



Electronic Health Records for Clinical Research

Deliverable 1.1

Scenarios, stakeholder requirements, standards, legal and regulatory constraints, gap analysis, medico-economic modelling framework

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1 Executive Summary

Work package 1 contains a set of tasks that collects and collates inputs to the development of the platform, to the pilots and contributes into the platform sustainability and EHR4CR Business Model. It is divided into five tasks, four of which were planned to be very active in year 1 of the project, and have been. This deliverable reports on those activities and presents the results obtained, as appendices.

Task 1.1 has focused on gathering the viewpoints of critical decision makers. The wide-scale acceptability and positioning of EHR4CR is essential for its success. Pilot work was done with different public bodies and ethics committees in Scotland, and used to develop a set of generic materials for use throughout Europe (Appendix 1). The results of interviews already undertaken in Scotland, as a pilot and to validate the interview materials, are reported in Appendix 2. A more detailed (in depth) workshop with ethics stakeholders is reported in Appendix 3.

Task 1.2 has developed the protocol feasibility scenario. Through detailed engagement with protocol managers within Pharma and the wider clinical research community, workflows were documented for establishing the feasibility assessment of a trial protocol (Appendix 4).

Task 1.3 has developed a formal and validated Software Requirements Specification (SRS), presented in Appendix 5. The requirements were informed by the Scenario workflow (Task 1.2), supplemented through interviews with Pharma & academic experts. The SRS contains ~75 use cases, over 200 requirements, a first user interface mock-up and a set of generic non-functional requirements.

Task 1.4 is responsible for ensuring the information governance of the project, of the end resulting platform and for contributing to the business model. Its work is in practice distributed across several tasks of the work-plan. The approach for engaging with ethics board and other Information Governance stakeholders has been developed within Task 1.1, and the results of an initial workshop in Scotland with ethics representatives are reported in Appendix 3. The non-functional requirements focusing primarily on the protection of privacy within the EHR4CR architecture, is included as a chapter within the SRS, Appendix 5. A template to collect ethics approvals and security measures in place at each of the pilot sites is presented in Appendix 6. An inventory of legal and regulatory constraints on the use of EHR data for research, and an analysis of the intended platform workflows, has been developed jointly with WP5 and is reported in Deliverable 5.1.

Task 1.5, dealing with evaluation criteria for the pilots, will be starting in April 2012.

These six reports (the appendices) have been developed during the first year of the project deliberately as freestanding working documents for internal dissemination and, in one case, publication. We have therefore presented these in their original form in this deliverable, and provided a brief summary of each in the immediately following pages. The next steps for this work package, for action during year 2, are also outlined in each of the following subsections.

There are complementarities between this deliverable and the work of work package 2, for example in relation to stakeholders, and this deliverable should therefore be read in conjunction with Deliverable 2.1.

2 Stakeholder Needs, Opportunities, & Challenges

2.1 Introduction

In Task 1.1 we are mapping out the challenges that will have to be addressed in the EHR4CR project. The complexities of local, national and international regulations, policies and health care organisations will be teased out and the key barriers to progress identified. A critical piece of work will be the identification of incentives and disincentives for each player to participate in both the EHR4CR development and crucially in its long-term sustainability.

2.2 Objectives

The objective of Task 1.1 is to determine and describe the concerns, needs, opportunities and perceived challenges of the complex network of stakeholders impacted by EHR4CR. Incentives and disincentives for participation by each stakeholder in both the EHR4CR development stage and the long-term sustainability platform are to be identified, described in detail and documented.

2.3 Problems being addressed

We will identify drivers for change and issues that will impact on data availability, quality and on the research environment itself. Description of new ways of working and their implications, particularly in the area of training requirements, will be an on-going responsibility. Outputs will feed directly into and inform the platform design and the business case.

