



Electronic Health Records for Clinical Research

Deliverable 2.1

Environment scan (including stakeholders, scenarios, constraints and opportunities)

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Table of Contents

1	Executive Summary	3
2	Environment Scan.....	5
2.1	Introduction.....	5
2.2	Objectives	5
2.3	Problems being addressed	5
2.4	Approach and activities undertaken	5
2.5	Results and outputs.....	5
2.6	Relationship to the rest of the project	5
2.7	Next steps.....	6
3	Platform sustainability business model options.....	7
3.1	Introduction.....	7
3.2	Objectives	7
3.3	Problems being addressed	7
3.4	Approach and activities undertaken	7
3.5	Results and outputs.....	8
3.6	Relationship to the rest of the project	8
3.7	Next steps.....	8
4	Business Model Innovation: strategic plan and value proposition	9
4.1	Introduction.....	9
4.2	Objectives	9
4.3	Problems being addressed	9

4.4	Approach and activities undertaken	9
4.5	Results and outputs.....	9
4.6	Relationship to the rest of the project	10
4.7	Next steps.....	10
5	List of appendices.....	11
5.1	Appendix 1: EHR4CR e-survey publication from iHealthConnections.....	11
5.2	Appendix 2: Sustainability model requirements	11
5.3	Appendix 3: Business Model Innovation: strategic plan & value proposition	11

1 Executive Summary

Work Package 2 focuses on the business model and sustainability plan for the project. It has a dual interest in:

- Developing the licensing and service model that should support the EHR4CR platform being constructed through Work Package Group 2;
- Taking a comprehensive view of the market including the sectors that will purchase or contribute data to the platform, other complementary market sectors whose products and tools will enrich the overall service offering available to purchasers, and public bodies and societal groups whose opinions will be essential to the success and acceptability of the solution.

For both threads of work it was important, especially in the first year of this project, to have taken an open-minded view about whether the end result of this project will be a single definitive resource to be deployed across Europe as an enabling infrastructure to the marketplace, or if this is to be a reference (example) product to inspire many other equivalent offerings and a downstream competitive marketplace for integrative platforms.

This deliverable reports three areas of work that have formed a substantial part of the year one work plan.

1. An E-survey was conducted during the Summer of 2011, comprising both internal and external stakeholders across industry, academia and a number of public bodies, including patient organisations. This has helped to confirm the perceived need and value of the solution we are developing, and also substantiated the major areas of perceived challenge that we must ensure we respond to, such as ethical acceptability, regulatory compliance and privacy protection. This survey has now been published, and a copy of this publication is included as Appendix 1.

2. A second area of work, still work in progress, is to develop a formal options appraisal for the licensing and service offerings, and the nature of the sustaining entity after the end of the four year funded project. An interim report of this is provided as Appendix 2, which summarises the outputs of a recent meeting which is intended as a briefing document for a planned follow meeting.

3. The wider exploration of the long-term business model, consideration of very diverse stakeholders to each of whom we have to have a clear relative positioning, the value proposition for EHR4CR as a whole, and how value is to be presented to each relevant stakeholder, are all the heart of this work package. Appendix 3 presents the work undertaken in year one to investigate this, in the form of a Business Model Innovation Value Proposition and Strategic Plan. This includes an initial assessment of our vision, mission and value statements and a strategy for evolving to a comprehensive and innovative business model downstream through the project.

These three 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 1, for example in relation to stakeholder engagement, and this deliverable should therefore be read in conjunction with Deliverable 1.1.

2 Environment Scan

2.1 Introduction

The environment scan aims at capturing the strategic insights from EU key stakeholders and partners regarding their specific needs, interests, expectations and concerns towards the EHR4CR platform and business model. Part of the broader EHR4CR environment scan initiative, an EHR4CR pan-EU e-survey was developed and conducted with EU stakeholder members of the EHR4CR research consortium, and with external informed stakeholders, both from the public and private sectors.

2.2 Objectives

The objective of conducting this initial EHR4CR pan-EU e-survey was to identify the perceived main opportunities and issues pertaining to the development and implementation of EHR4CR services towards building a sustainable EHR4CR technological platform and business model.

2.3 Problems being addressed

It was important for the EHR4CR consortium to first conduct this pan-EU survey to collect early strategic insights on the perceived advantages and value of EHR4CR clinical services, to inform the PEST and SWOT analyses, and to define the pillars of the EHR4CR value proposition. This survey also revealed potential key opportunities and issues that will need to be further defined until project completion, as well as the likely main drivers and obstacles for delivering, implementing and using the EHR4CR services. This survey also highlighted important elements and expectations useful to defining the scope of EHR4CR services and to designing a sustainable EHR4CR platform and business model.

