



The ACGT Initial Exploitation Plan

Project Number: FP6-2005-IST-026996

Deliverable id: D 16.1

Deliverable name: The ACGT Initial Exploitation Plan

Date: 27 March, 2007



COVER AND CONTROL PAGE OF DOCUMENT	
Project Acronym:	ACGT
Project Full Name:	Advancing Clinico-Genomic Clinical Trials on Cancer: Open Grid Services for improving Medical Knowledge Discovery
Document id:	D 16.1
Document name:	The ACGT Initial Exploitation Plan
Document type (PU, INT, RE)	PU
Version:	1.0
Date:	27.03.2007
Authors: Organisation: Email Address:	Andreas Persidis Biovista andreas@biovista.com

Document type PU = public, INT = internal, RE = restricted

ABSTRACT: Exploitation is understood to be an important objective of the project which ensures use of project outcomes and therefore extraction of benefit (a) by 3rd parties and (b) beyond the end of the project.

The Exploitation Plan is a formal management instrument that describes goals and actions the consortium intends to take for the remainder of the project. It is an active document and future versions will record developments to date as well as any changes that have been necessary in response to new findings or re-alignment of exploitation priorities.

The current plan identifies main stakeholder groups that are targeted by the consortium, shows which outcomes are directed to which group and identifies 'exploitation materials' that need to be developed in the coming months as part of the execution of the plan.

The plan identifies 2 major initiatives the consortium has conceived of in order to boost awareness and encourage 3rd party participation, both of which are considered central to the success of the project. It also identifies 13 perceived risk factors and 12 success criteria that will be used by the Project Management Board to assess the success of work.

Actions that the plan foresees to be specifically undertaken in Year 2 of the project are listed in an Appendix for easy reference.

KEYWORD LIST: exploitation plan, stakeholders, exploitation materials, open source exploitation models, exploitation initiatives, exploitation risk factors, exploitation success criteria

MODIFICATION CONTROL			
Version	Date	Status	Author
0.1	19.03.2007	1 st Draft	Andreas Persidis
0.5	23.03.2007	2 nd Draft	Andreas Persidis
1.0	27.03.2007	Final	Andreas Persidis

List of Contributors

- Christos Andronis, Biovista
- Andreas Persidis, Biovista
- Ourania Konstanti, Biovista
- Norbert Graf, USAAR
- Georgios Stamatakos, ICCS-NTUA
- Gabriele Weiler, FHG-IBMT
- Christine Desmedt, IJB
- Francesca Meteora Buffa, UOXF
- Manolis Tsiknakis, FORTH

Contents

EXECUTIVE SUMMARY	5
1 SCOPE OF THE EXPLOITATION PLAN	7
1.1 EXPLOITATION WITHIN THE SCOPE OF ACGT	7
1.2 PURPOSE OF THE DOCUMENT	7
1.3 WHO IS THIS DOCUMENT FOR?	8
1.4 STRUCTURE OF THE DOCUMENT	8
1.5 DOCUMENT VERSIONS AND UPDATE PROCEDURE	9
2 EXPLOITATION MODELS	10
2.1 INTRODUCTION	10
2.2 EXPLOITATION MODELS OF OPEN SOURCE	10
2.3 CHARACTERISTICS OF MODELS BUILDING ON OPEN CORES	11
3 BASIC DIMENSIONS AND LEVELS OF THE EXPLOITATION PLAN.....	12
3.1 EXPLOITATION PLAN DIMENSIONS	13
3.2 EXPLOITATION PLAN LEVELS	14
3.2.1 Consortium Level Exploitation	15
3.2.2 Partner Level Exploitation.....	15
3.3 EXPLOITATION PLAN INITIATIVES.....	15
4 STAKEHOLDER GROUPS.....	16
4.1 INTRODUCTION	16
4.2 CLINICIANS	17
4.3 BIOLOGY BIOMEDICINE RESEARCHERS.....	19
4.4 SOFTWARE DEVELOPERS AND VENDORS	21
4.5 PATIENTS AND PATIENT ADVOCACY GROUPS.....	23
4.6 REGULATORY BODIES.....	25
4.7 CONSULTANTS.....	27
4.8 GENERAL PUBLIC.....	29
5 ACGT EXPLOITABLE RESULTS.....	30
5.1 INTRODUCTION	30
5.2 EXPLOITABLE OUTCOMES.....	30
5.3 PARTNER-SPECIFIC ACTIVITIES.....	33
6 THE ACGT READY INITIATIVE	36
6.1 JUSTIFICATION	36
6.2 DESCRIPTION	36
7 THE ACGT COMPETITION	38
7.1 JUSTIFICATION	38
7.2 MAIN ELEMENTS OF THE COMPETITION.....	38
8 MANAGEMENT OF THE EXPLOITATION PLAN.....	40
8.1 RISK FACTORS	40
8.2 SUCCESS CRITERIA AND METRICS	43
9 APPENDICES.....	44
9.1 APPENDIX 1: SUMMARY OF EXPLOITATION ACTIONS AND DELIVERABLES FOR YEAR 2.....	45
9.2 APPENDIX 2: STRUCTURED APPROACH TO GENERATING TARGETED COMMUNICATIONS MATERIALS..	46
9.3 APPENDIX 3: PERSON-MONTH ALLOCATION	48
9.4 APPENDIX 4: PARTNER CONTACT PERSONS FOR EXPLOITATION ISSUES	49
9.5 APPENDIX 5: LIST OF ABBREVIATIONS.....	50

Executive Summary

Purpose of the Document

The purpose of this document is to provide a formal instrument that will describe, guide and coordinate all project activities that relate to the exploitation of project outcomes. At its heart the exploitation plan aims to answer the following six principal questions:

- Who are the main stakeholder groups that are involved in clinical trials and could therefore be seen as potential 'customers' of ACGT results?
- What are the exploitable results that ACGT aims to deliver?
- In what ways can we exploit the ACGT results?
- How do we "get the message across" to each stakeholder?
- When and in what sequence do we take each action?
- How do we measure success and ensure use of outcomes post project end?

How do we understand exploitation?

In the context of our objectives and plan, exploitation is taken to mean any use of outcomes (resources and services) that are developed within the project, by third parties or indeed consortium members out with the framework of the project itself and more importantly after its official end.

Exploitable Outcomes

ACGT exploitable outcomes can be arranged in one the following groups:

- **Software:** individual s/w modules, algorithms or the entire ACGT environment
- **Work practices:** usually internal processes that could be changed as a consequence of the introduction of project software
- **IP:** anything that is considered to have patenting potential [Note: Software as it is, is not subject to patents.]
- **Educational materials and courses:** for example course materials developed by academic partners, courses for training on running ACGT trials and tools for clinicians etc.
- **Resources:** for example web site, ontologies and such
- **Real estate:** space on the ACGT portal
- **Infrastructure:** access to the ACGT infrastructure
- **Expertise:** know how on legal, ethical and other issues that fall within the scope of ACGT

Dimensions of the Exploitation Plan

With the goal of providing structure and context to the exploitation plan we have identified exploitation plan *dimensions* and *levels* that serve to organise activities in a focused and systematic way.

The main dimensions are the following:

- **Stakeholder Groups:** We have identified the following stakeholder groups: Clinicians, Biology/Biomedicine Researchers, Patients and Patient Advocacy Groups, Software

developers and other vendors, Regulatory Bodies, Consultants, The General Public. Each represents a unique context that guides the generation of exploitation materials and exploitation related actions we intend to pursue.

- **Outcomes:** these are the expected results of ACGT and represent what we have to offer to the various stakeholder groups. Different groups will have different needs for the various outcomes and it is important to correctly match the two together so as to maximize chances of successful uptake.
- **Timing:** ACGT results will not be delivered at a single point in time but progressively as the project unfolds. The question of when we present what to whom becomes an important consideration of the plan. The plan therefore accounts for this by organizing deliverables and actions over time.
- **Messages:** Messages must be highly customised in order not to be discarded by target audiences. The exploitation plan presents the broad framework for the development of target and context-specific messages that cover all stages of the target group 'sales process'.
- **Plan Management:** In considering the management of the exploitation activities and plan itself, we have identified 13 main perceived risk factors and discuss checkpoints as well as corrective measures. We have also identified 12 success criteria and their corresponding metrics.

Levels of the Exploitation Plan

Exploitation of ACGT outcomes is envisaged both at the consortium level and at the level of individual partners. While both levels fall under the general remit of the project, the former will be the main focus of the exploitation plan during the lifetime of the project, individual partner activities being 'exploited' for the collective purpose on an "as needed" basis and reported in subsequent updates of this plan.

