzi**

Risk Identified	Proposed Contingency plan
Lack of commitment of technical WPs in the development of evaluation and validation procedures. Risk SCORE: 3	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.
Lack of follow-up of the evaluation and validation procedures Risk SCORE: 4	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.

5.17. WP14

WP Number: 14**WP Name: Training****Risk Owner (WP Leader): O Zelch**

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 and students) should provide a model for how the training modules have to be developed.</p>
<p>Most of the ACGT users find the training modules as irrelevant or helpless</p> <p>Risk SCORE: 2</p>	<p>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.</p>
<p>Most of the ACGT users are not able or are not happy to use the ACGT portal</p> <p>Risk SCORE: 4</p>	<p>This risk is related to 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.</p>

5.18. WP15

WP Number: 15**WP Name: Dissemination****Risk Owner (WP Leader): Y Legre**

Risk Identified	Proposed Contingency plan
<p>Lack of Coordination in Dissemination activities</p> <p>Risk SCORE: 6</p>	<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 audio-conferencing, mailing-lists, wiki...) will help avoid the emergence of potential information bottlenecks in this project.</p>
<p>Limited Dissemination Resources</p> <p>Risk SCORE: 9</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: 6</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</p>

	release of information will have to be planned carefully, taking into consideration the respective progress made within these different areas.
<p>Failure of other activities and lack of success stories</p> <p>Risk SCORE: 4</p>	<p>Dissemination will not produce the success stories from scratch and it shall rely on the success of the other more “technical” activities. These activities shall also inform dissemination WP about their successful achievements in order to transform them in a success story which will contribute to the good name of ACGT.</p> <p>This risk can be overcome with a regular activity report from each WP15 contact points which will allow WP15 to be aware of all major progress in the project.</p>
<p>The material produced is not relevant or failed to reach the targets</p> <p>Risk SCORE: 2</p>	<p>Despite the attention which is given to produce high quality material some of the material produced could be find irrelevant or of less interest by the expected target. All people in the project using dissemination material shall inform as soon as possible the dissemination manager of justified criticisms on the dissemination material and we will look to potential improvement.</p>

5.19.

5.20. WP16

WP Number: 16

WP Name: Exploitation

Risk Owner (WP Leader): A Persidis

Risk Identified	Proposed Contingency plan
<p>Results are not “good”, meaning a critical mass of services is not achieved or the mix of services offered has low utility</p> <p>Risk SCORE: 6</p>	<p>Ensure good technology results and that a sufficient number of services (supporting a clearly specified need) exist early enough in the project. The first requirement is hard to monitor early on and will have to wait for the 2nd period of the project for a proper assessment, once the first ‘batch’ of services become available. The ‘proper mix’ requirement is theoretically met ‘by design’ given the input from the end users. Once again a more rigorous assessment will only become possible once a prototype is deployed in the user environments. The plan decided upon is to attempt a rapid deployment of existing technologies from the various partners and an assessment early in period 2. Corrective measures include the development of additional services or in the worst scenario a re-definition of the use-case scenario if the existing ones are shown to be unattainable.</p> <p>First assessment point is around month 15.</p>
<p>Exploitation activities become fragmented</p> <p>Risk SCORE: 6</p>	<p>Ensure from beginning of project central coordination of activities; at the initial stages of the project it is difficult for a lot of partners to have a concrete idea of what/how to exploit. This is compounded by the open source model adopted by ACGT. The exploitation plan that has been devised takes the above into account and aims to undertake a series of activities to increase awareness of the project. Increased exposure and the use of the web site as a focal point that offers significant value <i>in addition</i> to the s/w resources eventually to come online are an example of these. A decision has also been made to coordinate the Exploitation with the Dissemination activities. A risk mentioned in connection with the latter is the relatively low budget which might become critical at the later stages of the project.</p> <p>Ensure continuity and adopt a staged approach that reflects the status of the project results. Care needs to be taken not to promise “too much too soon” but also to offer results at a steady pace and all pulling in the same direction. A risk here is that partners are not</p>

	<p>committed enough or do not have the appropriate resources. This has been raised at the PMB level and corrective action is expected for the subsequent stages of the project.</p> <p>First assessment point is around month 24.</p>
<p>Low attractiveness because ACGT has not addressed the appropriate stakeholders</p> <p>Risk SCORE: 4</p>	<p>The decision has been taken to 'go wide' from the start. A number of distinct stakeholder groups have been identified (e.g. patient advocacy groups) and where possible and within the scope of the project specific actions are taken to address their needs/interests with appropriate value adding 'services'. At the initial stages of the project (period 1 and 2) the web site will be the major delivery medium of these services. Some of the services under consideration were not foreseen in the original Technical Annex but have strong support from the end user partners and will therefore be implemented. Efforts will also be made to contact these other categories of stakeholders which are not currently represented in the consortium (the goal being to attract their support/interest <i>without</i> the compensation of making them members of the consortium. Selection of the additional services will have to be made with care since fail to deliver will probably result in alienating the hoped for supporters.</p> <p>At the present time services are being discussed within the consortium. Early in period 2 and once first prototypes are available partners will be in a better position to select the appropriate ones to offer. A reassessment of this criterion is expected around month 20 of the project.</p>

6. Conclusion

The main recommendation of this risk assessment is to monitor closely the following potential critical points and to implement relevant contingency plans throughout then entire project duration.

Mitigating risks, or lessening their adverse impacts, is at the heart of the effective risk management. Unfortunately in project management risk mitigation is sometimes undertaken only at a rather superficial level.

ACGT is already conducting periodic technical, legal and managerial watch of the potential issues that may arise. This pro-active approach is reinforced by the regular meeting and audio-conferences that help the project monitor most aspects of this threat exposure.

To this end, the project is mostly trying to avoid the potential issues. Yet, there are four main ways in which risks can be dealt with within the context of a risk management strategy. Risks can be:

- Avoided, but also
- Reduced or eliminated
- Transferred
- Absorbed or pooled.

The ACGT project is aware that in spite of its proactive approach, situations may arise.

Nevertheless, the expertise of the management and of the scientific coordination, as well as the expertise of the ACGT Partners, will be a valuable asset to address these particular issues that are bound to arise.