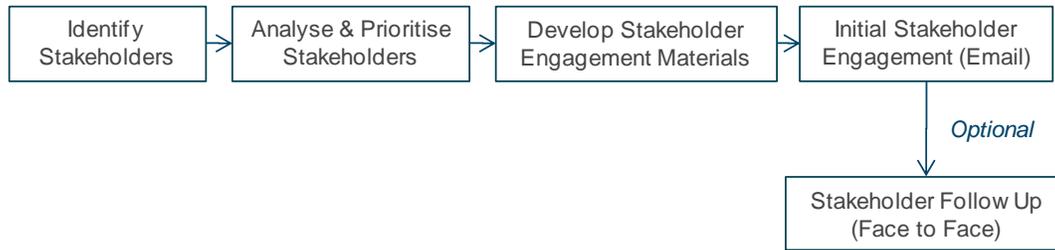
2.4 Approach and activities undertaken

2.4.1 Stakeholder Management pilot

Stakeholder management activities will continue throughout the full four year lifecycle of the project. The initial phase of the work was to conduct an extensive pilot exercise in Scotland to develop a best practice approach for local national stakeholder identification, analysis, engagement and management during the development phase of the EHR4CR project and to make recommendations to those who will be involved in rolling out these stakeholder management activities across Europe

2.4.2 Stakeholder Management Process Overview

The Scottish Stakeholder Management pilot activity has been completed and a report written. The process taken is summarized below:



Stakeholders included senior Scottish NHS staff involved in patient care and research support, academic and NHS researchers, NHS IT staff, patients and carers, ethics committee members and medico-legal experts. Interactions ranged from individual face-to-face meetings through to group meetings with the Scottish Health Informatics Programme.

Meetings focused on the key objectives of EHR4CR: Clinical trial feasibility; facilitation of patient identification and recruitment; clinical trial execution; evaluation of the safety of medicines; and business model development.

2.4.3 Development of Generic Stakeholders Engagement Materials

The Scottish experience was used to develop a set of generic materials for use throughout Europe. These materials included: a two page project summary; a structured questionnaire in two versions targeting a) ethics committee members, b) all other stakeholders; recommended approaches for identifying and approaching stakeholders and for interview conduct. The materials were made available for review by the other project partners, updated and finalised.

2.5 Results and outputs

The completed Generic Stakeholder Management Materials pack is included in this deliverable (Appendix 1).

A report has been written summarizing the experience of the Scottish Stakeholders Engagement is also included (see Appendix 2).

The Generic Stakeholders Engagement Materials were presented and reviewed at a special workshop on EHR4CR at a training meeting of 90 members of Scottish Ethics Committees. A report and analysis of this exercise is included (Appendix 3).

2.6 Relationship to other project areas

The Draft Generic Stakeholders Engagement Materials were presented at the EHR4CR Annual conference in Frankfurt in October 2011 and made available for comments on the EHR4CR project collaborative space.

2.7 Next steps

Next steps are to roll-out the stakeholder engagement process across Europe, and to collect and analyse the data and information.

3 Scenarios for the EHR4CR Platform and Business Model

3.1 Introduction

Scenarios describe the critical business interactions (the goals, motivations, inputs, steps, events, and/or actions which occur during the interaction) for the delivery, control and use of EHR4CR services. They clearly establish the vision, scope and expectations for the future environment to be tested by the EHR4CR platform and business model with enough detail to indicate their anticipated operation.

Four clinical research scenarios were defined within the scope of this project and prioritized by the Executive Committee:

1. Clinical protocol feasibility
2. Patient identification and recruitment
3. Clinical trial execution
4. Adverse event reporting

During Year 1 we have progress scenarios for Clinical protocol feasibility and for Patient identification and recruitment

3.2 Objectives

- Define the approach and terminology to be used for scenario development as part of the requirements engineering process
- Develop domain and usage scenario descriptions for Protocol Feasibility based upon the passing of clinical research protocol population definitions via the EHR4CR platform and business model to query healthcare datasets and to extract aggregated population statistics.
- Initiate development of scenario descriptions for the Patient identification and recruitment domain

3.3 Problems being addressed

These “word pictures” of the intended future describe the information/work flows and system/actor interfaces related to the EHR4CR platform/business model. They are based upon internal stakeholder needs and expectations and need to be further adapted throughout the entire project duration as

information is gathered from external stakeholders and as other work packages develop information and outputs. They will therefore go through several stages of iteration and refinement.