Exploitation Plan Initiatives

We believe that in addition to the stakeholder targeted actions we envisage, we can raise awareness of the ACGT effort more effectively by organising 2 initiatives as follows:

- The **ACGT Ready Initiative:** this will help create an ACGT brand, that will not only provide a mechanism for guaranteeing compatibility and compliance with the ACGT technical standards but will also represent a label by which 3rd parties will be able to differentiate their ACGT compatible offerings in return for the investment they will need to make to develop these offerings.
- The **ACGT Competition Initiative:** in addition to raising the public profile of the project, this initiative addresses the requirement for the development of a sufficient number of modules and prototypes that will help demonstrate practical utility to end users.

1 Scope of the Exploitation Plan

1.1 Exploitation within the scope of ACGT

ACGT was conceived with the goal of providing information technology solutions to support clinico-genomic clinical trials and knowledge discovery, the ultimate goal being individualised medicine and healthcare delivery. To achieve its mission, ACGT will provide open source resources and infrastructure that target all major groups with an interest or stake in clinical trials and research in a post genomic environment.

WP16 is tasked with the objective of ensuring that most project results will be used by the appropriate stakeholder groups, especially after the project ends so as to maximise Return On Investment (ROI) and ensure that the project's goals and objectives are served beyond its current contractual timeframe.

In the context of our objectives and plan, exploitation is taken to mean any use of outcomes (resources and services) that are developed within the project, by third parties or indeed consortium members out with the framework of the project itself and more importantly after its official end.

Exploitation is seen to be very tightly linked with the dissemination and training activities of the project and therefore this document should be read in conjunction with the corresponding documents from work packages 14 (deliverable D14.1) and 15 (deliverable D15.2)

1.2 Purpose of the Document

The purpose of the document is to provide a formal instrument that will describe, guide and coordinate all project activities that relate to the exploitation of project results. At its heart, the exploitation plan aims to answer the following six principal questions:

- Who are the main stakeholder groups that are involved in clinical trials and could therefore be seen as potential 'customers' of ACGT results?
- What are the exploitable results that ACGT aims to deliver?
- In what ways can we exploit the ACGT results?
- How do we "get the message across" to each stakeholder?
- When and in what sequence do we take each action?
- How do we measure success and ensure use of outcomes post project end?

While each partner is encouraged to take those actions that best fit their capabilities and objectives, they are also encouraged to coordinate their efforts with others since it is felt that in this manner they will be able to take advantage of any synergies and benefits of the critical mass that the project affords. With this in mind, the document also hopes to provide a tool for achieving this coordination by helping to deliver consistent messages, planning the delivery of results and timing activities to reflect the status of the project.

1.3 Who is this document for?

The primary target audience of this document are partners who aim to exploit their results and wish to do so in the framework of the project, taking advantage of the synergies and critical mass afforded by the ACGT consortium. This document however is also addressed to the Project Management Board (PMB) which is responsible for over-viewing exploitation activities and ensuring that they unfold in sync with the other activities of the project.

By presenting exploitation actions and goals in the context of the project, the document targets “exploitation” and “business development” personnel who are tasked with developing the requisite exploitation materials and implementing the elements of the plan for their respective organization.

It is also a tool for the WP Manager since it allows forward planning of actions, supports their coordination and provides a mechanism for assessing work done to date.

1.4 Structure of the Document

This document is arranged in 7 chapters that discuss main parameters that have impacted the design of the exploitation plan as well as laying out the plan itself, the intention being to allow this document to be used as a tool for managing the implementation and assessment of exploitation activities for the remainder of the project. More specifically:

Chapter 2 discusses models that have been used in the context of exploiting open source and/or freeware cores. This we believe is relevant since ACGT will be producing open source modules in addition to the grid infrastructure itself.

Chapter 3 continues the ‘background analysis’ of Ch.2 by discussing basic dimensions and levels of the exploitation plan. These are effectively the main parameters that we consider to influence most the design of the specific activities we envisage.

Chapter 4 discusses the main stakeholder groups we have identified as having a significant interest in connection with clinical trials and supporting IT infrastructure and covers exploitation activities at the consortium level.

Chapter 5 then proceeds to view exploitable outcomes and actions from the individual partner perspective while Chapters 6 and 7 present two specific initiatives we have conceived of with the aim of creating a strong branding for ACGT (the **ACGT Ready** initiative) and increasing awareness beyond what is possible through smaller targeted actions (the **ACGT Competition** initiative)

Chapter 8 concludes the presentation of the exploitation plan by discussing management related aspects. It presents risk factors we have identified as well as success criteria and metrics we shall use to assess the progress and overall achievement of our work.

Finally, this document includes a collection of appendices that contain useful information relating to WP16.

1.5 Document Versions and Update Procedure

While this document presents the overall plan as it stands at the present time, it is regarded as a “live resource” that will evolve as the project unfolds.

Future version will be released annually and will include updates on achievements to date as well as any new actions that have been identified in response either to the results of earlier actions or of new findings and goals that transpire in the interim periods.

All communications regarding the current version or future amendments should be sent directly to Andreas Persidis, Biovista at andreasp@biovista.com and copied to acgt-wp16@inria.fr .

2 Exploitation Models

2.1 Introduction

The exploitation goal of ACGT is challenging in that in addition to the actual use of project outcomes by the intended end users (a form of exploitation) we are considering the option of the *commercial* exploitation of what is essentially a freeware/open source product.

Within this seemingly paradoxical context, we explore in this chapter various existing models for the exploitation of freeware/ open source and identify key characteristics that the open source or freeware cores share that make their commercial exploitation viable.

Based on this analysis, the chapters that follow put forward a plan of action for ACGT that is ambitious yet reflects the special considerations imposed by the project's open source nature.

2.2 Exploitation Models of Open Source

While the concept of open source does not at first sight lend itself to commercial exploitation a number of models already exist that demonstrate that it is possible for commercial enterprises to create viable businesses on the basis of freeware. In what follows we present some of the better known examples and identify some of the important characteristics that must be present for such models to be viable. These characteristics will in turn become requirements of the ACGT infrastructure.

Adding value to freeware/open source cores

In this model a for-profit company takes a freeware/ open source core and adds value by providing amongst others custom packaging, other customization, technical or other support, and documentation. An example here is Cygnus Solutions which provides commercial GNU development tools. Another example are Red Hat, Mandrake and SuSe (amongst roughly 383 at the present time) who offer their own versions of Linux.

Using expertise to offer services on open source core

In this model, developers of the open source leverage their expert knowledge of the core to offer value adding products/services. An example here is Apache which is run by a group of 13 co-equal developers where each an use their own and their group's knowledge of the core to offer additional products/services.

Aggregating open source in a specific mix

In this model, a provider mixes a number of open source modules to provide a new service/package that addresses a need that none of the open source elements on their own address completely. The basis of this model is 'convenience' as well as the value represented by the particular mix of capabilities.

Collaborative Development

Asynchrony.com (<http://www.asynchrony.com/>) is a US site which enables software developers around the globe to meet each other, collaborate on software programs, and share in the revenues of the products they create. The site is keen to emphasize its ability to provide a rapid beta testing mechanism presumably aided by the fact that beta testers share in revenues generated through eventual software sales.

Selling access to the infrastructure

In this model the popularity of a service/product that is based on a freeware core attracts third parties that are willing to pay a fee for the privilege of being associated in some way with the infrastructure. Examples of associations are advertising of their own (presumably related) products/services and the linking of their own (for fee) products/services that add value to the freeware core. While not freeware the Google site is an example of an infrastructure that attracts 3rd parties who advertise their products/services.

2.3 Characteristics of models building on Open Cores

Examining the examples mentioned above it is possible to identify a few core characteristics that are common to all and that make possible the exploitation of the cores by interested parties. These characteristics are the following:

1. *Solve a problem that lots of people care about*: in all successful cases of freeware cores that have been exploited commercially, both the core itself and the value adding products/services address an important problem that affects a large number of people. Linux is an example at hand and therefore in the case of ACGT the consortium should ensure that the ACGT infrastructure works 'as advertised', especially for the end users.
2. *Modular design*: this means that the core offers a lot of possibilities for creating value-adding products/services and does not constrain 3rd parties in un-necessary ways, odd formalisms or standards. A strong plug-in interface seems to be a prerequisite here since it allows many contributors to join.
3. *Facilitate 3rd parties as much as possible*: this boils down to providing excellent APIs, documentation, examples and in general all the support that a 3rd party needs in order to adopt and build on the freeware core. The more comprehensive this support package the better the chances of adoption will be.

