CONTRACT
CONSENT IN A TRIAL & CARE ENVIRONMENT

SEVENTH FRAMEWORK PROGRAMME

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Project dissemination and exploitation plan

D6.2

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Project Overview

Project Name: Consent in a trial and Care Environment

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Contract No: 261412

Partners: Leibniz Universität Hannover (LUH), Custodix (Custodix), Interdisciplinary Centre for Law & ICT– K.U.Leuven (ICRI), Technological Education Institution of Crete (TEIC), Universitaet des Saarlandes (USAAR)

Document History

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0.5	12 March 2011	M. Tsiknakis	TOC definition
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Executive Summary

The purpose of the present document is to provide a structured plan for the required dissemination activities of the project and to also perform an initial analysis and structuring of the exploitation activities foreseen.

The objective of the Dissemination Plan – on the one hand - is to provide a formal planning document for using and disseminating knowledge throughout the project – ideally including target audiences and metrics for success. For this it is vital that all those involved have a clear understanding of what the aims of the dissemination activities are and what is realistically achievable. The plan highlights the key messages, potential audiences, roles and responsibilities, the methods of communication to be utilised as well as metrics for success.

On the other hand, the purpose of the Exploitation Plan 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 principal questions:

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

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 outside of the framework of the project itself and more importantly after its official conclusion.

The main scientific outcomes of the CONTRACT project will be intangible goods, i.e. facts and figures and will thus not be exploitable in a strictly commercial sense. They are however explicitly intended for future use by both the European Commission and the cooperating research projects. The policy recommendations and guidelines concerning informed consent and the protection of privacy should be of great interest and relevance to policy-makers and researchers and could form a basis on which to build further actions. CONTRACT's main exploitable outcome – as documented in the DoW of the project – will be the "helpdesk" to be established by the project, which will be supported by the involved partners after the end of the project. The helpdesk is foreseen to enable the creation of:

- A **help forum** for legal, ethical, IT-related and clinical questions related to **informed consent and data protection** in translational research
  - Initially available for partner projects
  - at the end of the project for the general public
- A data-protection framework ready to run.

The **helpdesk** will be established and maintained as a fundamental source for consent related issues and it is envisaged that this will be launched publicly towards the end of the project. CONTRACT partners will use their own resources to maintain at least the fundamental services of the helpdesk after the project completion. Additionally, specific services – like specific advice on data protection issues of informed consent in running projects – could be offered to interested projects for a small payment, thereby guaranteeing the sustainability of the helpdesk. If the helpdesk meets the market demand we expect, it could also be the cornerstone for a

consent related competence centre on informed consent issues that could achieve its own legal personality as a non-profit organisation.

1 Introduction

The purpose of the Dissemination and Exploitation (D&E) Plan is to provide a formal planning document for using, disseminating and exploiting knowledge and other outcomes throughout the project and after its completion (including target audiences and metrics for success). It is vital that all those involved in the project and in dissemination or exploitation related activities have a clear understanding of what the aims of the dissemination activities are and what is realistically achievable. Specifically, the dissemination plan highlights the key messages, potential audiences, roles and responsibilities, the methods of communication to be utilised as well as metrics for success.

1.1 Project Objectives

CONTRACT seeks to establish methods to understand the way the *European Data Protection Directive*[1]and the *Clinical Trials Directive*[2] have had and continue to have an impact on the success of translational research. The project is focusing on informed consent as a fundamental precondition for the legal processing of personal data and for carrying out a legally admissible clinical trial. CONTRACT vision is to support the European Commission to achieve a "*clear Community framework [in order] to support dynamic and sustainable health systems by providing clarity regarding application of EC law to health services and support Member States in areas where coordinated action can bring added value to health systems.*"[3] The project is doing so by delivering a survey showing how ongoing and upcoming European and national translational research projects on cancer deal differently with consent issues, defining good practices, giving policy recommendations and offering a help desk for partner projects on consent issues.

Both mentioned Directives define (informed) consent. However, already the definitions differ significantly.[4] A closer look clearly shows that not only the definitions are different but that the legal concepts behind them differ as well. CONTRACT will help to

[1] Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data ("*Data Protection Directive*").

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0058:en:HTML

[2] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws,regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use" ("*Clinical Trials Directive*").

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0020:EN:HTML

[3] WHITE PAPER, Together for Health:A Strategic Approach for the EU 2008-2013, COM(2007) 630 final, 9.

[4] Art. 95/46/EC defines the data subject's consent (Art. 2 h) as: "any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed." The *Clinical Trials Directive* defines 'informed consent' (Art. 2 j): "decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.nal cases, as provided for in national legislation."

understand how the differing concepts of informed consent have consequences on translational research activities and how new legal approaches could help to support a more efficient execution of translational research on the one hand and on the other to protect patients' rights at the same time.

Translational research requires – as the term implies – the translation of basic discoveries in clinical applications and – vice versa – the translation of clinical knowledge in new research approaches. Translational research is therefore about communication, exchange and sharing of information. The flow of data crossing boundaries – between care and research, between different clinical disciplines and between different research groups in different nations – is a fundamental precondition for translational research. The possible benefits for research and care are clearly visible and make it easy to see why the Commission has decided to place translational research at the centre of 2010's activities in the health domain.

The data to be shared or exchanged is in most cases personal data. Behind every dataset there is a human being's biography and anamnesis. Every patient is concerned about privacy issues and expects – with good reason – that his personal data is processed legally. Data protection regulations require that the data are only collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. They require in many cases the patient's informed consent for processing the data. Doctors are – for obvious ethical and legal reasons – aware of the risks that going beyond this informed consent might entail. They are also quite aware that they need to ask for prior consent when treating a patient and when asking a patient to participate in a trial.

