Consensus

Project Review Report (FP6) for NoE / IP

Project no	IST-2004-026996
Project acronym	ACGT
Title	Advancing Clinico-Genomic Trials on Cancer: Open Grid Services for Improving Medical Knowledge Discovery
Instrument type	Integrated Project
Thematic Priority	Information Society Technologies – ICT for Health
Start date of project	1 February 2006
Duration of project	48 months
Total Budget	16,747,206€
EC contribution	11,887,000€
Date of review	23-24 April 2007
Place of review	Poznan Poland
Period covered by review	from 1 February 2006 to 31 January 2007
Coordinator name	Bruno Le Dantec
Coordinator organisation	GEIE ERCIM
Name(s) of reviewer(s)	Olle Björk – David Ingram – Luca Toldo
Name of rapporteur	Luca Toldo

Introduction

The following template should be used by the independent reviewer(s) to draft the review report with the conclusions and recommendations following a project review.

If several reviewers are involved, it is preferable that a consolidated report be prepared by one reviewer chosen as 'rapporteur'.

Questions to be answered by the reviewer(s)

1.EXECUTIVE SUMMARY

With a short description on what the project is about. Includes key results and overall comments on the project's technical progress, management, and exploitation and whether it should: proceed as is, or proceed with some modifications, or whether remedial action is needed.

The ACGT project aims to deliver the cancer research community an integrated Clinico-Genomic ICT environment, through an integrated workplan. The environment is going to be validated with 3 ongoing clinical trials on Cancer. Although the final goal is the promotion of a European Biomedical Grid on Cancer, based on open source and open access; this project targets the results of this project for exploitation through the pharmaceutical industry. The project has focused key scientific and technological players, and has already delivered valuable state-of-the-art analysis of technologies and science in a variety of fields. A large momentum and a good communication environment had been established through the consortium, and all deliverables delivered in time. The management of the consortium have succeeded in enabling a quick start, through a highly communicative and cooperative management style. The primary end users of the targeted application areas are clinicians, which are being well integrated in the consortium and are providing guidance for their real needs. The project shall proceed with its current structure and mechanisms, however Project Management must provide a risk management and resource management of much higher quality. The next phase of the project will be the crucial phase, as it shall proof whether a unifying information ontology can be crafted that achieves the practical engagement of researchers and integration of research information that is necessary. Likewise, it shall verify whether the principles of the data protection framework proposed so far can achieve the level of trust required within the community that needs to be engaged, in terms of research subject consent and agreement from responsible parties to the terms of the various proposed data management contracts. The work plan for the second 18 Months is coherent with the aim of the project, and the proposed update to the Implementation Plan is satisfactory from scientific, technical and management point of views. At dissemination level, particular attention shall be given to further increase the visibility in the "cancer world", and in the ethical issues. Remedial actions shall be considered at the next review; where it is recommended to pay particular attention at resource usage.

2.ORGANISATION AND LOGISTICS

Comments on the review meeting: Were timing and schedule adequate? Were copies of the slides distributed in advance? Were demonstrations performed well?
Comments on the reports and deliverables received: timely reception, completeness, had the reviewers enough time to study the documentation?
Comments on the partners present at the meeting: were all there? (See list of participants, list of reports and deliverables & agenda (appended to this report)).

Comments:

It was an excellent meeting, with good logistic and technical support.
The presentation of work and demonstrators required 16 hours; while only 12 were scheduled.
Copies of the slides were distributed in advanced, demonstrators were excellent.
There was a representative for each WP.
The consortium reports shall strive for conciseness and avoidance of repetitions.

OVERALL OBJECTIVES OF THE PROJECT

Have the main objectives for the period been achieved?

Yes ☒ No ☐ Partially ☐

Comments:

The reviewers were very pleased to see the range of demonstrations of the work of the project as requested in the previous review; and that all the recommendations made there had been addressed.

Are the project's objectives (a) still relevant and (b) still achievable within the time and resources available to the project?

(a) Yes ☒ No ☐ Partially ☐

(b) Yes ☒ No ☐ Partially ☐

Comments:

The biobanking objective has been de-scoped, or at least postponed to a much later stage since the user community is not ready for it.
Legal, ethical and scientific conflicts of interests are not yet resolved.
Furthermore it requires a completely different infrastructure which is very costly.

Do you recommend changes in the objectives of the project in order to keep up with current state-of-the-art?