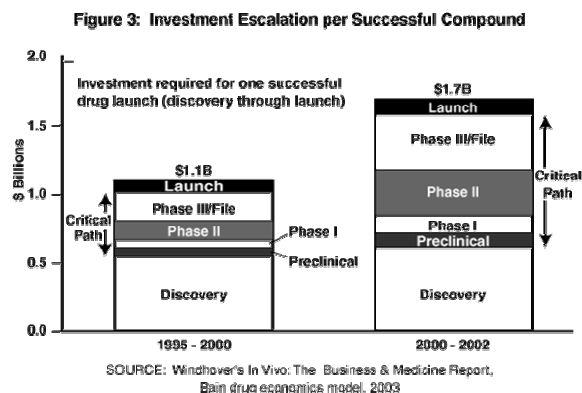
3 Basic Dimensions and Levels of the Exploitation Plan

Why do we need an exploitation plan if the core objective of ACGT is to develop resources and infrastructure that will be open source (i.e. freely available to anyone)?

While this might seem a trivial question, it is useful to keep in mind the answer since it helps clarify our objectives and provides a basis for identifying the main dimensions and parameters of the plan.

ACGT needs an exploitation plan for 4 main reasons:

- First, ACGT will be competing with other similar initiatives (present and future) for end users' attention. While open source that is freely available opens doors, end users must firstly be aware and secondly be convinced of the benefits of choosing ACGT over other offerings to support them in their daily activities. One main goal of the exploitation plan must therefore be to achieve the level of persuasion that will get ACGT outcome "through their door".
- Second, ACGT outcomes, like other similar offerings, will not be truly "free". End users will be required to invest time and intellectual effort to understand, adopt and use them in their daily activities and workflows. Identifying those groups for which this investment is most likely to pay off becomes therefore a significant goal.
- Third, ACGT is a multi-faceted initiative. It is not only about infrastructure, or about s/w modules but about providing a variety of resources and capabilities that can *collectively* lead in the long term to better, personalised health care. Only by making progress in most of these facets simultaneously can we hope to attain the sought after levels of use *out with the confines of the consortium itself and after the end of the 4 year funding period*.
- Fourth, clinical trials are becoming an increasingly important element of the drug development process representing a growing percentage of the overall cost of circa 1.7B\$ (2002 figures) that is typically needed to take a new compound to the market. This is graphically shown in figure 3.1 below and shows why clinical trials represent a central element of the US-FDA's "Critical Path" initiative.



The figure shows one estimate of the total investment required to "launch" (i.e., market) a successful drug in two time periods. Most of the recent cost increases are within the "critical path" development phase, between discovery and launch.

The overall increase between 1995 - 2000 and 2000 - 2002 is estimated to be 55 percent.

Figure 3.1 The increasing cost of developing new medications

The soaring costs of clinical trials offer ample justification for any initiative that aims to streamline the process, reducing time and cost, and therefore represents an excellent opportunity and basis for exploiting the outcomes of the project.

With the above in mind we have designed the ACGT exploitation plan in terms of *dimensions* and *levels* that serve to organise activities in a focused and systematic way. Sections 3.1 and 3.2 discuss these respectively. We have also conceived of two initiatives that will help raise the profile of the project. These are introduced in Section 3.3 and presented in detail in chapters 6 and 7.

3.1 Exploitation Plan Dimensions

Exploiting project outcomes successfully cannot be achieved in a generic manner, or as an afterthought towards the end of the project. We recognise that exploitation takes time, requires following up with the 'customer' and in an age of numerous choices and information overload must be highly targeted and context specific.

We identify therefore the following main dimensions that have shaped the ACGT exploitation plan.

Stakeholder Groups: while ACGT is primarily an IT infrastructure project, it addresses a number of 'end users', which we collectively refer to as 'stakeholder groups', with an interest in a variety of aspects surrounding clinical trials in a post-genomic environment. Each group has slightly different priorities and represents different 'user requirements'. From an exploitation viewpoint however, they can all impact the eventual success or failure of ACGT and therefore it is important to identify them and target our exploitation actions accordingly. We have identified the following stakeholder groups:

- Clinicians
- Biology/Biomedicine Researchers
- Patients and Patient Advocacy Groups
- Software developers and other vendors
- Regulatory Bodies
- Consultants
- The General Public

Chapter 4 discusses each of these in turn and presents our planned activities that target them.

Outcomes: these are the expected results of ACGT and represent what we have to offer to the various stakeholder groups. Different groups will have different needs for the various outcomes and it is important to correctly match the two together so as to maximize chances of successful uptake. Outcomes are presented in Ch. 5.

Timing: ACGT results will not be delivered at a single point in time but progressively as the project unfolds. Given also that 'sales' of complex, knowledge-intensive offerings take time, the question of when we present what to whom becomes an important consideration of the plan. The plan therefore accounts for this by organizing deliverables and actions over time. This organization is seen in Chapter 4, where the production of the so-called 'exploitation materials' is presented for each of the remaining 3 years of the project

Messages: Communication is a major part of any exploitation (sales) activity. It helps establish initial awareness of the exploitable outcomes of the project and more importantly helps convert *potential* users into *actual* users of ones offerings. Once again messages must be highly customised in order not to be discarded by target audiences. Deliverable 15.2 discusses the content of the initial awareness messages per stakeholder group. Chapter 4 of this deliverable presents the broader framework for the development of additional target and context-specific messages that cover the subsequent stages of the 'sales process'.

Target Achievements: No plan is complete from a management point of view without stated goals and performance levels. In Ch. 8 we therefore discuss the management of the exploitation plan covering main perceived risk factors as well as success criteria and metrics that we feel represent the nature of ACGT as an EC co-funded project.

3.2 Exploitation Plan Levels

Like with all EC projects, exploitation of ACGT outcomes is envisaged both at the consortium level and at the level of individual partners. These two levels are not considered incompatible or going against the spirit of the project since activities and results at one level can complement those at the other.

While both levels fall under the general remit of the project, the former will be the main focus of the exploitation plan during the lifetime of the project, individual partner activities being 'exploited' for the collective purpose on an "as needed" basis and reported in subsequent updates of this plan.

3.2.1 Consortium Level Exploitation

By 'consortium level' exploitation we understand all actions that will be taken by the partners *collectively* to promote and exploit ACGT as a single initiative.

While the option of creating a single commercial entity ("ACGT NewCo") still remains open and under discussion, at this point in time it is not being pursued. Past experience has shown that with large consortia that represent a wide and often non-converging spectrum of interests, creating such a NewCo especially during the lifetime of the project is not a realistic proposition.

Chapters 4, 6 and 7 therefore discuss in detail the main elements of the plan at the consortium level.

3.2.2 Partner Level Exploitation

By 'partner level' exploitation we understand all actions that will be taken by ACGT partners either during or after the project's end to promote and exploit their work.

Activities at this level are most likely to occur post-project. Nevertheless in some cases they may occur during the project itself taking advantage of the critical mass of the consortium but also helping the collective goals.

Chapter 5 discusses in detail the organization of exploitable results and specific partner level exploitation activities as they have been expressed until the present point in time. Subsequent versions of this plan will report any developments that take place.

3.3 Exploitation Plan Initiatives

We believe that in addition to the stakeholder targeted actions we envisage we can raise awareness of the ACGT effort more effectively by organising 2 initiatives as follows:

- The **ACGT Ready Initiative**: this will help create an ACGT brand, that will not only provide a mechanism for guaranteeing compatibility and compliance with the ACGT technical standards but will also represent a label by which 3rd parties will be able to differentiate their ACGT compatible offerings in return for the investment they will need to make to develop these offerings. The ACGT Ready initiative is discussed in detail in Ch. 6.
- The **ACGT Competition Initiative**: in addition to raising the public profile of the project, this initiative addresses the requirement for the development of a sufficient number of modules and prototypes that will help demonstrate practical utility to end users. The ACGT Competition initiative is discussed in detail in Ch. 7.

4 Stakeholder Groups

4.1 Introduction

Identifying major groups with an interest and stake in post genomic clinical trials and their supporting technologies and services is of course one of the main goals of an exploitation plan. Not only does it ensure uptake of eventual project results but also it helps direct project work and takes advantages of synergies that can help with the establishment of the ACGT infrastructure as a point of reference in the space.