A problem is that these different manifestations of consent are not homogenous. They differ in scope, necessity and in the conditions they need to comply with in order to be valid. They differ in their legal basis, in their doctrine and in the consequences a breach of consent might have. Those differences cause a tremendous legal and ethical complexity which becomes even more prevalent when the patient belongs to a vulnerable group. This complexity produces uncertainty and doubt among researchers and clinicians. Due to this complexity, IT-systems set up for care and for trials are frequently seen as different worlds. They lack the interfaces needed to make the data transferable. Doubt and complexity in relation to the legal, ethical and technical side of a framework for a trial can cause the end of translational research before it has even begun and this effect has a dramatic impact on patient groups already disadvantaged by their specific vulnerability.

CONTRACT plans to assess the impact of EU and related national legislation relevant for consent issues on translational research activities, not only from a narrow legal point of view but in order to gain a wider insight on the related effects from a clinical and IT perspective.

CONTRACT also plans to support translational research projects – both ongoing and upcoming. It is geared towards developing a multidisciplinary approach in delivering facts and figures on different approaches to informed consent both in European projects and in European Member States. CONTRACT will also analyze the IT-related

representation of these different understandings and the outcome of these differences in the daily clinical and/or research routine.

CONTRACT will furthermore advise translational research projects in all issues of informed consent and will deliver concrete policy recommendations as to how the European Union could jointly protect patient's rights and support translational research by a better structured approach towards consent issues. CONTRACT will focus on issues of informed consent in vulnerable patient groups as the requirements are of the most demanding complexity there.

With the overarching aim of identifying barriers caused by EU legislation in this area, CONTRACT will focus on legal issues of informed consent in translational care and transnational research projects, primarily with vulnerable patient groups. Vulnerable patient groups are of specific interest as consent issues are more sensitive in such cases than with *sui juris* patient groups. Those patients are deemed to need the maximum level of protection and ethical consideration. Measures applied for such groups could therefore be taken as the highest standard.

Dealing with the legal issues requires a holistic approach including IT- and security related aspects and the day to day handling of the legal/technical requirements in the clinical care and research setting. Therefore, the legal work will constantly be supported by technical and clinical feedback within and outside the project.

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 disseminating and exploiting of project results. At its heart, the D&E plan aims to answer the following principal questions:

- Who are the main stakeholder groups that are involved in clinical trials and could therefore be seen as potential 'customers' of CONTRACT results?
- What are the exploitable results that CONTRACT aims to deliver?
- In what ways can we exploit the CONTRACT results?
- How do we "get the message across" to each stakeholder?
- 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.

1.1 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 CONTRACT consortium. This document however is also addressed to the Project Management Board (PMB) which is responsible for monitoring exploitation activities and ensuring that they unfold in sync with the other activities of the project.

By presenting D&E actions and goals in the context of the project, the document targets “dissemination” and “exploitation” 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.

1.3 Structure of the Document

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

Chapter 2 focuses on the Dissemination aspect. It discusses the main stakeholder groups we have identified as having a significant interest in connection with clinical trials and supporting IT infrastructure and covers dissemination activities at the consortium level.

Chapter 3 then proceeds to discuss the exploitation objectives, dimensions of exploitation and exploitation levels foreseen. It analyzes in more detail the key exploitable outcomes of the project and lists related actions from the individual partner with the aim of creating a strong branding for ***CONTRACT*** .

Chapter 4 concludes the presentation of the dissemination and 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.

1.4 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 when appropriate (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.

2 Part 1 – Dissemination Plan

It is our belief that dissemination has two distinct and different in nature dimensions. The first is scientific dissemination whilst the second is general dissemination to specific target audiences. These two dimensions are interleaved and, unavoidably, they influence each other.

CONTRACT's plans for disseminating its work and achievements – in both of these dimensions – will be subsequently analysed, and the main audiences of the project are identified and their needs defined.

2.1 Plans for Scientific dissemination

The dimensions of scientific dissemination are: scientific journal papers, scientific conference papers, liaison with SDOs (Standard Development Organizations), white and position papers, etc

It is obvious that scientific dissemination can not be the responsibility of anyone else but those doing the scientific work. For this reason all partners of the CONTRACT consortium have been assigned man-effort in WP6, mainly to fund their scientific dissemination activities.

The responsibility for the coordination of the scientific dissemination of the project lies with the scientific coordinator of the project. WP6 of the project has defined a number of activities with the objective to assist him on this task.

Scientific dissemination will be carried out at different academic levels, in particular at the coordinating institution (IRI) where different teaching modules allow the opportunity to teach issues of privacy and informed consent such as the Master course in Legal Informatics.

The presentation of the project results will be given to students of both undergraduate and post-graduate level in order to sensitize them in the necessity of harmonizing informed consent in Europe. Moreover, general presentations will be carried in the two planned workshops as well as consortium and coordination meetings.

Following the previous discussion, it becomes obvious that WP6 can assist the scientific coordinator by providing:

(a) a link to the most relevant scientific conferences, journals, etc to the project and online notification of relevant calls for papers, workshops, etc and

(b) a repository of the scientific dissemination of the project, i.e. PDF versions of papers and conference presentations made by the project, so that it can be accessible through the public web site of the project.

Publication of reports and articles are planned in a number of different on-line and paper based high impact factor scientific journals. As a central aim of its dissemination strategy, the CONTRACT consortium will strive to ensure open access to any publications arising from the project, where necessary, following an agreed embargo

period. This will have the dual benefit of raising the visibility of the results of the project and that of EU-funded research more generally.

At this point in time detailed plans have been developed for the presentation of the CONTRACT project, its objectives and current achievements in the following scientific events, in which Consortium Members are participating as PC members, in an advisory capacity or as presenters.