The scenarios need to accommodate the variability of European geographies/cultures, legal /regulatory/ethical constraints, and clinical research therapeutic areas/clinical trial stage requirements.

3.4 Approach and activities undertaken

- Development of an approach and terminology to be used for scenarios development as part of the requirements engineering process
- Understanding of the protocol feasibility and the patient identification and recruitment domains based upon input from internal and external stakeholders and EHR4CR work packages
- Development of a shared vision of future states for Protocol feasibility and for Patient identification and recruitment scenarios. Breakdown of the domain scenarios into high-level 'Usage Scenarios' that describe the critical business interactions (the goals, motivations, inputs, steps, events, and/or actions which occur during the interaction) with enough detail to indicate their anticipated operation for the delivery, control and use of protocol feasibility services.
- Development and formal release of version 1 of the Protocol feasibility scenario at the domain and selected usage levels (see figure below) in sufficient operational detail to drive user requirements development and planning of the technology environment for the first protocol feasibility pilot.

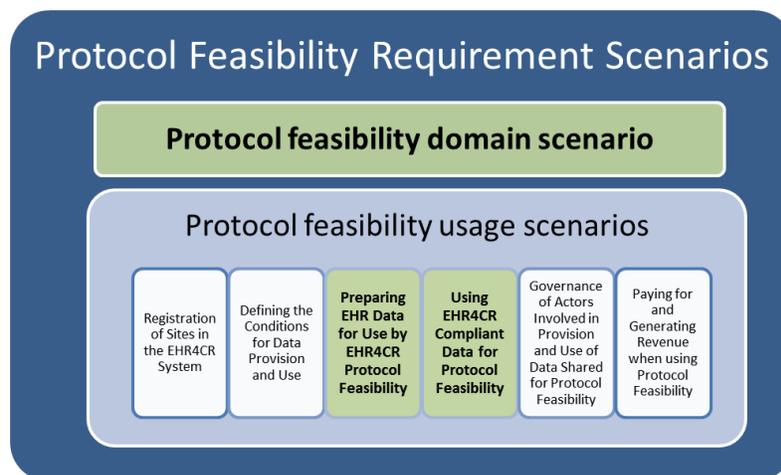


Figure: Protocol Feasibility scenario content included in release 1 (in green)

- Development of first pass content for the Patient identification and recruitment scenario that will be used as input to the second round of user requirements development beginning in Year 2

Milestones Achieved:

- 20 July 2011 – Internal review release of “Requirement Scenarios for EHR4CR Protocol feasibility” for Pilot 1 (Version 1.2). Internal review release of “Proposed Hierarchy and Terminology for Scenarios”.
- 28 August 2011 – Pre-Release “Requirement Scenarios For EHR4CR Protocol Feasibility” (Version 1.3) for WPG2 workshop, User requirements development, review by work package leads and members
- 27 September 2011 – Final Release of “Requirement Scenarios For EHR4CR Protocol Feasibility” (Version 1.4)

3.5 Results and outputs

Requirement scenarios for EHR4CR Protocol feasibility, version 1.5, dated 22 February 2012, are included as Appendix 4. The version has been updated to reflect constraints for the first pilot, approved user requirements and feedback received since a preliminary version was disseminated internally on 27 September 2011.

3.6 Relationship to other project areas

The scenario descriptions direct user requirement development and inform other tasks and work packages on scope and expectations. The scenario development process for Protocol feasibility therefore had extensive participation from other work package representatives during workshop activities and wide distribution as part of the communication process. Technology and pilot constraints have been fed back into the scenarios via the user requirements development process.