We have identified 7 main stakeholder groups that will be targeted for exploitation activities, as follows:

- Clinicians
- Biology/biomedicine Researchers
- Software Developers and Vendors
- Patients and Patient Advocacy Groups
- Regulatory Bodies
- Consultants
- The General Public

Deliverable 15.2 discusses why each of these groups has been targeted and the dissemination messages that will be communicated to each. In the sections that follow we discuss each group using the following format:

- **Why:** this explains why each group is important from the exploitation viewpoint.
- **Aim of the exploitation activities:** this describes what we hope to achieve from an exploitation viewpoint with each group.
- **What does ACGT offer to this group:** lists what we envisage offering each group.
- **Terms of use:** discusses any conditions we pose to each group on the use of ACGT outcomes.
- **Materials:** this presents in a table format supporting exploitation materials that we plan to create as part of WP16. Exploitation materials are discussed as a function of specific exploitation objective which may differ from one group to another and in time as the project unfolds.

4.2 Clinicians

Why:

ACGT was conceived in large part to address important issues facing clinicians in connection with the use and management of information resources that promise to increase their effectiveness towards personalised medicine and treatment in a post genomic environment.

Aim of exploitation activities:

To convince them to use modules and services in their daily activities

What does ACGT offer to this group?

- Access to tools to help them perform their job such as:
 - Oncosimulator
 - Literature mining tool
 - Ontology browser
 - CRFs editors
- Legal resources
- Facilitation of SUSAR reporting
- Possibility to implement new Clinical scenarios in response to clinicians requests
- Support in connection with the use of biobanks and exchange of biological material in the context of clinical trials

Terms of use:

- Free with support during project. Support available after project end at developer's discretion
- Aim to elicit feedback in return where possible

Materials:

Exploitation objective	Year 2	Year 3	Year 4
Awareness ¹	<ul style="list-style-type: none"> • Introduction letter • Publications and presentations • 1-2 Prototypes • Case study elicitation • Resource user documentation • Terms of use document 	<ul style="list-style-type: none"> • As for Y2 but in addition show more prototypes and any Advanced Prototypes where available 	<ul style="list-style-type: none"> • As for Y2 but in addition show Advanced Prototypes where available
Trial use		<ul style="list-style-type: none"> • 2-4 Advanced Prototypes 	<ul style="list-style-type: none"> • 3-6 final Modules and services
Adoption		<ul style="list-style-type: none"> • Draft User Manuals 	<ul style="list-style-type: none"> • Case Studies Report(s) • User Manuals • Testimonials

¹ Throughout this chapter awareness refers to actions that aim to make ACGT known to the various stakeholder groups. Many of these actions will be coordinated with WP15 which will be creating dissemination and related materials that can be used for raising awareness of ACGT.

4.3 Biology Biomedicine Researchers

Why:

One of the main targeted functions of the ACGT infrastructure is to support biology and biomedicine researchers in knowledge discovery so as to accelerate understanding of biological processes and disease mechanisms. This has become increasingly important, especially in recent years where initiatives such as the “Critical Path” of the FDA aim to reduce the cost and time needed to take a drug candidate to market.

Aim of exploitation activities:

To convince them to use ACGT modules and services in their research labs.

What does ACGT offer to this group?

- Access to tools to help them perform their job such as:
 - Oncosimulator
 - Literature mining tool
 - Ontology browser
 - Bioinformatics applications
- Legal resources
- Support in connection with the use of biobanks and exchange of biological material in the context of clinical trials

Terms of use:

- Free with support during project. Support available after project end at developer’s discretion
- Aim to elicit feedback in return where possible

Materials:

Exploitation objective	Year 2	Year 3	Year 4
Awareness	<ul style="list-style-type: none"> • Introduction letter • Publications and presentations • 1-2 Prototypes • Case study elicitation • Resource user documentation • Terms of use document 	<ul style="list-style-type: none"> • As for Y2 but in addition show more prototypes and any Advanced Prototypes where available 	<ul style="list-style-type: none"> • As for Y2 but in addition show Advanced Prototypes where available
Trial use		<ul style="list-style-type: none"> • 2-4 Advanced Prototypes 	<ul style="list-style-type: none"> • 3-6 final Modules and services
Adoption		<ul style="list-style-type: none"> • Draft User Manuals 	<ul style="list-style-type: none"> • Case Studies Report(s) • User Manuals • Testimonials

4.4 Software Developers and Vendors

Why:

One of the objectives of ACGT is to offer an open source infrastructure that will allow third parties to contribute useful modules/services or use ACGT consortium developed modules/services in their own products. Third party software developers and vendors can help disseminate ACGT results and increase the group of active users, helping push ACGT towards becoming a recognised standard and resource in the field. Vendors can also provide future income or other benefits through the placement of advertisements on the ACGT web site. We envisage at least 3 distinct categories in this stakeholder group:

- Academic researchers who wish to research technologies and offer their own solutions
- Commercial Software developers who wish to offer their own products services or incorporate ACGT resources in their offerings
- Commercial medical or research instrument suppliers who wish to augment the capabilities of their offerings by making them compatible with selected ACGT modules/resources

Aim of exploitation activities:

- To convince them to provide their own modules and services that are *ACGT Ready*
- To convince them to use ACGT modules / services in their own offerings

What does ACGT offer to this group?

- An infrastructure and, if ACGT is successful, a standard which they can join in order to promote their own products and services
- Access to open source modules that they can incorporate in their own offerings
- Access to the collective expertise of the ACGT consortium and to all public project results

Terms of use

- Free with support during project. Support available after project end at developer's discretion
- Aim to elicit feedback in return where possible
- Aim to convince them to offer own modules under open source terms

Materials:

Exploitation objective	Year 2	Year 3	Year 4
Awareness	<ul style="list-style-type: none"> • Introduction letter • Publications • Terms of use document 	<p>As for Y2 but in addition offer</p> <ul style="list-style-type: none"> • new versions of the ACGT Ready Specifications • New System manuals 	<p>As for Y2 but in addition show Advanced Prototypes where available</p>
Own Module contribution or ACGT Module reuse	<ul style="list-style-type: none"> • "ACGT Ready" Specifications • Sample Code and system manuals 	<p>As for Y2 but in addition offer</p> <ul style="list-style-type: none"> • new versions of the ACGT Ready Specifications • New System manuals 	<p>As for Y3 but in addition offer</p> <ul style="list-style-type: none"> • new versions of the ACGT Ready Specifications • New System manuals
ACGT Competition	<ul style="list-style-type: none"> • Publication of ACGT Competition Call 	<ul style="list-style-type: none"> • The ACGT Competition 	<ul style="list-style-type: none"> • Incorporation of competition entrants' offerings to ACGT pool of resources • Optional rerun of the ACGT competition
ACGT Ready Certification		<ul style="list-style-type: none"> • Document describing the certification process 	<ul style="list-style-type: none"> • Certification of all available submitted resources
Placement of advertisements			<ul style="list-style-type: none"> • Advertisement cost schedule and contract documents

4.5 Patients and Patient Advocacy Groups

Why:

Patient Advocacy Groups (PAGs) can be powerful drivers for significant developments since they are often very active and well connected at multiple levels (medical, government, financial, regulatory). They tend to have strong and personal interests in seeing developments in the medical field of their focus and can help catalyze events. PAGs often have financial resources to back research efforts and could therefore be seen as a source for future work fields of ACGT.

Aim of exploitation activities:

To convince them to offer broad support (including dissemination and awareness) to ACGT and request their doctors to use ACGT resources and outputs.

What does ACGT offer to this group?

- Resources to help them support their members
- Helps them identify research projects
- Helps them manage research projects they fund (e.g. by identifying overlaps or synergies)
- Helps them indirectly to raise funds for more research (through the services they offer to their members and target communities)

Terms of use:

- Free during project.
- Aim to elicit end user needs, introductions to related initiatives and other support where possible

Materials

Exploitation objective	Year 2	Year 3	Year 4
Awareness	<ul style="list-style-type: none"> • Introduction letter • Publications • Demonstration materials • PAG needs elicitation letter 	<p>As for year 2 but, where appropriate, with additional</p> <ul style="list-style-type: none"> • Publications • Demonstration materials 	<p>As for year 3 but where appropriate, with additional</p> <ul style="list-style-type: none"> • Publications • Demonstration materials
Endorsement		<ul style="list-style-type: none"> • Tutorials for use of ACGT Resources • Materials for joint dissemination activities 	<ul style="list-style-type: none"> • Testimonials
Support			<ul style="list-style-type: none"> • Project proposal(s) to PAGs

4.6 Regulatory Bodies

Why:

Regulatory bodies such as EMEA and the FDA are coming under increasing pressure to streamline their approval process in order to reduce the cost and time needed to bring new drugs to market and meet their objectives of serving public health. Like PAGs they carry of course significant weight in the industry and should they adopt or endorse any of the ACGT outcomes, could help promote the project's own goals. Due to the nature of these bodies, the chances of achieving our 'exploitation objectives' with this stakeholder group are slim. Nevertheless it is deemed worthwhile to undertake at least some actions that are targeted towards them since they too can act as catalysts for further developments in the area.