1. The 1st contract-workshop (15th of September) in Hannover, Germany.
2. The Conference Law in Politics, Politics in Law, Cambridge 2011 http://conference.legalscholars.ac.uk/cambridge/index.cfm. A member from the research group of IRI - Marc Stauch - is accepted as a speaker there and will speak about CONTRACT and its objectives.
3. Internationales Rechtsinformatik Symposion 2012, see http://www.univie.ac.at/RI/IRIS2011/ for further reference (in German). Prof Nikolaus Forgo is a member of the scientific committee and will give a presentation and/or host a workshop.
4. The VPH-FEZT Conference “Technologies for the Future of the Virtual Physiological Human”, 27th of June 2011, London. Prf Nikolaus Forgo will be present as a member of the scientific advisory board of the VPH-NoE and will give a presentation regarding CONTRACT.
5. The yearly conferece of the "Gesellschaft für Recht und Informatik", see http://www.dgri.de/veranstaltungen/tagungen/0170-20111110/ (in German) where we plan for a presentation.
6. The 10th International Workshop on Biomedical Engineering, Kos Island, Greece, Oct 2011. Prof Tsiknakis is a member of the Programme Committee and is planning for a presentation on CONTRACT and the results of the first CONTRACT workshop to be held in September in Hannover.
7. The 34th Annual International Conference of the IEEE Engineering in Medicine and Biology Society, San Diego, California, Aug 2012. The technological partners of the project will plan to present the main technological finding of the CONTRACT project regarding suggestions of innovative technological solutions and security policy recommendations to stimulate patient empowerment and address the identified stumbling blocks for exchange between data processed for care and for research purposes.
8. The2nd contract-workshop (September 2012) in Hannover, Germany.

In addition mature plans for CONTRACT’s participation in the following events are been developed:

- K.U.Leuven meta-forum on total genome sequencing. A position paper on clinical, ethical and legal aspects will be presented after the summer of 2011.
- The 50th FITCE Conference, ICT: bridging an ever shifting digital divide, 31 August - 3 September 2011, but we have no news on acceptance yet.

- A paper on consent has been submitted to the Communication and Strategies DigiWorld Economic Journal issue on ICT and Health. No information on acceptance yet.

Additonal plans for scientific publications are in developmet, and they will be reported in subsequent versions of the D&E plan of the project.

2.2 Plans for General dissemination

The general dissemination of the project is the task of WP6. General dissemination also has several dimensions and it will evolve as the project starts-matures-and approaches completion.

It is our belief that in order to define and execute an effective dissemination strategy and plan one must:

(a) Identify the messages that need to be conveyed.
(b) Identify the target audiences to which the messages needs to be conveyed and
(c) Deliver the messages through appropriate and effective channels, taking into consideration the resources allocated to such an activity.

In the subsequent sections we discuss these three dimensions and indicate work done to date as well as the main planning for the next 18 months.

2.3 Key audiences for the project

For an effective dissemination strategy, given the resource constraints of the project, it is very important to focus the dissemination activities to the appropriate audiences and target groups.

Currently, we have identified the following major categories of audiences:

- Organizers of multicenter, international trials inside Europe.
- Patients and patient organisations.
- European regulatory and other bodies responsible for policy development.
- General Public.

The importance of these target audiences is not, obviously, the same. Organisers of multicentric, international trials in Europe, medical professionals, life science researchers and other IT solution developers represent the most important target audience of the project at this point in time. It is also evident that each of these target audiences requires quite specific and potentially different in nature information with respect to the project. As a result the main messages will have to be adapted to the specific role and expectations of each of these target groups. Also, dissemination information has to be made available in several alternative ways, whenever possible.

In the following sub-sections the main messages per targeted audience, the means and our current plans for successfully conveying these messages are presented.

2.3.1 Organizers of multicenter, international trials inside Europe

Why?

In most clinical trials sensitive personal data is processed. It is therefore a day to day experience within any research oriented hospital that processing of existing personal health data for research purposes is an issue. Whenever a (retrospective) clinical trial is set up, it is more than doubtful whether any legitimate basis for data processing exists. The situation is made more complex when different partners try to harmonize their infrastructure for joint efforts in research and want to use existing patient data. If those partners are residents of different European Member States the situation due to differences in national implementations of the *Data Protection Directive* becomes very unclear. Due to this unclear situation, IT- and security-solutions provided in research oriented hospitals either for research or for care purposes do not interact.

The anonymization of patients' data is in many cases not effective. A re-identification of the patient's data or samples is needed for ethical and legal reasons in cases when research results have specific impact on his or her treatment. More importantly, real anonymization is impossible in many cases due to either design reasons of the trial and the security infrastructure used to manage the trial or the nature of the data processes (genetic data for example).Trial sponsors therefore need to deal with the fact that the data they are processing is personal and sensitive in the understanding of the *Data Protection Directive* and therefore subject to the whole legal protection regime derived from this directive: Processing this sensitive personal data is – in principle – forbidden; consent may set the frame in which this processing is (by way of exception from the principle) legal. Translational research therefore does not only require compliance with the legal regime for trials but also with the rules on data protection.[5]

Main messages?

The main message towards this community are:

- CONTRACT will advise translational research projects in all issues of informed consent and will deliver concrete policy recommendations as to how the European Union could jointly protect patient's rights and support translational research by a better structured approach towards consent issues.
- CONTRACT will focus on issues of informed consent in vulnerable patient groups as the requirements are of the most demanding complexity there.
- CONTRACT will generate easy to use educational and training assets (e.g. guides, FAQ, Case study descriptions of best practices, etc) that will enable the community to capitalize on the work and the expertise of the project, during its lifetime but after its conclusion as well.

As the project matures and the vision (we believe) is gradually turned into reality, the messages will have to become stronger and stronger with the objective of motivating the community for uptake of the technology.

How to disseminate?

The main dissemination channel towards this stakeholder group will be the project web site and the material and tools that will gradually be made available in the Helpdesk of the project.

[5] Elmar Mand, Biobanken für die Forschung und informationelle Selbstbestimmung, MedR 2005, 565-575, 566.

Apart form textual material available on the web site and the Helpdesk of the project, which will present existing challenges, the vision of the project and the main messages, CONTRACT has to be disseminated within scientific papers and on scientific meetings and congresses by all partners.

Material to produce:

- website content
- on line demonstrators presenting the CONTRACT knowledge base and how they respond to real analytical and other discovery needs of clinical or translational research.
- Scientific papers

Time line:

- website content: T0+6
- on line visual training material in the Helpdesk: T0+18
- scientific papers: T0+24

2.3.2 Patients and Patient Associations

Why?