3.7 Next steps

Activities scheduled for the first three quarters of 2012 are:

- March 2012: Gathering of user stories for Patient identification and recruitment and update of first pass content as input to workshop #3.
- April 2012: Workshop #3 in Dusseldorf to develop content for Patient identification and recruitment and to start to develop usage scenarios that cross domains (registration of sites, defining the conditions for data provision and use, governance of actors, paying for and generating revenue)
- July 2012: Pre-release of Patient identification and recruitment scenarios for work package review
- August 2012: Release of approved scenarios for finalisation of user requirements on Patient identification and recruitment

4 Requirements

4.1 Introduction

A well conducted requirements gathering and analysis process is an important first step in the development of a usable and efficient application. This process provides a system overview of the envisaged EHR4CR system including definitions, goals, objectives, context, and major capabilities and consolidates all collected needs, constraints and requirements in a structured way in a Software Requirements Specification (SRS) document containing in addition to the use cases, functional and non-functional requirements.

4.2 Objectives

- Define system (platform) requirements based on operational scenarios, stakeholder inputs, and inputs from staff at the pilot sites
- Develop use cases and workflows to elaborate the requirements and steer the development of tools and services

4.3 Problems being addressed

With the requirement engineering process a tool exists for the thorough examination of the envisaged application with the aim to discover the functionalities and the behaviour of the product. In general, the requirements should be expressed in a technologically neutral way; they are a pure expression of the business needs, constraints and requirements associated with the product. Because requirements' gathering is most effectively done as a collaborative activity, brain storming sessions were complemented with structured interviews conducted with selected experts.

State-of-the art processes were determined, and similarities and differences between Pharma and academia were identified. The requirements for temporal query formulations turned out to be especially complicated. Especially the handling of temporal relations and time-based data in EHR4CR demands the development of additional requirements.

4.4 Approach and activities undertaken

We adopted a standard requirements gathering and analysis process for EHR4CR consisting of the elicitation, analysis, specification and validation of the requirements. As a first step, we developed a comprehensive understanding of the envisaged EHR4CR system using detailed discussions with project team, the envisaged user groups, and experts from Pharma and academia. The following activities have been undertaken for the requirements engineering process:

- Brainstorming and Requirements Elicitation Workshop in Leverkusen (7.-8.July 2011)
- Developing a common understanding of the domain/user needs
 - Eight telephone interviews were conducted with experts from Pharma industry and academia, proposed by WP members as being leading experts in the field of protocol

feasibility. All telephone interviews were documented and transformed into requirement statements and analysed.

- Discussions/refinement of Requirements Scenarios provided by R.Perkins, A.Yeomans
- Initial set of requirements and use cases developed at the WP 1 workshop in Leverkusen
- Analysis and development of a framework for handling of temporal relations in queries in EHR4CR (C.Ohmann, T.Karakoyun, W.Kuchinke)
- Analysis of the „temporal“ capabilities of „query“ tools, such as FARSITE, i2b2
- Conceptual modelling of the feasibility scenario (UML use case diagrams and descriptions)
- Requirements Specification
 - Formal specification and complete description of the behaviour of the envisaged EHR4CR system (Protocol Feasibility)
- Collaboration of WT 1.3 and WPG 2 to create common understanding and to synchronize requirement activities
 - EHR4CR Protocol Feasibility Scenario Discussion Document (B. Claerhout, M. Cuggia, J. Devlies, T. Karakoyun, D.Voets)
- Establishment of a process to validate the developed requirements
- Compilation of the Software Requirements Specification (SRS)
 - Review and revision of the Software Requirements Specification within WP1
 - Requirements validation workshop with domain experts in St. Malo (6.-7.12.2011)
- Stage Gate Process: Official project requirements document freeze

4.5 Results and outputs

The main result of this task comprises the validated Protocol Feasibility Software Requirements Specification v 1.0 containing following sections (see Appendix 5):