2.4 Approach and activities undertaken

The survey was conducted in two successive waves. Using an “internal” perspective, the first wave was conducted from June 22-July 04, 2011 with participating EHR4CR EU partners also members of the EHR4CR consortium (total of 78 respondents). Using an “external” perspective, the second wave was conducted from July 05-September 6, 2011 with informed external stakeholders and collaborators (total of 125 respondents).

2.5 Results and outputs

The results from both waves of the EHR4CR e-survey confirmed the underlying assumptions of the project and showed a high degree of consistency across most aspects. The results are summarized in the following publication (included as Appendix 1): Kalra D, Schmidt A, Potts HWW, Dupont D, Sundgren M, De Moor G, on behalf of the EHR4CR Research Consortium. Case Report from the EHR4CR Project – A European Survey on Electronic Health Records Systems for Clinical Research. *iHealth Connections* 2011; 1(2): 108-13.

2.6 Relationship to the rest of the project

The results of the EHR4CR pan-EU e-survey were presented in details to the WPGs leaders and consortium members at the annual EHR4CR meeting in Frankfurt (October 18-21, 2011), as well as to the members of the EHR4CR Business Model Innovation Strategic Forum (BMI-SF) composed of

invited business leaders from participating EFPIA partners. The above publication was also distributed to all consortium members by year-end and is available for further consultation on the EHR4CR Collaborative Space. Again, the results will continue to guide the development of a sustainable EHR4CR platform and business model until project completion.

2.7 Next steps

The objective is to complement and enrich this initial pan-EU EHR4CR e-survey with the results from interviews being conducted by WP1 with informed EU stakeholders, which are expected to reveal more in-depth opinions and insights. The overall results of all EHR4CR Environment Scan initiatives will be most useful to further inform the development of the EHR4CR platform and business model. All environment scan initiatives conducted by the EHR4CR consortium could also lead to a key note publication which would contribute to building further interest and momentum across EU.

3 Platform sustainability business model options

3.1 Introduction

In order to ensure the sustainability of the EHR4CR project assets, an operational framework describing all aspects of the EHR4CR business model needs to be developed and aligned with the strategic business plan (1-3 yrs. time horizon).

The goals for this task will include the production of a robust strategic transition plan for the sustainable entity and the operating cost projections for the early years of operation. The successful implementation of the plan will ensure a seamless transition from the project phase to the creation of a sustainable entity.

3.2 Objectives

- Define the economic and organisational environment necessary for the successful deployment, Identify and establish the organisational structure and associated services and service providers necessary to ensure execution of the EHR4CR business model
- Develop the plan for transition from “project” to sustainable entity

3.3 Problems being addressed

This task addresses the problem of sustaining the EHR4CR assets beyond the lifetime of the project to the benefit of all stakeholders. There are two fundamental questions to be addressed:

- What needs to be sustained after the project period?
- How will it be sustained?

3.4 Approach and activities undertaken

Activity in Task 2.1 was not schedule to begin until Q5 in the project plan set out in the funding proposal.

However, as the project has progressed over the initial 9 months, it has become clear that (i) there is a high degree of dependency between Task 2.1 and Task 2.2 (ii) the decisions concerning the business model and sustainability strategy made in WP2 directly affect both the requirements activities of WP1 and the deliverables of WPG2. Consequently, activity in Task 2.1 has commenced earlier than planned in the original proposal.

To achieve the objectives of WP2.1 we have:

- Identified and documented the key issues that need to be resolved to progress the sustainability strategy
- Presented the document at the Frankfurt face-to-face meeting.
- Established a tight working relationship with WP2.2 Business Model
- Held a workshop in Feb 2012 to resolve the key questions around the sustainability strategy and business model with representatives from all stakeholder groups. The output of the workshop is the consensus view on the sustainability requirements, and a common understanding amongst the stakeholders.
- Analysed the workshop output to produce the sustainability requirements

3.5 Results and outputs

The output of the sustainability requirements workshop and subsequent analysis is contained in the document in Appendix 2.

3.6 Relationship to the rest of the project

This output was created by drawing in expertise from all the stakeholder groups across the project. The sustainability requirements will be used to develop the sustainability strategy that will inform future work in WP1 and WPG2.