The recruitment of patients in post-genomic clinical trials is perhaps the most expensive and challenging stage of the clinical trial process. Hospitals and pharmaceutical company investigators have a tedious and time consuming task, trying to locate patients whose profiles provide an adequate match for the complex trial inclusion/exclusion criteria.

Studies reveal that over 855 of all industry related trials fail to meet deadline, translating into estimated lost sales of $1.4 Million per day per trial[6]. With the number of patients required for participation in all types of clinical trials rising, there is an obvious need for a total revamping of existing recruitment practices.

On one hand it is difficult to enrol new patients in prospective randomized trials and on the other hand only 5-10 % of adults with cancer take part in such trials. There is on one side the “reluctance” of physicians to take part in clinical trials and on the other side the “unwillingness” of patients to be a participant of a trial. Both aspects have to be addressed.

For a lot of physicians clinical trials are only seen as something that is time consuming and not seen as a possibility to offer the best available treatment for their patients. Treating patients in clinical trials is not part of a quality process for a physician, meaning that a physician does not need to offer a trial to a patient, even if a trial for his specific patient is ongoing.

Since the implementation of the EU Clinical Trials Directive (EU CTD), it became clear that even the well established clinical trial groups and national groups are struggling to meet the increased requirements of the EU CTD. A majority of clinical trials in cancer

[6] Reported in various presentations during the Clinical Trials Working Group Expo at MedInfo 2004

fall under the label “non-commercial” and they often have no specific funding. The increased cost of running non-commercial clinical trials has had a very inhibitory effect on translational clinical research on cancer in Europe. It is certain that this was not the intention of the EU CTD and the clear framework that the EU CTD has put in place is welcomed, nevertheless it has caused a barrier to the collaborative execution of international translational clinical trials on cancer. Due to different national interpretations of the EU CTD, solutions for running clinical trials in one country are found not to work in another, often preventing a second country from joining a study they would have taken part in the past. Sponsorship, insurance and indemnity are only two aspects that make investigator initiated trials more difficult to run today. This difficulty is a major aspect, why clinicians are more and more reluctant to open new randomized trials and enrol patients in prospective trials.

The knowledge about possible clinical trials and the initial information given to a patient for taking part in a clinical trial is most important and always critical in the way, that it determines to a high percentage the participation of a patient in a trial.

One of the main reasons for the deficit in protocol enrolment is the lack of awareness by the public, community and healthcare systems that outcome for cancer patients may be better in clinical trials. In parallel, the issue of adequate protection of the patient’s rights and data is also an inhibiting factor. .

The idea of informed consent protects the patient’s autonomy and responsibility for his condition here.[7] Patients trust – and a rather rigid legal regime gives reason for this trust – that their personal (care) data is processed in a way compliant with data protection and data security standards and the information they give is seen as confidential[8] meaning that no unauthorized person may have access to it.

Therefore, informed consent is indeed a major ethical and legal issue in the every day of the patient-doctor relationships and deficiencies here might cause serious liability risks for the treating doctor yet the focus clearly lies on care and research, not on data protection issues.

CONTRACT will deliver best practice guidelines which will be drafted and oriented in a comparative fashion and will take into account both European comparative legislative study and other EU related projects.

How to disseminate?

By

- providing information on CONTRACT’s data-protection framework which will be ready to run.
- making sure that we document the strict security mechanisms implemented by the CONTRACT data protection framework, and thus reassure patient’s regarding their personal data by projects compliant with the CONTRACT data protection framework.

[7] Jessica W. Berg,Paul S. Appelbaum, Charles W. Lidz, Lisa S. Parker, Informed Consent: Legal Theory and Clinical Practice, New York 2001, 14.

[8] See Tamara K. Hervey, Jean V. McHale, Health Law and the European Union, Cambridge 2004, 161.

➲ establishing and continue to support a **help forum** for legal, ethical, IT-related and clinical questions related to **informed consent and data protection** in translational research

Material to produce:

- web site content.
- FAQ help forum, through the project's helpdesk.
- Newsletter.

Time line:

- web site content: T0+15
- Helpdesk: T0+18

2.3.3 European regulatory and other bodies responsible for policy development.

Why?

It has already been mentioned in relevant literature that the legal regime on clinical trials, mainly the *Clinical Trials Directive*, is already a challenge for the setting up of new trials.[9]The problems become more serious when the trial is set up on a trans - European level as different national implementations of the Directive have a tremendous impact on the legal situation covering the trial.[10].

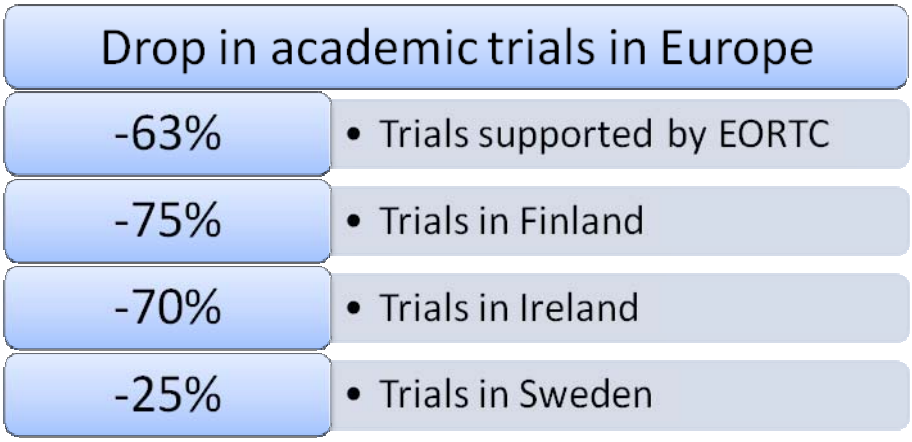

Figure 1: Drop in academic trials in Europe[11]

Brandon Keim writes in Nature Medicine: "The cost of academic cancer trials has doubled since 2004**,** according to Cancer Research UK, the countries largest sponsor of academic cancer research. The European Organization for the Research and Treatment of Cancer estimates that expenses have risen by 85% and says the number

[9] See for example Christiane Druml, Informed consent of incapable (ICU) patients in Europe: existing laws and the EU Directive, Current Opinion in Critical Care 2004, 10:570–573.