- Requirements elaborated based on interviews with Pharma and academic domain experts
- Approx. 75 feasibility use cases, over 200 requirements and first GUI-Mock-up
- Tools, methods and approach sections, which illustrates the used tools, methods and approaches in the specification for the EHR4CR platform
- Actors, which provides a brief description and the associated responsibilities of the actors/roles
- Use cases, which specifies the envisaged usage of the EHR4CR system in terms of a conceptual model
- Functional requirements, which documents and specifies required functionalities of the envisaged system
- Non-functional requirements (quality factors)
- Data Requirements

4.6 Relationship to other project areas

The protocol feasibility Software Requirement Specification (SRS) document contains all necessary use case based requirements for the further project development, and delivers input especially to the

technical work package (WPG 2). The WPG 2 team will translate the use cases and requirements into a software system. In addition the SRS is relevant for the pilot WP (WP 7) members, who will use the document for the employment and evaluation of the developed software.

4.7 Next steps

- Update of the requirements engineering process and requirements specification document
- Refinement and discussion on scenarios provided by Task 1.2 (R. Perkins and A. Yeomans) for the next scenario (Patient identification and recruitment)
- Requirements engineering for the second scenario (patient identification and recruitment)

5 Governance Success Factors

5.1 Introduction

This task focuses on several dimensions of governance that the project, the platform and the business model will address. These dimensions include the protection of privacy of individuals when patient level data are accessed by the platform, a means of assuring organizations and the public that privacy is well protected and, in parallel, ensuring that research uses of EHR data are of societal value and that this is understood by external stakeholders.

5.2 Objectives for year 1

- To collaborate with WP5 on an inventory of relevant legislative and regulatory requirements the project must meet.
- To develop non-functional (information governance) requirements for the platform, initially focusing on the protocol feasibility scenario.
- To reach an initial level of understanding of the concerns from a wider stakeholder community on the EHR4CR approach, how these concerns might best be addressed, and to begin promoting the value of EHR4CR to this community.

5.3 Problems being addressed

There are several information governance challenges that are being tackled within this project.

1. Ensuring that the identity of individuals whose data are analysed, communicated and stored within the platform architecture is protected, and that the processing of all personal data

conforms to EU data protection legislation, to national and regional policies and regulations, and to industry best practices.

2. Ensuring that the platform minimises the risk of identification of individuals and maximises organisational, jurisdictional and societal trust by keeping to a minimum the direct access to identifiable data, minimising the communication of patient-level data across borders, and maximising the use of aggregated, anonymised and pseudonymised data.
3. Ensuring that the information handled by the platform and its services are of sufficient quality, and have suitable provenance metadata, to be used for regulated clinical research purposes.
4. Understanding the ethical and privacy protection concerns, and expectations, of stakeholders (specifically including decision-makers) in public and professional bodies and in industry.
5. Ensuring that the pilot sites have the necessary permissions to utilise EHR data for this project's activities, and are applying good practices in information governance and information security.
6. Identifying the key governance success factors for the business model and platform for long-term acceptability.

5.4 Approach and activities undertaken

Progress has been made in all six of the above areas during year one of the project. The outputs for each area are summarised below. Rather than isolate this work, where possible we have integrated the ethical, legal and regulatory dimensions across the project, and so the outputs of Task 1.4 are integrated within other project outputs where meaningful. However, they are each summarised below together with a pointer to where the relevant material may be found.

5.4.1 *Protecting the identity of individuals*

The main year one activity for this object has been to produce an inventory of relevant legislation, standards, regional and national policies and regulatory obligations. This work has been undertaken in collaboration with work package 5. This inventory and analysis of the environment is presented in Deliverable 5.1. We have established links with other EU projects involved in the same area: CONTRACT, TRANSFORM, PONTE, AGCT, etc. in order to share knowledge and experience.

5.4.2 *Ensuring that the platform minimises risk*

The main contribution into the design of the platform is the collection of requirements. The requirements specification for protocol feasibility is complete, as reported under Task 1.3. This specification has a final chapter of non-functional requirements which are predominantly of an information governance and information security nature. Tasks 1.3 and 1.4 have collaborated on this section, which has also had input from the Chair of the EHR4CR Ethics Board and our lead patient organisations' representative.