3.7 Next steps

1. Construct two (possibly three) sustainability strategies that are parameterised in accordance with the output of the criteria assessment exercise. (March 2012)
2. Undertake a full appraisal of these sustainability strategies with the stakeholder group. (March 2012)
3. Disseminate the sustainability strategies and appraisal to the EHR4CR consortium for comment. (April 2012)
4. Agree sustainability strategy with the Steering Committee and the Executive Committee (July 2012)

4 Business Model Innovation: strategic plan and value proposition

4.1 Introduction

The business model innovation (BMI) task consists of designing and validating an innovative and sustainable business model to support the EHR4CR platform, aligned with specific customers' needs. In order to achieve this, a strategic plan was developed and presented at different forums to provide a systematic approach towards designing a sustainable EHR4CR business model and a targeted value proposition.

4.2 Objectives

The objective was to develop a systematic strategic planning approach relevant to designing a sustainable EHR4CR business model and value proposition, and to mobilize key internal and external stakeholders accordingly. Using the results from the pan-EU EHR4CR e-survey, special attention was given to addressing the key drivers and challenges for designing a sustainable EHR4CR platform and business model.

4.3 Problems being addressed

The EHR4CR BMI strategic plan was developed to provide a systematic approach to defining the EHR4CR Vision, Mission and Value statements, to aligning the next steps, and to mobilizing internal and external stakeholders towards building a sustainable business model and a customized value proposition. Importantly, the strategic plan provides a common BMI strategic framework to be used by all EHR4CR consortium members, contributing to building further understanding, alignment and focus, which is crucial to the success of the project.

4.4 Approach and activities undertaken

Two versions of the EHR4CR BMI & VP strategic plan were produced (Version 1.0 September 2011, Version 2.0 December 2011). An initial version was drafted and circulated in Q3 for further internal input from WPG1 and ExCo members. A consolidated version was circulated in Q4 based on the feedback received and on the results of the pan-EU EHR4CR e-survey results.

4.5 Results and outputs

The EHR4CR BMI strategic plan (refer to Appendix 3) provides a framework for further defining the EHR4CR Value, Mission and Values statements, as well as the BMI strategic goal, strategic imperatives, strategic objectives, and proposed strategies over the 4-year duration of the project. It also describes the business model "building blocks", including the strategic framework for developing a differentiating and customized value proposition. The EHR4CR BMI strategic plan also includes perceived success factors and challenges, based on a comprehensive PEST and SWOT analyses which will need to be updated at least once yearly over the duration of the project due to the rapidly changing environment. Finally, the EHR4CR BMI strategic plan introduces state-of-the-art business model innovation building tools (Business Model Canvas© and Business Model Innovation Foundry©) for upcoming business model design and financial simulations purposes.

4.6 Relationship to the rest of the project

Beyond circulating the EHR4CR BMI strategic plan to ExCo and WPG1 members, the key elements of the EHR4CR BMI strategic plan were also presented to all EHR4CR consortium members at the EHR4CR Frankfurt plenary session (Oct 18-21, 2011), and to participating EFPIA business leaders invited to attend the EHR4CR BMI-SF (strategic forum) on that occasion. The consolidated Version 2.0 of the EHR4CR BMI strategic plan is since available to all on the EHR4CR Collaborative Space.

4.7 Next steps

The WPG1 Science Day in Frankfurt (October 18-21, 2011) highlighted the need to create an EHR4CR BMI-TF (task force) composed of ExCo and WPG1 task leaders in order to build BMI momentum and to drive the next steps in due time.

A first EHR4CR BMI-TF meeting was hosted on Feb 02, 2012 on the theme of: “Aligning the EHR4CR Platform and Business Model Building Blocks Towards Sustainability”. Further to that productive meeting, a joint plan of action was developed and is now being implemented by the EHR4CR BMI-TF members, in preparation for the next EHR4CR BMI-TF meeting scheduled on March 26th and 27th 2012. The objective is to deliver the EHR4CR Vision, Mission and Values statements, and a draft EHR4CR business model canvas and value proposition by the end of Q1 2012, jointly with key recommendations for sustainability strategies.

Once the draft EHR4CR business model canvas is agreed upon, this will drive the deployment of more specific and in-depth EHR4CR market analyses that will then inform the EHR4CR business plan and business model simulations (2012, and on).

The EHR4CR BMI-TF is also working towards surveying EU key stakeholders on the EHR4CR draft business model canvas and value proposition at the “First Annual European Summit on Trustworthy Reuse of Health Data” on May 14-15, in Brussels.

5 List of appendices

5.1 Appendix 1: EHR4CR e-survey publication from iHealthConnections

5.2 Appendix 2: Sustainability model requirements

5.3 Appendix 3: Business Model Innovation: strategic plan & value proposition