[10] See Kathy Pritchard-Jones, Clinical trials for children with cancer in Europe - Still a long way from harmonisation: A report from SIOP Europe. European Journal of Cancer 2008, 44:2106-2111,;

Brandon Keim, Tied up in red tape, European trials shut down. Nature Medicine 2007, 13:110,.

[11] Source: Brandon Keim, Tied up in red tape, European trials shut down. Nature Medicine 2007, 13:110.

of trials it supports has dropped by 63%. The Save European Research campaign, which represents more than 3,000 scientists, says academic drug trials have dropped by 70% in Ireland and 25% in Sweden. The number of Finnish academic drug trials shrunk by 75%".[12] [See Figure 1]. Key issues for cancer trials are summarized by Kathy Pritchard-Jones in the European Journal of Cancer[13].

One of the central outcomes of the CONTRACT project will be a policy oriented study giving recommendations as to how far different concepts of informed consent and its backing could be better coordinated or harmonized within Europe. The CONTRACT project will produce concrete recommendations concerning the possible legal and political instruments to foster adequate technical and clinical implementations necessary for the proper handling of informed consent given by the patients and their representatives in translational research. The aim here is to lessen the inconsistency and fragmentation in the legal interpretation of the informed consent in the different European projects and of the interpretation of the Community legislation across Member States.

Main messages?

Legal frameworks and structures that facilitate more clinical trials and that can bridge the gap between treatment given to patients today and research to find better treatment for patients are therefore of the utmost importance. In all such scenarios a proper handling of consent is an important success factor.[14]

The CONTRACT project will provide an in depth analysis of the current situation and identification of possibilities and ways for better coordinating different forms of informed consent in translational health research from a data protection and a clinical trial perspective.

How?

Apart from general material available through the website, the main dissemination channel towards this audience is the scientific conferences, and workshops of the project.

The project will produce a ***White Paper*** with recommendations for this target audience.

Material to produce:

- web site content
- scientific papers
- White paper

Time line:

[12] Brandon Keim, Tied up in red tape, European trials shut down. Nature Medicine 2007, 13:110.

[13] Kathy Pritchard-Jones, Clinical trials for children with cancer in Europe - Still a long way from harmonisation: A report from SIOP Europe. European Journal of Cancer 2008, 44:2106-2111, Although this article deals with clinical trials for children, most of these points are relevant for clinical trials in adults as well.

[14] A.Cahana, S. Hurst, Voluntary Informed Consent in Research and Clinical Care: An Update, Pain Practice, Volume 8, Issue 6, 2008 449: "Studies of physicians' views do identify informed consent as a barrier to research participation. In a study of 170 breast cancer specialists in eight countries, 89% considered the need to obtain informed consent to be an important obstacle recruitment."

- web site content: T0+15
- White paper: T0+24

2.3.4 General Public

Why?

Informed consent is a very important basis for making the processing of the patient's personal data lawful. The principle is quite simple: Art. 8 Sec. 1 of the *Data Protection Directive* declares the processing of sensitive data (which is, inter alia, health data) as being *prima facie* illegal. There are only very few exceptions mentioned in Art. 8 Sec. 2 of the Directive: the first being that "the data subject has given his **explicit** consent to the processing of those data".

However, patients giving (explicit) consent in a defined care scenario on their data being processed are a rather rare phenomenon. Patients are not normally asked to consent explicitly to the processing of their personal data whenever they seek for help in a care unit. There are different legal reasons for this of which the most important one is Art. 8 Sec. 3 of the Directive. The provision says that Member States are not obliged to prohibit the processing of personal data *"where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy."*

Therefore, informed consent is indeed a major ethical and legal issue in the every day of the patient-doctor relationships and deficiencies here might cause serious liability risks for the treating doctor yet the focus clearly lies on care and research, not on data protection issues. Obviously physicians and lawyers dealing with issues of health law tend to concentrate on consent to treatment or for care rather than for data protection.

Consent becomes (only then) a necessity when research shall be performed. The consent given for research purposes therefore has a double function: On the one hand it works as an important and increasingly used[15] legal basis for the research done with the patient's body material and data; on the other hand it is also the legal grounding for the legitimacy of the data processing in the understanding of Art. 8 of the *Data Protection Directive* and in accordance with Art. 3 paragraph 2 (c) of the *Clinical Trials Directive*.[16] The consent is therefore not only needed for the sampling of body material but also for the processing of the data (the *information*) about the body material.

Due to the increasing availability of patient data in comparison with patient material, a sublimation effect tends to occur – information becomes more important than the (physical) data carrier bearing the information – still the "typical" legal medical doctrine

[15] Elmar Mand, Biobanken für die Forschung und informationelle Selbstbestimmung, MedR 2005, 565-575, 570.

[16] A clinical trial may be undertaken only if, in particular: […] (c) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with Directive 95/46/EC are safeguarded.”.

mainly deals with the material.[17] The more important the data and the information included in the data become in relation to the specimen, the more important a proper data protection regime with a proper understanding of informed consent in the privacy related meaning of the term is.[18]

Main messages?

Legal frameworks and structures that facilitate more clinical trials and that can bridge the gap between treatment given to patients today and research to find better treatment for patients are therefore of the utmost importance.

In all such scenarios a proper handling of consent is an important success factor.

How?

Apart from general material available through the website, the main dissemination channel towards this audience is the scientific conferences, and workshops of the project.

Material to produce:

- web site content
- scientific papers
- White paper

Time line:

- web site content: T0+15
- White paper: T0+24

2.4 Summary of Dissemination Activities

A summary of the main dissemination activities and their target audience is shown below.