Yes ☐ No ☒ Partially ☐

Comments:

3.PROJECT WORKPLAN AND RESOURCES

A. WORKPLAN

Has the project as a whole been making satisfactory progress, notably in relation to the Description of Work (Annex I to the contract)?

Yes ☒ No ☐ Partially ☐

Comments:

This is a very ambitious project, and the review contained excellent demonstrations of outputs from all of the work packages.

Is the work planned in each work package (WPs) on schedule for the reporting period?

Yes ☒ No ☐ Partially ☐

Comments:

Have planned milestones and deliverables been achieved for the reporting period?

Yes ☒ No ☐ Partially ☐

Comments:

Future workplan: Is the work-plan coherent and are the timing of milestones and future activities of the project still valid?

Yes ☒ No ☐ Partially ☐

Comments:

B. RESOURCES AND EXPENDITURES

Have resources been deployed as foreseen in Annex I, overall and for each participant (**see Table 3 - Budget vs. Actual Costs and Table 4 - Person-months Status Table from the Periodic Management Report**)?

Yes ☐ No ☐ Partially ☒

Comments:

The deviation in resource usage (PM) from the planned has increased from the 1st ATR. However, the Project Coordinator gave sufficient explanations for this deviation.

Have expenditures been demonstrated as being economic and necessary for the work performed (Are expenditures consistent with the work achieved? Are the major cost items appropriate?)

Yes ☒ No ☐ Partially ☐

Comments:

4.WORKPLAN OF NoEs and IPs

A. WORK CARRIED OUT IN THE PREVIOUS REPORTING PERIOD

Has the overall *Implementation Plan* (IPs) or *Joint Programme of Activity* (NoEs) been adhered to as described in the *Description of Work (Annex I of contract)*?

Yes ☒ No ☐ Uncertain ☐

Comments:

2 Deliverables have been delayed, however the PM has justified the reasons.

For NoEs: Is there evidence of real integration and restructuring of activities between partners (to be evaluated against Indicators of Integration, e.g. exchanges of personnel, shared infrastructures, joint research and training activities, changes of research orientation of individual partners to better integrate into the NoE, etc).

Yes ☐ No ☐ Partially ☐☐ Not applicable ☒

Comments:

B. WORK PLANNED FOR THE NEXT 18-MONTH PERIOD

Is the proposed update to the *Implementation Plan* (IPs) or *Joint Programme of Activity* (NoEs) for the next 18-month period satisfactory
a. from scientific/technical point of view

Yes ☒ No ☐ Uncertain ☐

Comments:

b. from management point of view including use of resources

Yes ☒ No ☐ Uncertain ☐

Comments:

c. concerning non-scientific activities (dissemination, science-society issues, further integration etc)

Yes ☒ No ☐ Uncertain ☐

Comments:

Particular attention shall be given to larger involvement in the "cancer world", such as but not only presentation of the ACGT Project at various Cancer-related conferences.

5.CONSORTIUM PARTNERSHIP

Is there evidence of meaningful cooperation and integration between all the partners?

Yes ☒ No ☐ Partially ☐

Comments:

Have the partners contributed as planned to the project and tasks assigned to them?

Yes ☒ No ☐ Partially ☐

Comments:

Do you identify any conflicts or evidence of underperforming partners, lack of commitment or change of interest of any partners?

Yes ☐ No ☒ Partially ☐

Comments:

The Consortium presents in a confident and united manner.

Do you recommend changes in partnership?

Yes ☐ No ☒

Comments:

The master ontology is playing a fundamental role and the production of a maintainable and coherent system is scheduled for the next period. The evidence on the scalability of the master ontology is not yet convincing. The consortium should bear in mind the need for potential changes in partnership structure, should this become a more significant problem.

6.MANAGEMENT

Has the technical management performed as required (efficient, effective accomplishment of planned technical management tasks)?

Yes ☒ No ☐ Partially ☐

Comments:

The technical management is confident and appears to be very well respected within the consortium. There is a significant challenge in this area in responding to concerns of the experts regarding the master ontology, which is fundamental to the methodology of the project and to its expansion and sustainability.

Has the administrative and financial management performed as required (efficient, effective accomplishment of planned tasks, including proper handling of the consortium agreement, intellectual property rights, technical collective responsibility, sub-contracting, competitive calls)?