5.4.3 *Ensuring the platform data meets regulatory requirements*

This work is at an earlier stage, with the higher-level requirements having been included in Deliverable 5.1, and a more formal specification to be developed during year two in collaboration with the architecture work package 3. The inventory and analysis reveal that there are various legislative approaches on national and regional levels throughout the different project site countries in Europe. All these requirements have to be taken into consideration while designing the platform data protection framework, which is presented in Deliverable 5.1 in a first version.

5.4.4 *Wider stakeholder viewpoints*

A detailed interview questionnaire, and briefing pack for interviewers, has been developed through Task 1.1, reported earlier in this Deliverable (Appendix 1). That task report also reports on an ethics workshop specifically focusing on the EHR4CR platform (Appendix 3).

5.4.5 *Governance of the pilots*

Building on work undertaken in past EC projects, a comprehensive template has been developed to capture and collate the necessary information from the pilot sites (see Appendix 6). In parallel, the pilot work package has been refining their EHR data requirements from each site. The sites are now in a position to report on the approvals and protection measures needed to utilise their own EHR patient level data, and so are beginning to populate these templates. The project will centrally and securely hold a register of these approvals and measures, for project governance purposes and, in the longer term, to produce a guidance communication pack for new hospitals that have accredited to the final EHR4CR Platform.

5.4.6 *Ethical inputs to the Business Model*

Specific questions exploring the importance of ethical issues were included within the Environment Scan survey undertaken in summer 2011. The results of this have been published, and are reported in Deliverable 2.1.

5.5 Results and outputs

- A report on the legal and regulatory requirements, and a confidentiality analysis of the proposed data flows for protocol feasibility have been published in Deliverable 5.1, as joint work between WP1 and WP5.
- The ethics stakeholder interviews are published in Appendix 2 (Task 1.1) and the outcomes of the ethics workshop are published in Appendix 3 (Task 1.1).
- The non-functional requirements have been published in Appendix 4 (Task 1.3).
- A report on the development of the pilot sites permissions and measures register is given in Appendix 6.

5.6 Relationship to other project areas

The non-functional requirements are being incorporated within the architecture of the platform by WP3.

The stakeholder interview process (including questionnaires and method of engagement) is now being taken forward in other countries by various partners.

The pilot site register is being promoted for completion by WP7.

5.7 Next steps

The main activities during year two will be to collate the register of permissions and security measures in place at all the pilot sites, to work further with work packages 3 and 5 on the specification of measures that protect the confidentiality of individuals within the platform, to extend the learning from the reported ethics workshop and interviews to other European countries represented within the consortium, and to agree a public engagement work plan with our patient organisation representative.

Some of the key areas to be explored in more detail are:

- What level of de-identification would stop medical data being interpreted as ‘personal data’ within the meaning of the EU Data Protection Directive and its enactments in Member States?
- What level of ‘consent’ may be necessary to process data across EHR4CR if the data are interpreted as ‘personal data’? How ‘broad’ can this ‘consent’ be? Will separate consent need to be sought to share data across EHR4CR?
- If the data are interpreted as ‘personal data’, then will EHR4CR be in a position to support data subject rights?
- What level of data access monitoring and audit is appropriate within EHR4CR?
- What variations across Member States and/or data sources will there be in terms of ‘approvals’ needed to permit data to be shared across EHR4CR? What level of control or accountability over access will data sources require?

6 List of appendices

6.1 *Appendix 1: Generic Stakeholder Management Materials*

6.2 *Appendix 2: Results of Scottish Stakeholders Engagement*

6.3 *Appendix 3: Results of workshop for Scottish Ethics Committees*

6.4 *Appendix 4: Protocol Feasibility Requirement Scenarios*

6.5 *Appendix 5: Protocol Feasibility Software Requirements Specification*

6.6 *Appendix 6: Template for ethics and security registration of pilot sites*