Target Audience	Main objective	Dissemination activities
Policy makers	Help to inform future policy-making to take accounts of needs identified; evidence based decision making	Invitation to attend workshops Short policy briefs throughout the project lifetime culminating in a set of policy recommendations Policy recommendations for the Commission (Project Deliverable D4.1) Website, newsletters
European (and national) research projects and related	Raise awareness of issues of informed consent	Distribution of questionnaires, structured interviews with selected

[17] See for a similar argumentation Spiros Simitis, Biowissenschaften und Biotechnologie – Perspektiven, Dilemmata und Grenzen einer notwendigen rechtlichen Regelung, Juristenzeitung 2008, 693-703, 700 and Nils Hope, Bioequity – Property and the Human Body. Ashgate Publishing 2009. 108

[18] See for a similar argumentation Elmar Mand, Biobanken für die Forschung und informationelle Selbstbestimmung, MedR 2005, 565-575, 565.

activities in the area of translational research on cancer and related areas		coordinators Workshops highlighting gaps in informed consent in care and research environments, good practice suggestions Helpdesk Website, newsletters
Other Users (e.g. hospitals, care environment)	Sharpen awareness of data protection and informed consent issues, improve quality in such procedures in terms of patient empowerment and ethical standards (?), corresponding to these standards, improve exchange between the research and care environment	Workshops highlighting gaps in informed consent in care and research environments, good practice suggestions. Helpdesk (FAQ, forum) Website, newsletters
Scientific community	Dissemination of the facts and figures from the survey, state-of-the-art analysis in Europe regarding informed consent.	Publication of scientific articles, presentations at the two main workshops and other selected conferences. White paper
General Public	Raise awareness of the issues of informed consent and data protection and the importance of these for research activities	Information leaflets / section on website for patients/research participants.

3 Part 2 – Exploitation Plan

3.1 Introduction

Why do we need an exploitation plan if the core objective of CONTRACT is to develop resources and basically knowledge (guidelines, facts, identify best practices) that will be open (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.

CONTRACT needs an exploitation plan for the following main reasons:

- First, CONTRACT will be competing with other similar initiatives (present and future) for end users' attention. While open in nature, end users must firstly be aware and secondly be convinced of the benefits of choosing CONTRACT over other offerings to support them in their daily needs wrt to consent management in translational research. One main goal of the exploitation plan must therefore be to achieve the level of persuasion that will get CONTRACT outcome "through their door".
- Second, CONTRACT 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.
- Finally, 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.

  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 CONTRACT exploitation plan in terms of *dimensions* and *levels* that serve to organise activities in a focused and systematic way. Sections 3.4 and 3.5 discuss these respectively. We have also conceived several initiatives that will help raise the profile of the project. These are introduced in Section 3.6 .

The exploitation goal of CONTRACT 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 open knowledge product.

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

3.2 Exploitation objectives of CONTRACT

The main scientific outcomes of the CONTRACT project will be facts and figures and will thus not be exploitable in a strict commercial sense. They are however explicitly intended for future use by both the European Commission and the cooperating research projects. The policy recommendations and guidelines concerning informed consent and the protection of privacy should be of great interest and relevance to policy-makers and researchers and could form a basis on which to build further actions.

We envisage exploitation of our project findings and results as follows:

- The **helpdesk** will be maintained as a fundamental source for consent related issues and it is envisaged that this will be launched publicly at the end of the project. CONTRACT partners will use their own resources to maintain at least the fundamental services of the helpdesk after the project completion. Additionally, specific services – like specific advice on data protection issues of informed consent in running projects – could be offered to interested projects for a small payment, thereby guaranteeing the sustainability of the helpdesk.
- If the helpdesk meets the market demand we expect it could also be the cornerstone for a consent related competence centre on informed consent issues that could achieve its own legal personality as a non profit organisation. In such a case CONTRACT will work as a **competence centre** for all consent issues in translational research with vulnerable patient groups. It is foreseeable that all partners – being experts in their respective fields constantly working on European level – will continue to exploit the main scientific results of CONTRACT. Most of the consortium partners are involved in academic activities. This involves transforming information awareness into knowledge and know-how capabilities via education. Educational activities will be designed to help teaching staff to build a knowledge based in the subject matter and bring it into their academic curricula.
- The goal of the project is to support the faster execution of translational research and enable finding in the “bench” to find their way to the clinic “as fast as possible”. Therefore the consortium is very much devoted in contacting every forum and every stakeholder – within the limits of time and resources available - for whom the findings of the project may be useful, as well as every project and forum which findings may be used to deepen the support activities done during the project and improve its results. The Consortium hopes that the helpdesk, being one of the main outcomes of the project, will be included in the ESFRI database of research infrastructures’ services, which would be an additional medium for D&E of project activities and to strengthen its international outreach.It is also envisaged that our **support network will be further extended and** offered to the cooperating projects during the lifetime of CONTRACT beyond the project duration to upcoming projects applying for funding under the FP7 HEALTH theme.

Finally, in the framework of WP6, we will further develop and expand our exploitation and dissemination plan to encompass additional exploitation opportunities where appropriate.

3.3 Dimensions of the Exploitation Plan

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 CONTRACT exploitation plan.

Currently, we have identified the following major categories of audiences (see section 2.3 for fuller discussion):

- Organizers of multicenter, international trials inside Europe.
- Patients and patient organisations.
- European regulatory and other bodies responsible for policy development.
- General Public.

The importance of these target audiences regarding exploitation is not, obviously, the same.

3.4 Exploitation Plan Levels

Like with any EC project, exploitation of CONTRACT 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.

3.4.1 Consortium Level Exploitation

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

While the option of creating a single commercial entity ("CONTRACT 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.

On the other hand, our plan to establish the project Helpdesk (see section 3.5) and potentially transform this into a competence center raises the following question: what is the appropriate business model that would guarantee long term sustainability of these structures?

The consortium is not ready today to provide and answer to this question. It will – on the other hand – focus on such a question, as the project evolves and the "exploitable" outcomes of the project gradually materialize.