Aim of exploitation activities:

To convince them to use ACGT resources or to make ACGT's own target end users aware of ACGT.

What does ACGT offer to this group?

- Access to tools to help them review drug applications
- Access to tools to help them create industry guidelines for the drug approval process
- Legal resources
- Facilitation of SUSAR reporting

Terms of use:

- Free with support during project. Support available after project end at developer's discretion
- Aim to elicit feedback in return where possible

Materials

Exploitation objective	Year 2	Year 3	Year 4
Awareness	<ul style="list-style-type: none"> • Introduction letter • Publications • 1-2 Prototypes • Terms of use document 	<ul style="list-style-type: none"> • As for Y2 but in addition show more prototypes and any Advanced Prototypes where available • ACGT Case studies 	<ul style="list-style-type: none"> • As for Y3 but in addition show Advanced Prototypes where available • ACGT Case studies
Trial use		<ul style="list-style-type: none"> • 2-4 Advanced Prototypes 	<ul style="list-style-type: none"> • 3-6 final Modules and services
Adoption	<ul style="list-style-type: none"> • Draft User Manuals 	<ul style="list-style-type: none"> • User Manuals 	<ul style="list-style-type: none"> • Regulatory Body Case Studies Report(s) • User Manuals

4.7 Consultants

Why:

The Consultants stakeholder group is understood to include Small-Medium Enterprises (SMEs), individuals or in general any third party that offers services that are related to or can take advantage of the exploitable results of ACGT and includes for example bioethics advisors, legal advisors, IT solutions consultants and others. Apart from making use of ACGT resources to offer a public service, this group can add value by creating important awareness opportunities and thus increase the user base of ACGT resources.

Aim of exploitation activities:

To offer them resources that promote their own activities, convince them to disseminate project results, contribute their own resources, and obtain relevant testimonials.

What does ACGT offer to this group?

- Access to resources to help them perform their job
- A focal point for offering their own services
- A focal point through which to advertise their offerings

Terms of use:

- Free with support during project. Support available after project end at developer's discretion
- Aim to elicit feedback in return where possible
- Payment options for advertising their offerings

Materials

Exploitation objective	Year 2	Year 3	Year 4
Awareness	<ul style="list-style-type: none"> • Introduction letter • Publications • Service submission document • Terms of use document • Mailing campaign 	<ul style="list-style-type: none"> • Mailing campaign 	<ul style="list-style-type: none"> • Mailing campaign
Trial use		<ul style="list-style-type: none"> • 2-3 Prototypes 	<ul style="list-style-type: none"> • 3-6 final Modules and services
Contribution of own offerings		<ul style="list-style-type: none"> • Support services by relevant ACGT consortium members 	<ul style="list-style-type: none"> • Support services by relevant ACGT consortium members
Placement of advertisements			<ul style="list-style-type: none"> • Advertisement cost schedule and contract documents

4.8 General Public

Why:

This stakeholder group is understood to include patients and/or their relatives who are not members of any PAG covering Wilm's tumour and breast cancer, as well as the general public with an interest in the focus areas of ACGT.

Aim of exploitation activities:

To promote ACGT to other disease areas or new geographic regions, offer the public valuable resources, allow members of the public to join one of the running CTs.

What does ACGT offer to this group?

- Online resources of value to themselves or their loved ones

Terms of use

Free with support during project. Support available after project end at developer's discretion

Materials

Exploitation objective	Year 2	Year 3	Year 4
Awareness	<ul style="list-style-type: none"> • FAQs through ACGT Site • Publications 	<ul style="list-style-type: none"> • As for Y2 with new materials added 	<ul style="list-style-type: none"> • As for Y3 with new materials added
Promotion		<ul style="list-style-type: none"> • Document and process new patient referrals 	<ul style="list-style-type: none"> • Testimonials • Document and process new patient referrals

5 ACGT Exploitable Results

5.1 Introduction

A significant component of the ACGT exploitation plan concerns itself with activities that are broadly connected with the exploitation potential of the project but do not result in directly monetisable outcomes.

To help organise and manage these activities at the partner level (as opposed to the consortium level that was discussed in Chapter 4) we have created a framework that identifies exploitable results and categorizes them in groups according to their nature and intended purpose. This framework we believe helps to rationalise activities and tailor them according to audience-specific needs. This framework is presented in section 5.2.

With the framework in place we present in section 5.3 intended partner-specific activities.

5.2 Exploitable Outcomes

At the basis of the ACGT exploitation plan lie the foreseen outcomes of the project with '*exploitation potential*'. Given that ACGT intends to make freely available all its results and that it includes a mix of research organisations, for profit companies and Clinical Trials (CT) centres, we begin by defining what is meant by 'exploitation potential'. For the purposes of ACGT exploitation potential includes the following:

- use of a result in current organizational process(es) (e.g. by CT doctors or biology researchers)
- use of a result for educational purposes
- use of a result as a basis for further research
- use of a result as a resource for the scientific and CT communities
- use of result for direct/indirect promotional purposes
- use of one or more result as-is either as a stand-alone product (s/w) or service
- use of expertise acquired as the basis for additional products or services

With the above in mind ACGT exploitable outcomes can be arranged in one the following groups:

- **Software:** individual s/w modules, algorithms, subsystems or the entire ACGT s/w environment
- **Work practices:** usually internal processes that could be changed as a consequence of the introduction of project software
- **IP:** anything that is considered to have patenting potential [Note: Software as it is, is not subject to patents.. There are huge discussions ongoing whether

patents for “computer implemented inventions” which are (on principle) patentable should be used within the OS-community or not. This is one of the key issues in the discussion process on the next version of the GPL.publications: any articles, white papers etc.]

- **Educational materials:** for example course materials developed by academic partners
- **Resources:** web site, lexical resources that could be used by the NLP community, ontologies and such
- **Real estate:** selling space on the ACGT portal
- **Infrastructure:** selling access to the ACGT infrastructure
- **Expertise:** for example know how on legal and ethical issues connected with CTs and related activities, or know how on developing modules that are *ACGT Ready* (see Ch. 6)

For each of these groups we list the outcome, the intended exploitation and envisaged target groups. The table below lists the current status of the results identified to date by the partners. The “Exploitation” and “Target Group” columns indicate in parentheses the partner(s) interested in performing the exploitation and targeting the specific group(s) irrespective of the origin of the result.

#	OUTCOME	EXPLOITATION	TARGET GROUP
SOFTWARE			
1	ACGT Grid Mining Module (FHG)	Customized distributed Data Mining Services (FHG)	Industrial customers in need of Grid enabled Data Mining (FHG)
2	The ACGT Mediator	Database integration service (UPM)	Researchers, query tools developers (UPM)
3	ACGT query tools	Database access end-user tools (UPM)	Researchers, clinicians (UPM)
4	ACGT modules	Literature Mining service and product	Researchers, librarians, medical doctors, regulatory body examiners (IJB, Biovista)
5	Ontology Browser tool		Biomedicine Researchers, clinicians, (UPM, Biovista)
6	Oncosimulator	Optimization of cancer treatment on the patient individualized basis. Deeper understanding of the multilevel natural phenomenon of "cancer"	Clinicians Researchers Medical and science students Interested patients and/or parents

7	Ontology based TrialBuilder (including a CRF creator) (FhG-IBMT)		Clinicians, researchers (FhG-IBMT, USAAR)
WORK PRACTICES			
8	Best practice biomedical data analysis workflow	Biomedical data analysis services (FhG-IAIS)	Customers from biomedical industry (FhG-IAIS)
9	ACGT Architecture	Access to multilevel heterogeneous data (Philips)	Research and development (Philips)
IP			
10	Nothing foreseen to date.		
PUBLICATIONS			
11	Various Papers produced by consortium	Attracting research collaboration (FhG - IBMT) Indirect promotion (Biovista, FhG) Attracting researchers in the ethical/legal domain (UHANN)	Academia and industry (ERCIM) Existing and potential customers (FhG, Biovista).
12	Scientific papers, posters and demos in scientific events	Awareness (FhG – IBMT - UPM) Knowledge creation and exchange (Philips)	Researchers as potential cooperation partners and 3 rd parties as potential early adopters (IJB – UPM - FhG) Scientific and technical communities (Philips)
EDUCATIONAL MATERIALS			
13	Tutorials	Offer to interested users of the ACGT infrastructure Internal visibility (Philips)	CT doctors (Saarland, IJB) Peers (Philips)
14	Case studies for legal education in data protection	Offer to law schools/students (UHANN)	the legal/ethical community (UHANN)
15	Mediator services documentation	Offer to developers interested in using the mediator (UPM)	Researchers, software developers (UPM)
16	Query tools manuals	Offer to people interested in querying integrated database system through a GUI (UPM)	Clinicians, researchers (UPM)
17	manual for ontology based TrialBuilder	Offer to people interested in setting up a clinical trial and in	Clinicians, researchers ((FhG-IBMT, USAAR, UPM)