Yes ☒ No ☐ Partially ☐

Comments:

The project coordinator acted very sharply and responded very rapidly and constructively to requests by the experts.

Has (electronic) information and communication networks been established as required to support interactive working between the teams involved?

Yes ☒ No ☐ Partially ☐

Comments:

Latest technologies are being used such as Skype.

Is the consortium interacting in a satisfactory manner with other related 5th and 6th Framework projects or other R&D programmes addressing aspects of ERA, e.g., EUREKA, eTPs, etc)?

Yes ☒ No ☐ Partially ☐

Comments:

We have heard evidence of links with other current initiatives in this field such as @NEURIST, Healthgrid, Transbig, EGEE and others. This IP builds on a number of projects already funded by the EU, such as Intelligrid.

7. USE AND DISSEMINATION OF KNOWLEDGE

Does the project have significant exploitation potential?

Yes ☒ No ☐ Partially ☐

Comments:

The project has huge exploitation potential, in itself and as a "seed" for other applications in other cancer types and other diseases. It has the potential to revolutionise the way medicine is done and make personalised medicine a reality. Beyond these major goals, a number of areas of technological progress could be exploited before the end of the project.
The 2nd ATR delivered additional "low hanging fruits", which add to those mentioned in the 1st ATR, such as:

- Semantic integration of heterogeneous databases;
- GRID-enabled visualisation of molecular dynamic simulations for the drug industry;
- Text mining …

Is the Plan for the Use and Dissemination of Knowledge [please refer to the Guidance notes on Project Reporting in FP6 (Appendix 1) (see h:// lu/f 6/fin h m# ing) developing in a satisfactory manner?

Yes ☒ No ☐ Partially ☐

Comments:

The plan for the use and dissemination of knowledge is of very good quality, however the scientific outcomes which are planned are not as high-pitching as they could and should be, given the resources mobilised by the project.
The Project Manager shall target higher goals, according to the D15.2 and the spirit of the project.
The web site has been redesigned and targets potential users in a more appealing way.

Have the contractors disseminated project results and information as foreseen by the contract and the plan for dissemination and use of knowledge (publications, conferences…)?

Yes ☐ No ☐ Partially ☒

Comments:

The participation to conferences and production of books or proceedings has proceeded well, however scientific papers have reached only too rarely journals with a wide audience and high impact factor. The contractors shall strive for producing innovations of higher scientific and technological impact, inline with the project vision, as presented in the DoW.

Where relevant, are potential users and other stakeholders in the research being suitably involved in the project?

Yes ☒ No ☐ Partially ☐

Comments:

The project would benefit from wider sampling of stakeholders beyond the contractual partners.

8.OTHER ISSUES

Can you identify any policy-related regulatory issues emanating from the project at this stage?

Yes ☒ No ☐ Partially ☐

Comments:

EU regulation on clinical trials have evolved, particularly in paediatrics, and made implementation much more complex. The project shall pay particular attention to this issue.

Has promotion of gender equality been successful?

Yes ☒ No ☐ Partially ☐

Comments:

There is evidence of good contributions at all levels by both genders.

Have the science and society issues related to the topics of the Integrated Project been adequately handled?

Yes ☒ No ☐ Partially ☐

Comments:

The Project is going to touch very sensitive topics, particularly attention shall be given in the handling of genetic information in public (e.g. public web site).

Has the training programme being adhered to as described in the contract?

Yes ☒ No ☐ Partially ☐

Comments:

In the current status of the project, no explicit training programme was scheduled in the contract.

Is the project fulfilling its contractual commitments, if any, concerning ethics and safety?

Yes ☒ No ☐ Partially ☐

Comments:

Legal aspects of the consent framework are expanding from the actual trial to other uses. This is a major change from current practice and therefore should be tested with patients and clinicians beyond the confines of the project. Special attention should be given to specific requirements of national legislations and the comprehensibility of the language used in the consent forms.

9.OVERALL ASSESSMENT

☐ Unsatisfactory project (The project has failed to achieve critical objectives and/or is not at all on schedule)

☐ Acceptable project (The project has achieved most of its objectives and technical goals for the period with relatively minor deviations)

☒ Good to excellent project (The project has fully achieved its objectives and technical goals for the period and has even exceeded expectations)

Recommendations

☐ the project should continued without modifications

☒ the project should continue with the following modifications (technical or administrative):

Scalability and sustainability beyond the immediate objectives of the first 2 clinical trials needs additional focus in the coming period. Particularly, the master ontology and meta data standards.