In any case, following initial analysis and debate during a recent Consortium Meeting regarding the applicability and relative value of each of our exploitation means (see section 3.5 for details) the following represent the tentative position of the Consortium:

- FAQ – we do not know whether we do it. It does not represent a priority.
- Case studies – SIOP should be our initial case study.
- Templates – to be developed within the guides.
- Forum – an initial invitation to asking questions vi a email. Subsequently, once it is populated with some questions we will publish it on the webpage our answers and put on the commenting function!
- eCourse – summerschool of the p-medicine (http://p-medicine.eu/) project could be an ideal place in which to initially collocate a course and subsequently evaluate whether the course is transformed into an eCourse. Needs further elaboration.

3.4.2 Partner Level Exploitation

By 'partner level' exploitation we understand all actions that will be taken by CONTRACT 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.

Section 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.

3.5 Exploitation Plan Initiatives

We believe that in addition to the stakeholder targeted actions we envisage we can raise awareness and exploitation of the CONTRACT results more effectively by focusing on the "service offering" through the CONTRACT Helpdesk.

The **CONTRACT Helpdesk**: this will help us create a CONTRACT brand, that will not only provide a mechanism for guaranteeing compatibility and compliance with the CONTRACT technical standards but will also represent a label by which 3rd parties will be able to differentiate their CONTRACT compatible offerings in return for the investment they will need to make to develop these offerings.

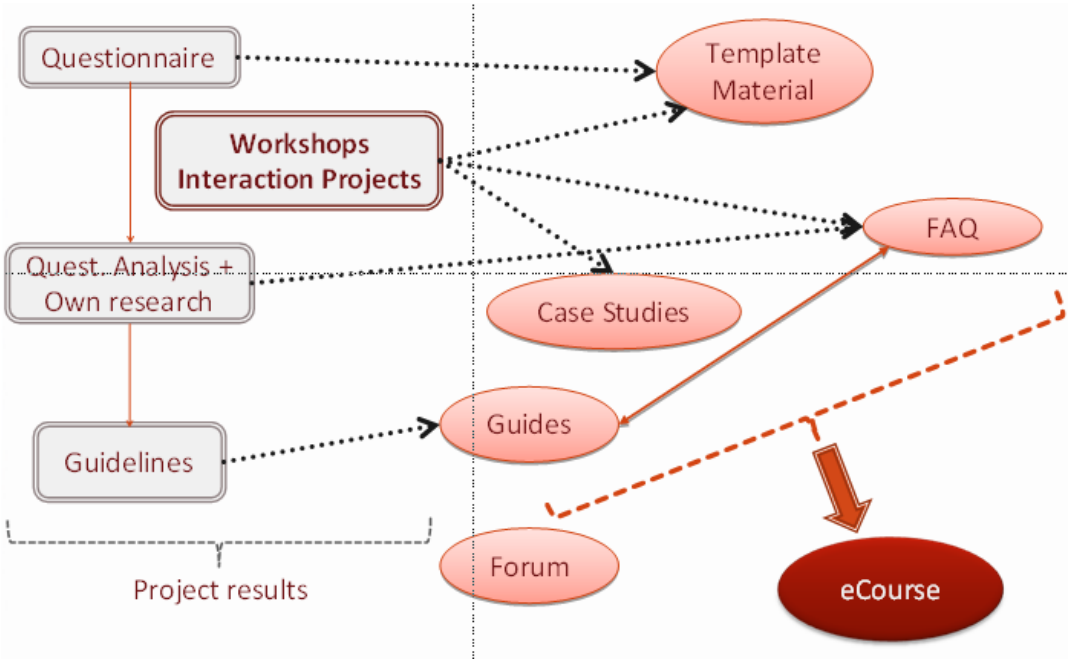

Figure 2: The main outcomes of the project and their interrelationships

The specific knowledge based services to be supported by the helpdesk are graphically presented in figure 2. These are described and analysed in more detail in the subsequent sub-sections.

3.5.1 Guides

The objective of this service would be to make available a number of "guides" for interested stakeholders. In achieving this objective the project has planned for a number of relevant project deliverables or milestones, such as:

- M3.1 - Selection of good practice cases for presentation at the first workshop (M10)
- D3.1 - Initial report and guidelines on identified good practice cases (M15) [finalised guidelines are a deliverable of WP4]
- M3.2 - Feedback on initial good practice cases and guidelines from ethical committees and first workshop (M15)
- M4.1 - Preliminary findings on good practice cases based on the results of problem analysis (M15)
- D 4.2 **-** Final guidelines for researchers for informed consent and for data security issues (M24)

Actions required: Efforts should be made for these deliverables to be prepared in such a way and with such a structure, which would ease the publishing through the Helpdesk

Timing:

- D3.1 to result in "draft guides" for helpdesk
- Initial deliverable M15 / Final deliverable M24

3.5.2 FAQ

The second service to be offered through the Helpdesk, which would potentially enable wide exploitation of project results (knowledge generated), is a “Frequently Asked Questions” service. Such a service – at this point in time – is seen as an interactive knowledge exchange and knowledge sharing service that could actually be optimised if supported by a web 2.0 technological collaborative platform. The implementation of such a platform is definitively outside the scope of the CONTRACT project.

In realizing this, we need to proceed with the following set of activities:

- Determine important initial questions for various communities;
- Derive some of these questions of interest from the questionnaire answers;
- Plan for an appropriate discussion at the project’s workshops and conferences,

so that we gradually built the question set, based on interaction with the interested communities and stakeholders.

Timing:

We initiate this effort following the initial completion of the questionnaire and the first workshop of the project.

3.5.3 Case studies

A case study is a research method common in social science. It is based on an in-depth investigation of a single individual, group, or event. Case studies may be descriptive or explanatory. The latter type is used to explore causation in order to find underlying principles.

Rather than using samples and following a rigid protocol (strict set of rules) to examine limited number of variables, case study methods involve an in-depth, longitudinal (over a long period of time) examination of a single instance or event: a case. They provide a systematic way of looking at events, analyzing information, and reporting the results. As a result the researcher may gain a sharpened understanding of why the instance happened as it did, and what might become important to look at more extensively in future research.

Our objective in providing an analysis of several Case studies would be the identification of best practices in handling informed consent.