	(including a CRF creator) (FhG-IBMT)	creating CRFs through a GUI (FhG-IBMT, USAAR) Offer to people interested in creating CRFs through a GUI (UPM)	
18	Training Materials on Gridge, Globus etc	Training services	S/W developers, IT departments in hospitals, pharma/biotech companies etc. (Siveco, Poznan)
RESOURCES			
19	Clinical Trials Ontology	Add to company product(s) (FHG – IBMT (ontology based CRF Creator))	Users of company products (Biovista)
20	CRF CREATOR		(IJB)
OTHER			
21	Web Site	Selling advertising space on the web site (ACGT Consortium)	Interested 3 rd parties such as pharmaceutical companies, reagent companies, vendors of nutraceuticals. (ACGT Consortium)
22	ACGT infrastructure	Selling access fees for right to link to ACGT infrastructure (ACGT Consortium)	3 rd party software vendors (ACGT Consortium)

Table 5.2.1: ACGT Exploitable results

5.3 Partner-specific Activities

In addition to exploitation activities to be carried out at the consortium level, a number of partners intend to exploit project outcomes individually. Table 5.3.1 presents a summary view of the planned exploitation activities foreseen by the various partners to date.

Some partners have also provided at this stage more specific plans and these are presented in the end of the section. As other partners clarify their own plans, these will be added to future versions of this document.

Exploitation-Related Activity	BIOVISTA	LJB	UHANN	PHILIPS	UPM	FHG-IAS	FHG - IBMT
Integrate one or more ACGT technologies into own system for internal use	X	X			X	X	X
Integrate one or more ACGT technologies into own system to create a s/w system to be sold externally/used in other public services							
Integrate one or more ACGT technologies into own system to create a service to be sold externally/used in other public services	X				X		X
Pursue OEM agreements							
Demonstrations to Industry/other public services of ACGT system (or part thereof) with goal of selling/promoting	X					X	X
Demonstrations to Industry of own ACGT-developed modules with goal of selling		X					X
Demonstrations to Academia of own modules to attract research collaboration	X	X	X	X	X	X	X
Demonstrations to Academia of ACGT as a whole to attract research collaboration	X		X			X	X
Demonstrations of own modules to industrial recipients to attract a cooperation towards a recipient-specific business solution			X	X		X	X
Development project to create industrial prototype (2 or more partners take some ACGT result(s) and work together to make the system more robust, better, bigger etc.)	X						X
Patent Search							X
Patent Application							
Presentation at research/trade fora to create early awareness	X	X	X			X	X
Presentation to existing clients / collaborators to create early awareness			X			X	X
Paper publications for exposure / dissemination	X	X	X	X	X	X	X
Re-use of methodologies			X	X	X	X	X
Feedback and input to standards			X	X			
Internal development project to create systems based on ACGT technology in other application areas as the initial case studies				X			
Consider extensions of the project into various dimensions						X	X
Demonstrations to customers and visitors				X			

Table 5.3.1: Summary of currently planned partner specific exploitation tasks

ICCS NTUA

ICCS is expected to have a reasonable share of the financial profits deriving from the eventual commercial use of the Oncosimulator. This expectation is based on the fact that ICCS will have provided highly specialized know-how during the Oncosimulator's development and testing procedures. It is noted that ICCS-NTUA has been developing this special knowledge during the last ten years and any financial profits will support its ongoing research activities.

Furthermore, the Oncosimulator will be used as a biomedical engineering education tool within the School of Electrical and Computer Engineering, National Technical University of Athens of which ICCS is a research entity.

Biovista

Biovista will be offering versions of its BEA Literature Mining and Knowledge Discovery tool to the ACGT grid users as well as other similar communities. In particular as per its current business development strategy the company aims to offer both licenses to its tool and services based on the use of these tools.

The ACGT community will be used as a case study, the aim being to attract special interest groups (in areas of cancer but also others such as neuroscience) including Patient Advocacy Groups such as "Autism today" with which already Biovista has had initial contacts at the Society for Neuroscience '06 annual conference in Atlanta (USA).

In addition to its existing tools Biovista is considering the development of an 'educational' version based on its core technologies. This would be used by medical doctors and patients alike in the course of the treatment and would involve a collaboration with Saarland and 3rd parties with required expertise. Biovista is adopting an 'early awareness' plan so as to be in a position to report tangible results by the end of the project.

6 The ACGT Ready Initiative

6.1 Justification

Branding is an important objective of any new offering, since it provides a mechanism that enhances recognition of that offering, thereby supporting its adoption within the end user communities.

With the **ACGT Ready** initiative we aim to establish a certification procedure that

- Ensures compliance of all services with the ACGT standards including interoperability, compatibility and end user utility.
- Provides a qualification that 3rd parties can use for their own purposes and that to a degree protects their investment in the development of their ACGT-ready offerings.
- Offers a distinct label that can be used for the promotional purposes of the project

6.2 Description

The ACGT Ready initiative is aimed at 3rd party s/w developers who wish to integrate their modules/services with the ACGT infrastructure. We aim to take appropriate actions to develop the branding of “ACGT Ready” so that it becomes a recognizable and sought after mark in the wider community. Work for this initiative will be coordinated by the ACGT Ready Board (ARB) whose members will be confirmed in the next PMB meeting.

Work for this initiative will include:

- **Creation of an ACGT Ready Introductory document:** this will allow interested parties to understand the aim and scope of the certification process as well as the benefits to interested parties.
- **Creation of a Submission Guidelines document:** this will outline all actions necessary for preparing and submitting a s/w module to the ACGT Ready certification process.
- **Creation of ACGT Ready Specification documents:** this will be one or more documents that will describe technical requirement of ACGT Ready applications as well as guidelines for developing such applications.
- **Creation of an ACGT Ready Maintenance document:** this will describe the possible evolution of the specification and the maintenance and other obligations of 3rd parties.
- **Creation and maintenance of an FAQ list:** a Frequently Asked Questions list will be created and maintained on issues relating to the ACGT Ready certification and published on the ACGT web site.

The ACGT Initiative depends on a number of technical specifications being available and relatively stable. For this reason tight collaboration with all technology providing work packages will be essential.

While work will begin during year 2 of the project, public roll-out of the initiative is expected sometime within the first half of year 3 (depending on technical progress and difficulties encountered). Nevertheless work on the Introductory Document, the Submission Guidelines document and the FAQ list will be undertaken in year 2 and continue through years 3 and 4 to reflect technical developments during the later stages of the project.

7 The ACGT Competition

7.1 Justification

ACGT being an infrastructure type initiative its success depends on its widespread adoption by the broader community of software and other resource providers for delivery of their own offerings.

Like other initiatives in this category it is subject to network economies in which the value of an offering increases exponentially as the number of users who adopt it increases. Network economies are well known for the initial time lag between initial availability and the hoped for exponential rise in the user base. For this reason, any action that accelerates initial uptake is of strategic importance. This becomes even more important in the case of ACGT, where the offerings themselves (infrastructure, services and other resources) will only begin to appear towards the end of the project, allowing very little time for uptake to occur in any significant degree during its lifetime.

In addition to being an infrastructure project, ACGT aims to support clinicians, biology researchers and other 'end users' in their daily activities, where the IT component is only a small part of their daily workflows. For this group solutions must be as transparent as possible and offer real value, if they are to stand a small chance of being introduced in existing working environments. It therefore becomes important for ACGT to ensure a sufficient number and scope of resources and modules that will be usable by the end users and will offer a solution to actual, present and pressing needs they have.

ACGT technology developing members "have their hands full" making their selected modules compatible with the unfolding infrastructure as this will gradually be deployed during the remaining periods of the project. It is therefore believed that external parties should be sought and convinced to develop additional modules and services that will complement the ones already being designed and developed.