Legal aspects of the consent framework are expanding from the actual trial to other uses. This is a major change from current practice and therefore should be tested with patients and clinicians beyond the confines of the project. Special attention should be given to specific requirements of national legislations and the comprehensibility of the language used in the consent forms.

Potential users and other stakeholders in the clinics are scarcely involved in the project. The project shall aim for higher visibility in the next period, involving the major players (e.g. CROs and Cancer trial groups).

The business exploitation of initial technological and knowledge achievements shall be pursued in a more active way.

☐ the project should be terminated (list main reasons):

Are there other issues you wish bring to the attention of the Consortium and/or the Project Officer?

Yes ☒ No ☐

Comments:

The next phase of the project will be the crucial phase, as it shall prove whether a unifying information ontology can be crafted that achieves the practical engagement of researchers and integration of research information that is necessary. Likewise, it shall verify whether the principles of the data protection framework proposed so far can achieve the level of trust required within the community that needs to be engaged, in terms of research subject consent and agreement from responsible parties to the terms of the various proposed data management contracts. Particular attention shall be given to further increase the visibility in the "cancer world", and in the ethical issues.

10. VISIBILITY ACTIONS

Please flag characteristics of the project which may be of interest to the Commission's services and visibility actions:

☒ high visibility/media attractive project

☒ project with an impact on EU policies

☒ project with a major role for women

☒ project with a significant impact on health, safety, environment

☒ project with ethical issues associated

☒ substantial breakthrough character

☐ significant impact on employment

☐ significant participation from outside EU

☒ involvement of the top researchers in the field

☐ involvement of the top economic actors in the field

Comments:

Name(s) and signature(s) of the reviewer(s):

Olle Björk

David Ingram

Luca Toldo

Date:

11.3 APPENDICES

Appendix 1

Status and approval of project reports and deliverables

Deliv. number	Title	Status (submitted/ delayed)	Accepted/ Rejected/To be modified	Comments	Deadline for (re) submissions
D1.2	Definition and guidelines for Quality Assurance Process	**Submitted**	Accepted		
D15.1	Project websites (internal and external)	**Submitted**	Accepted		
D12.1	Definition of the ACGT clinical studies according to the clinical scenarios	**Submitted**	Accepted		
D1.1.1	Six-Monthly Progress Reports	**Submitted**	Accepted		
D1.3	Project Handbook for *ACGT*	**Submitted**	Accepted		
D1.4	Risk Analysis of ACGT	**Submitted**	Accepted		
D2.1	User Requirements and Specification of the ACGT internal clinical trials	**Submitted**	Accepted		
D14.1	Functional & technical specification of the *ACGT* portal	**Submitted**	Accepted		
D3.1	The ACGT initial architecture	**Submitted**	Accepted		
D4.1	Report on security infrastructure	**Submitted**	Accepted		
D5.1	Consolidated requirements and specifications for data access	**Submitted**	Accepted		
D6.1	Consolidated requirements analysis report for data mining, analysis and the visualization environment	**Submitted**	Accepted		
D7.1	Consolidated requirements on Ontological approaches for integration of multi-level biomedical information	**Submitted**	Accepted		
D8.1	Consolidated Requirements (including information flows) of the in silico simulation models	**Submitted**	Accepted		
D11.1	Consolidation of security requirements of ACGT and initial security architecture	**Submitted**	Accepted		
D15. 2	Initial Dissemination plan	**Submitted**	Accepted		
D9.1	Integration requirements and guidelines	**Submitted**	Accepted		
D10.1	Production of informed-consent form in compliance with the clinical trials, post-genomic research and genetic data handling requirements	**Submitted**	Accepted		
D10.2	The ACGT ethical and legal requirements	**Submitted**	Accepted		

D12.3	Report on requirements for cross platform data integration	**Submitted**	Accepted		
D14.2	Visual prototype and report of the ACGT Portal	**Submitted**	Accepted		
D16.1	The ACGT Initial exploitation plan	**Submitted**	Accepted		