Best practices are generally-accepted, informally-standardized techniques, methods or processes that have proven themselves over time to accomplish given tasks. Often based upon common sense, these practices are commonly used where no specific formal methodology is in place or the existing methodology does not sufficiently address the issue. In addition, a "best" practice can evolve to become better as improvements are discovered. Best practice is considered by some as a business buzzword, used to describe the process of developing and following a standard way of doing things that multiple organizations can use.

The identification and analysis of case studies is a demanding process. The project will attempt to:

- Engage in really working out a case for a project/trial
- A first case could be worked out with Prof Norbert Graf for the SIOP trial, with the objective of identifying generic messages and templates for documenting best practices.

Timing:

We initiate this effort following the initial completion of the questionnaire and the first workshop of the project.

3.5.4 Template material

The development of a set of Templates (e.g. Consent forms, Contracts, etc) as a standardized and pre-formatted example on selected problem domains, that would provide value to stakeholders and enable a more standardised treatment of these issues across Europe.

In assisting the project to evaluate the value of this service offering and its exploitation potential, a number of “research questions” have been introduced in the questionnaire of the project, e.g.:

- Did you use a template to write the consent forms for your project?
- Would a template have been helpful?
- Would you be willing to pay for such a template/service?

In parallel project partners will attempt to identify answers to other relevant questions, such as:

- IC forms, other templates relevant?
- Will/can the templates suit every country? (irrespective of translation)

Timing:

Following this initial analysis, the project will focus on this service offering following the initial completion of the questionnaire and the first workshop of the project.

3.5.5 Forum

An important potential exploitation dimension of the project, is the creation and management of an online, internet forum through the Helpdesk.

An Internet forum, or message board, is an online discussion site where people can hold conversations in the form of posted messages. They differ from chat rooms in that messages are at least temporarily archived. Also, depending on the access level of a user and/or the forum set-up, a posted message might need to be approved by a moderator before it becomes visible.

Depending on the forum set-up, users can be anonymous or have to register with the forum and then subsequently login in order to post messages. Usually you do not have to log in to read existing messages.

The different type of services to be offered to “subscribed users” include:

- "helpdesk" type consultancy offered to projects
- Forum for discussions
  - Doesn't take much effort to set up, but needs to be populated with discussion topics.
  - The need for a discussion forum needs to be evaluated. During the lifecycle of the project the annual workshops do fulfill this need.
- Forum for specific questions to CONTRACT (entry point for giving support)
  - Need to ensure a reply (at least a reaction) within a certain time period ◊ commitment

Timing:

Following this initial analysis, the project will focus on this service offering following the initial completion of the questionnaire and the first workshop of the project. Based on the feedback received it will evaluate the potential demand for such type of services, and it will act accordingly.

3.5.6 eCourse

The ultimate exploitation outcome of the project would be the production of an eCourse addressing the issue of informed consent.

Taking into consideration the academic nature of the project coordinating institution (IRI) where different teaching modules allow the opportunity to teach issues of privacy and informed consent such as the Master course in Legal Informatics. The presentation of the project results will be given to students of both undergraduate and post-graduate level in order to sensitize them in the necessity of harmonizing informed consent in Europe. Moreover, general presentations will be carried in the two planned workshops as well as consortium and coordination meetings.

The availability of such a eCourse – accessible through the Helpdesk – and its gradual uptake and utilization by other academic institutions as the reference material in teaching privacy and informed consent issues related to multicentric, post-genomic translational research on cancer, would represent a significant and far-reaching exploitation of project results.

At the same time the production of the eCourse would enable the execution of a number of spin-off activities, such as:

- Opens door for sustainability outcome (summer schools, certification, …)
  - If not monetary ◊ "academic exploitation"
- Production of a printed handbook.

Timing:

Following this initial analysis, the project will focus on this service offering following the initial completion of the questionnaire and the first workshop of the project. Based on

the feedback received it will evaluate the potential demand for such type of services, and it will act accordingly.

4 Conclusions

One of the central outcomes of the CONTRACT project will be a policy oriented study giving recommendations as to how far different concepts of informed consent and its backing could be better coordinated or harmonized within Europe.

This will provide policy makers and the European Commission with an analysis of the current situation and identify possibilities and ways for better coordinating different forms of informed consent in translational health research from a data protection and a clinical trial perspective.

In addition the CONTRACT project will produce concrete recommendations concerning the possible legal and political instruments to foster adequate technical and clinical implementations necessary for the proper handling of informed consent given by the patients and their representatives in translational research. The aim here is to lessen the inconsistency and fragmentation in the legal interpretation of the informed consent in the different European projects and of the interpretation of the Community legislation across Member States.

In more detail, specific outputs of the project include:

- A clear picture of the obstacles in setting up, managing and running translational clinical trials with vulnerable patient groups being the result of different forms and lack of common understanding of informed consent.
- Concrete policy recommendations for the European and national legislators to inform future legislative initiatives and to outline how to coordinate fundamental concepts of informed consent in care, research and data protection.
- A multidisciplinary enquiry office for issues of informed consent in translational research in Europe offering feedback loops to existing and upcoming European projects.
- Identification of good practices of handling consent issues in vulnerable patient groups in Europe.
- Networking with other related projects and associations in the area to share results and good practices guidelines. A non-exhaustive list of such projects and associations are further given below.

In order to enable effective dissemination of project outputs and results and to enable the sustainable exploitation of all – or some – of these results after the end of the project we have worked on the detailed specification of a Dissemination and Exploitation Plan.

Our key objective in so doing has been the elaboration of the various forms of dissemination that could be exploited, the definition in more detail the user groups representing the target audiences of the project, the classification of the potential project outcomes and the definition of indicators, which will be used to monitor and evaluate the effectiveness and breadth of our dissemination activities. Finally an analysis of our exploitation plans and opportunities – as understood by the consortium at this point in time in the time plan of the project – has been concluded. Based on this analysis,

targets for internal activities have been set up, so as to assist project management in their monitoring of those activities which – we believe – would enable the widespread utilisation (and thus exploitation) of project results.

It is our objective to update this initial D&E plan, at least once on month 13, based initial experiences and reactions from our target user communities.