7.2 Main Elements of the Competition

With the above in mind, we have conceived of the ACGT Competition as follows:

- **Aim:** to attract as many 3rd parties as possible and have them develop and submit *ACGT Ready* applications and resources that will subsequently be available to interested 3rd parties and end users.
- **Target group:** the competition will be open to all interested parties. Emphasis will be given to academic institutions although no group will be excluded.
- **Competition categories:** ACGT faces technical and other challenges in a variety of areas including identification of use cases, availability of useful services and others. The nature and number of the categories will be analysed and decided by the ACGT Competition Board (see below). Examples of competition categories to be considered are the following:

- Most innovative use case
 - Most innovative service
 - Service using ACGT infrastructure most effectively
 - Most useful general resource
 - Etc.
- **Coverage:** No restriction on geographic origin of entries.
 - **Organization:** The ACGT Competition will be organized by an **ACGT Competition Board (ACB)** whose members will be confirmed in the next PMB meeting.
 - **Format:** Electronic submission (to be confirmed at a future PMB meeting)
 - **Award Ceremony:** Public with all finalists invited and expenses paid for each category winners.
 - **Location and time:** to be decided at a future PMB meeting.
 - **Prizes:** Cash (to be decided at a future PMB meeting - of the order of 1000-3000 Euros for winners). To encourage more participants to join, the monetary sum to be awarded will increase from a minimum amount linearly with the number of participants, each new participant adding, say, 100Euros to the total award until the agreed upon maximum is reached. The aim of this formulation is to encourage the viral spreading and adoption of the competition. Prizes in the form of PDAs, etc will be sought from event sponsors.
 - **Event announcement:** at various fora, blogs, bulletin boards and chat rooms, through the ACGT web site and in targeted publications
 - **Event Materials:** these will include the following
 - the document describing the competition itself
 - Expression of Interest form
 - Entry submission form
 - **Panel of Judges:** Well known professionals in a variety of fields will be invited. Judges will be sought primarily from industry and end user type establishments but also from academic institutions.
 - **Wining criteria:** To be finalised by the ACB. Criteria will emphasize utility to the targeted stakeholder groups (clinicians, biology researchers, PAGs etc) as well as novelty and scientific excellence.
 - **Sponsorship:** will be sought in the form of prizes for the contestants. Sponsorship of the ceremony will also be sought if deemed appropriate by the ACB.

8 Management of the Exploitation Plan

The implementation of the exploitation plan is itself a complex operation that for a project of this size needs to be closely managed in order to ensure the desired outcomes. With this in mind, we discuss here risk factors, success criteria and metrics associated with the exploitation of ACGT results. Finally Appendix 2 describes a 'communications materials matrix' that allows us to coordinate the generation of context specific exploitation materials during the various stages of the project.

8.1 Risk Factors

By risk factors we understand events, developments or actual exploitation materials that can lead to a "below expectations" adoption of ACGT offerings and work. These risk factors represent technological, human, commercial and working environment parameters and are presented in Table 8.1.1 together with check points and corrective measures we foresee.

	Risk Factor	Check Point	Corrective Measure
1	Preparation of exploitation materials falls behind schedule	Middle of year 2 and on a continuous basis thereafter	<ul style="list-style-type: none"> Tight management schedule and reallocation of resources if and where appropriate
2	Early prototypes fail to raise interest	At time of first deployment of prototypes – end of year 2	<ul style="list-style-type: none"> Actions to elicit feedback for assessment of reasons for failure
3	Use Case studies not convincing	At time of first deployment of prototypes – mid to end of year 2	<ul style="list-style-type: none"> Rationalization of case studies to ensure they represent clear, present and important needs of ACGT's targeted end user communities Involvement of further end user groups
4	Final offerings fail to meet expectations	Years 3 and 4 of the project	<ul style="list-style-type: none"> Report listing reasons of failure, lessons learned and recommendations for other groups
5	Failure to identify and 'enlist' the most active PAGs	Year 3	<ul style="list-style-type: none"> Assessment of reasons and new plan based on findings, to be implemented in year 4
6	Legal/ethical impediments	Year 3 once use of	<ul style="list-style-type: none"> Realignment of objectives

	to widespread use	tools go beyond prototype demonstration phase	<p>and/or content of demonstrators</p> <ul style="list-style-type: none"> List of recommendations for s/w and other resource developers Recommendations/requests to groups dealing with legal/ethical issues
7	Personal agendas reduce adoption	End of year 3 and year 4	<ul style="list-style-type: none"> Actions to assess reasons of failure Realignment of demonstrators List of recommendations for s/w and other resource developers
8	Competing initiatives achieve critical mass or backing by important stakeholder groups overshadowing ACGT	Start of Year 3, once ACGT has obtained initial momentum and initial conclusions can be drawn. On a continuous basis thereafter.	<ul style="list-style-type: none"> Actions to assess reasons of failure Intensification of effort to establish alliances and recruit early adopters. Repeat of the ACGT Competition initiative in Year 4. As a final measure towards Q2 of year 4, intensification of effort to align ACGT with those initiatives ("If you can't beat them, join them" tactics)
9	Awareness efforts lag	End of year 2 and on a continuous basis thereafter	<ul style="list-style-type: none"> Identification of new target groups to contact Follow up actions with initial contacts Assessment and corrective actions by the PMB
10	Technological developments in the area of Grid services render ACGT options obsolete	Year 2 and on a continuous basis thereafter	<ul style="list-style-type: none"> Recommendations for adoption of alternative technological base

11	Failure to convince 3 rd parties s/w providers to contribute to ACGT	End of Year 3 and beyond	<ul style="list-style-type: none"> • Assessment of reasons and recommendations for corrective measures • Search and selection of additional 3rd parties whose priorities align with ACGT
12	Working environment and administrative complications hinder adoption	Year 2 at time of deployment of first prototypes in ACGT user partner working environments and on a continuous basis thereafter	<ul style="list-style-type: none"> • Assessment of reasons, recommendations for corrective measures and where appropriate relevant guidelines • Possible changes to case studies and/or prototypes
13	Legal and ethical considerations provide larger than expected restrictions	Year 2 at time of deployment of first prototypes in ACGT user partner working environments and on a continuous basis thereafter	<ul style="list-style-type: none"> • Report on exact nature and reason of difficulties. • Recommendations for action. • Reports to appropriate legal/ethical committees

Table 8.1.1: Exploitation Plan Risk factors

8.2 Success Criteria and Metrics

We discuss in this section main exploitation success criteria we have identified and appropriate metrics for each. Given the nature of ACGT, criteria selected aim to be 'realistic for EC projects' and are subject to the significant effort required on the part of partners actually being made available during periods 2-4 of the project.

#	CRITERION	METRIC
1	Trial end users, in User Partners using prototypes	At least 4 who are not in each partner's active ACGT team
2	3 rd parties submitting modules, resources or services	At least 3 that are not directly related to ACGT
3	PAGs	At least 1 for each of the medical conditions covered by ACGT
4	ACGT Awareness	As discussed in deliverable D15.2
5	Success of ACGT Competition	At least 5 groups entering the competition in its first incarnation. At least 15 groups entering the 2 nd incarnation if one is organised.
6	ACGT Ready Certifications	At least 1 by end of year 3. At least 3 by end of year 4.
7	Web site visits	As discussed in deliverable D15.2
8	Downloads/Use of available resources	At least 5 unique 3 rd party instances by end of project.
9	Knowledge discovery	At least 1 instance that is publishable and demonstrates the use of ACGT infrastructure to make important knowledge discovery or demonstrably accelerate existing process.
10	3 rd party publications mentioning ACGT outputs	2 by end of year 2 7 by end of year 4.
11	3 rd parties requesting advertisement space on ACGT web site	At least 3 by end of year 4.
12	Maintenance of ACGT after Year 4	Commitments or actual use after project end

Table 8.2.1: Exploitation Success Criteria and Metrics

9 APPENDICES

9.1 Appendix 1: Summary of Exploitation Actions and Deliverables for Year 2

This appendix summarises in list form the actions and expected deliverables that are planned for year 2 of the project. The availability column indicates the final date – in some cases (e.g. elicitation of more case studies) - materials might be produced earlier.

EXPLOITATION MATERIAL / ACTION	AVAILABILITY
Clinicians and Biomedicine Researchers	
Introduction letter	M17
Elicit more case studies where possible	M24
Introductory user documentation on ACGT resource usage	M18
Terms of use Document	M21
S/W Developers and Vendors	
Introduction letter	M17
Terms of use Document	M21
Sample code	M16
System Manuals	M24
Patient Advocacy Groups	
Introduction letter	M17
Demonstration Materials	M24
PAG needs elicitation doc	M21
Regulatory bodies	
Introduction letter	M17
Terms of use Document	M21
Draft User manuals	M24
Consultants	
Introduction letter	M17
Service Submission Document	M21
Terms of Use Document	M21
Mailing Campaign	M24
Public	
FAQ list	M16
ACGT Ready Initiative	
Introduction document	M18
Submission guidelines document	M21
FAQ list	M18
ACGT Competition	
Announcement Doc	M21

In addition to the above:

- All publications and s/w prototypes produced will be used on a 'where appropriate' basis
- Any documents or actions described as corrective measures in Section 8.1 will be produced if and when the need arises.