Appendix 2
List of participants

Name	Organisation
Remi Ronchaud	ERCIM
Manolis Tsinakis	FORTH
Norbert Graf (WP2 leader)	USAAR
Jarek Nabrzyski (WP3&4 Leader)	PSNC
Anca Bucur (WP5 Leader)	Philips
Stefan Rueping (WP6 Leader)	Fraunhofer
Luis Martin (WP7 Leader)	UPM
Georgios Stamatakos (WP8 Leader)	ICCS (NTUA)
Stelios Sfakianakis (WP9 Leader)	FORTH
Nikolaus Forgo (WP10 Leader)	LuH
Brecht Claerhout (WP11 Leader)	Custodix
Christine Desmedt (WP12 Co-Leader)	IJB
Andreas Persidis	Biovista
Holger Stenzhorn	IFOMIS
Francesca Buffa	University of Oxford
Yannick Legre	Healthgrid
Fatima Schera	Fraunhofer IBUT
Robert Belleman	University of Amsterdam
George Potamias	FORTH
Jerden Vrijnsen	Philips
Radu Gramatovici	Siveco
Aurelie Foure	Healthgrid
Nathanel Verhaeghe	Healthgrid
Thierry Sengstag	SIB
Juliusz Pukacki	PSNC
Olle Björk	Private expert
David Ingram	Private expert
Luca Toldo	Private expert
Ragnar Bergström	European Commission

Appendix 3
Agenda of the review meeting

23-24 April 2007 Poznan, Poland

8:20 Arrival of Participants

Day 1 – Activities and Achievements	
8:30 – 8:40	Opening of review meeting [Ragnar Bergström]
8:40 – 8:45	Round table presentation [Remi Ronchaud]
8:45 – 9:10	Project Status: Achievements and Challenges [Manolis Tsiknakis] - Includes a short introduction to the ACGT Demonstrators - 5-10' Q&A
9:10 – 9:35	User needs & requirements [Norbert Graf] - Including 5-10' Q&A
9:35 – 10 :00	The Clinical Trials: Design, objectives, implementation status (Christine Desmedt) - Including 5-10' Q&A
10 :00 :10 :15	***Coffee Break***
10:15 – 10:40	Ethical & Legal framework [Nikolaus Forgo] - Including 5-10' Q&A
11:40 – 11:05	The ACGT Architecture (includes the ACGT security architecture) - Including 5-10' Q&A
11:05 – 11:35	The ACGT Master Ontology [Matthias Brochhausen] - process and status of development - plan for its future developmnet and maintenance - Including 5-10' Q&A
11:35 – 12:00	The ACGT Mediator [Luis Martin] - alternatives and scientific approach chosen - implementation experiences, challenges - Including 5-10' Q&A
12:00 – 12:30	Distributed Data Access and Applications [Anca Bucur] - Including 5-10' Q&A
12:30 – 14:00	**Lunch**
14:00 – 14:25	The ACGT analytical tools and services [Stefan Rueping] - Including 5-10' Q&A
14:25 – 14:50	The ACGT technologies for In-Silico modelling [George Stamatakos] - Including 5-10' Q&A
14:50 – 15:15	The Integrated *ACGT* Environment [Stelios Sfakianakis] - Workflow Services - Metadata Services - Integration Guidelines - Including 5-10' Q&A
15:15 – 15:40	The ACGT Portal

15:40 – 16:00	Dissemination plan (Yannick Legre) - Including 5-10' Q&A
16:00 – 16:20	Initial exploitation plan (Andreas Persidis) - Including 5-10' Q&A
16:20 – 16:35	**Coffee Break**
16:35 – 18:00	The ACGT Demonstrators - Several demonstrators will be presented. Each demonstrator (a) relates to one or more of the ACGT "scenarios" and fulfills expressed user needs and (b) realizes part of the ACGT architecture and its services.
18 :00 – 18 :30	Questions and Concluding Discussion

8:20 Arrival of Participants

Day 2 – Administration &Finance / New Implementation Plan / Reviewers' deliberation	
8:30 – 10:15	WP1 - Project Management [Remi Ronchaud] - Administrative, financial and contractual management of ACGT - Including 20 ' Questions
10:15 – 10:30	*Coffee Break*
10:30 – 11:15	Second Implementation Plan [Manolis Tsiknakis] - Scientific and technical workplan over next 18 months (deliverables & milestones)
11:15 – 12:15	Reviewers' Deliberation *(restricted to Reviewers)*
12:15 – 12:45	Conclusions and Recommendations [Ragnar Bergström]
12:45	End of meeting
12:45 – 14:00	Lunch
14:00 – 16:00	*Private meeting for Reviewers to prepare evaluation Report*