9.2 Appendix 2: Structured Approach to Generating Targeted Communications Materials

We have design a simple resource that supports a structured and verifiable approach to generating dissemination/exploitation materials that are targeted to specific audiences at different points in time reflecting current project progress and needs.

In general, the resource is based on the view that messages and materials should have a number of 'dimensions' that reflect the target audience, the goal of the communication as well as the status and objectives of the project and consortium at the time of their release.

With this in mind the following matrix will be used to select message content and also to identify missing messages that need to be generated. The most important dimension is the Target Group. The other dimensions are also shown.

In this matrix we define a 'CASE' to be a specific context that drives the creation of a communication material (e.g. a document, an email, a leaflet, a conference presentation etc.). Each case consists of one or more parameters (e.g. for whom, goal, level etc) that are covered in a single communication material. Using the matrix below we shall be in a position to identify important contexts to cover (e.g. C1, C2, C3 etc.) by the generation of appropriate materials and later on see which contexts are not covered by actions to date, allowing us to plan the generation of further materials.

MESSAGE PARAMETERS	CASE	C1	C2	C3	...
FOR WHOM					
Researchers					
Advocacy Groups/patients		X			
Vendors					
Regulatory Bodies					
Patients					
GOAL OF DOCUMENT/COMMUNICATION					
Awareness		X			
Contribution of X					
Exchange of info		X			
Participation in ACGT event		X			
LEVEL					
Intro		X			
Detailed					
WHAT IS ACGT ABOUT					
Personalized medicine		X			
Improved treatment / diagnosis		X			
Wilm's Tumor		X			
Breast Cancer		X			
Other					
HOW ARE WE GOING ABOUT THE 'WHAT'					
Post-genomics research					
Combined genetic and clinical trials					
IT technologies and infrastructure		X			
Data Integration					
TECHNOLOGIES / RESOURCES USED					
GRID					
Document mining					

In the example shown (see case C1) a message aimed as an introduction to advocacy groups does not mention the technical details but what ACGT is about, simply mentions IT infrastructure as the approach and aims to raise awareness and explore possibilities of collaboration. A sample email/letter that was created based on this mix of dimensions and their specific content is shown below.

Sample email to the EuropaDonna PAG

In *blue italics* are comments explaining the structure of the email.

Dear Ms Solomon:

Why are we writing to the target recipient – what is this about

I am writing to you in connection with EuropaDonna, wishing to make you aware of the ACGT consortium and explore potential collaboration options.

Brief ACGT Background

Launched in February 2006, ACGT (Advanced Clinico-Genomic Trials) is an international collaborative project that aims to support clinicians and researchers develop personalized diagnosis and treatment. Comprising 25 research institutions, companies and organizations, and co-funded by the European Commission, ACGT currently focuses on 2 forms of cancer – breast cancer and Wilm's tumour (child nephroblastoma) – with other major conditions to follow in the future.

Part of email that makes it relevant to the target audience (customization)

With this email I would like to invite you to explore with me and our consortium possibilities for collaboration. Many of the 10 goals of ED are objectives of ACGT as well and I would hope to start a dialog with you in order to see how best to proceed.

Concrete Proposal

Examples of collaboration that spring to mind include anything from the mutual exchange of links to making resources mutually available, to participating in common events.

I trust you will find this interesting and look forward to continuing this exchange at your soonest convenience.

Sincerely

PS: For more information on the ACGT project, please browse our site at <http://eu-acgt.org>

9.3 Appendix 3: Person-Month Allocation

At 2% of the overall effort for Year 1, the exploitation work-package was relatively under-resourced. Nevertheless this is not perceived to have caused any problems, given that most effort in year 1 of ACGT was dedicated to understanding the problem and challenges at hand and developing the mutual understanding required for such a complex project to succeed.

This issue was recognised by the PMB and corrective actions have been taken as reflected in the submitted DoW for period 2 of the project.

Total allocated PM effort has more than doubled for Period 2 to a total of 36 PMs, up from 15 PMs for Period 1. This is deemed necessary given the extensive actions and 'exploitation materials' that are foreseen by the plan.

The following table summarises the PM effort per partner for period 2:

PARTNER	PMs
ERCIM	2
FORTH	3
INRIA	0
UvA	0
PHILIPS	2
UB	1
SIB	0
LUNDU	0
UMA	0
UPM	2
FHG	1
BIOVISTA	6
UOC	0
UHANN	0
PSNC	2
CUSTODIX	3
HEALTHGRID	3
ICCS	2
USAAR	2
SIVECO	2
FUNDP	0
UH	3
UOXF	2
UHOK	0
IEO	0

9.4 Appendix 4: Partner Contact Persons for Exploitation Issues

ORGANIZATION	#	NAME SURNAME	POSITION	EMAIL	TEL
ERCIM	1	Remi Ronchaud	Project Manager	remi.ronchaud@ercim.org	+33 4 92 38 50 12
FORTH	2	Manolis Tsiknakis	Principal Investigator and Leader	tsiknaki@ics.forth.gr	+30 2810 391690
FORTH	2	Angelina Kouroubali	Affiliated Research Scientist	kouroub@ics.forth.gr	+30 2810 391680
PHILIPS	5	Erwin Bonsma	Senior scientist	erwin.bonsma@philips.com	+31 40 27 42675
PHILIPS	5	Anca Bucur	Senior scientist	anca.bucur@philips.com	+31 40 27 44609
Jules Bordet Institute	6	Christine Desmedt		christine.desmedt@bordet.be	+32 2 541 31 07
UPM	10	Luis Martin		lmartin@infomed.dia.fi.upm.es	
UPM	10	Alberto Anguita		aanguita@infomed.dia.fi.upm.es	
UPM	10	Victor Maojo	Associate Professor	vmaojo@infomed.dia.fi.upm.es	+34 91 336 6897
FRAUNHOFER - AIS	11	Francois Perrevort		francois.perrevort@ais.fraunhofer.de	+49 2241 14 2723
BIOVISTA	12	Andreas Persidis	CEO	andreasp@biovista.com	+30 210 9629848
CUSTODIX	16	Brecht Claerhout	COO	brecht.claerhout@custodix.com	+32 9 210 78 97
ICCS NTUA	18	Georgios S. Stamatakos	Research Associate	gestam@central.ntua.gr	+30 210 7722288
ICCS NTUA	18	Dimitra Dionysiou	Researcher	dimdio@esd.ece.ntua.gr	+30 210 7722288
USAAR	19	Norbert Graf		Norbert.Graf@uks.eu	+49 6841 1628397
USAAR	19	Alexander Hoppe		Alexander.Hoppe@uks.eu	+49 6841 1628405
SIVECO	20	Radu Gramatovici	Project Coordinator	radu.gramatovici@siveco.ro	+40 21 3181200
UOXF	23	Prof. Adrian Harris	Director of Cancer Research UK	harrisa@cancer.org.uk	+44 1865 222443
UOXF	23	Francesca Buffa	Research Scientist	francesca.buffa@imm.ox.ac.uk	+44 1865 222443
INTERESTED PARTNERS WITH NO PMs					
IRI	14	Nikolaus Forgó		nikolaus.forgo@iri.uni-hannover.de	+49 511 7628159
IRI	14	Marian Arning		arning@iri.uni-hannover.de	+49 511 7628163
IRI	14	Tina Krügel		kruegel@iri.uni-hannover.de	+49 511 7628275
CRID - Notre Dame	21	Jean-Marc van Gyseghem	Senior Researcher	jean-marc.vangyseghem@fundp.ac.be	+32 81 72 52 12
CRID - Notre Dame	21	Jean Herveg	Senior Lecturer and Researcher	jean.herveg@fundp.ac.be	+32 81 72 47 68
CRID - Notre Dame	21	Cécile de Terwangne	Professor	cecile.deterwangne@fundp.ac.be	+32 81 72 47 72

Principal contact person in **bold**.

9.5 Appendix 5: List of Abbreviations

API:	Application Programmatic Interface
BEA:	Biolab Experiment Assistant. A software tool developed by Biovista for Literature mining
CT:	Clinical Trials
EMA:	European Agency for the Evaluation of Medicinal Products
FDA:	Food and Drug Administration
GUI:	Graphical User Interface
IP:	Intellectual Property
PAG:	Patient Advocacy Group
ROI:	Return On Investment
SUSAR:	Suspected-Unsuspected Serious Adverse Reaction