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Business analysis for a sustainable, multi-stakeholder ecosystem for leveraging the Electronic Health Records for Clinical Research (EHR4CR) platform in Europe

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ABSTRACT

Introduction: The *Electronic Health Records for Clinical Research* (EHR4CR) technological platform has been developed to enable the trustworthy reuse of hospital electronic health records data for clinical research. The EHR4CR platform can enhance and speed up clinical research scenarios: protocol feasibility assessment, patient identification for recruitment in clinical trials, and clinical data exchange, including for reporting serious adverse events. Our objective was to seed a multi-stakeholder ecosystem to enable the scalable exploitation of the EHR4CR platform in Europe, and to assess its economic sustainability.
Materials and methods: Market analyses were conducted by a multidisciplinary task force to define an EHR4CR emerging ecosystem and multi-stakeholder value chain. This involved mapping stakeholder groups and defining their unmet needs, incentives, potential barriers for adopting innovative solutions, roles and interdependencies. A comprehensive business model, value propositions, and sustainability strategies were developed accordingly. Using simulation modelling (including Monte Carlo simulations) and a 5-year horizon, the potential financial outcomes of the business model were forecasted from the perspective of an EHR4CR service provider.
Results: A business ecosystem was defined to leverage the EHR4CR multi-stakeholder value chain. Value propositions were developed describing the expected benefits of EHR4CR solutions for all stakeholders. From an EHR4CR service provider's viewpoint, the business model simulation estimated that a profitability ratio of up to 1.8 could be achieved at year 1, with potential for growth in subsequent years depending on projected market uptake.
Conclusions: By enhancing and speeding up existing processes, EHR4CR solutions promise to transform the clinical research landscape. The ecosystem defined provides the organisational framework for optimising the value and benefits for all stakeholders involved, in a sustainable manner. Our study suggests that the exploitation of EHR4CR solutions appears profitable and sustainable in Europe, with a growth potential depending on the rates of market and hospital adoption.

1. Introduction

The research and development (R&D) of new medicines has become increasingly challenging. Studies estimate that it now costs between USD 161 million and 2 billion to bring a new drug to

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market [1]. The main obstacles to conducting clinical trials today include high cost, lengthy time frames, administrative barriers and delays in study execution [1,2]. Specific challenges include assessing the feasibility of study protocols, targeting the right patient populations, identifying suitable patients for recruitment in clinical trials, and enhancing clinical data exchange. These factors explain the interest of transforming existing clinical research models so to bring innovative medicines to healthcare faster, and at lower cost [2,3].

In addition, achieving success in today's economy not only demands clever innovation and highly performing technology, but agile and incentive-based business models [4]. While the term " business model" is often used, it is seldom defined explicitly [5]. Nonetheless, it has evolved considerably in the past decade with the development of taxonomies and categorizations [6–13], including the emerging concept of business model innovation [14–20]. Nowadays, business models use a system-level approach to define the manner and framework within which organisations will create, deliver and capture value [20]. In 2009, the "Business Model Canvas" was introduced as a pragmatic approach to business modelling [20]. With its nine building blocks, this systematic approach also has the merit of synthesizing and providing a general overview of the business model, which modular components can be easily updated or reorganised in response to a rapidly evolving market. By defining the organisational framework that can optimise full business potential, business models also assist funding and capital investment decisions.

The objective of the *Electronic Health Records for Clinical Research* (EHR4CR) (http://www.ehr4cr.eu/) was to develop a scalable pan-European platform during a 5-year European research project (2011–2015) funded by the European Commission and by the European Federation of Pharmaceutical Industries and Associations (EFPIA), in the frame of the Innovative Medicines Initiative Joint Undertaking Programme (IMI-JU) [21]. More specifically, this project has developed adaptable, reusable and scalable tools and services for reusing data from electronic health records (EHR) systems for clinical research purposes. With a budget of over 16 million Euros, the EHR4CR consortium involved 34 academic and private partners (10 pharmaceutical companies), and included 11 hospital sites in France, Germany, Poland, Switzerland and the United Kingdom. It is to date one of the largest of the IMI public-private partnership in this area [21].

Importantly, the EHR4CR platform has been specially designed and engineered to unlock the contribution of health data from hospital EHR systems, in compliance with the ethical, regulatory and data protection policies and requirements of each participating country, to enable three clinical research scenarios (S): Scenario 1 (S1): Improving protocol feasibility assessments, Scenario 2 (S2): Enhancing and speeding up patient identification for recruitment in clinical trials, and Scenario 3 (S3): Optimising clinical trial data exchange, including for the reporting of severe adverse events (SAE) [21]. Detailed descriptions of the EHR4CR platform and services have been published [21,22]. The EHR4CR platform supports distributed querying to enhance and speed up clinical trial feasibility assessments, patient identification for recruitment, and clinical study execution. The platform has been piloted at several large academic hospital sites across Europe to demonstrate its functionality, and the effectiveness and security of its tools and services. For this purpose, interfaces between the EHR systems and the central EHR4CR platform have been established. Semantic mapping between local terminologies and the central EHR4CR terminology has been conducted. Clinical data warehouses, compliant with the EHR4CR platform and the associated extract–transform–load processes have been designed and tested. An inventory of data elements corresponding to the most frequently occurring eligibility criteria has been defined. Approval of all data processing steps was gained in accordance with local ethical and legal regulations at each site. In particular, as the pilot sites were active in clinical research, they were able to provide exemplary local governance requirements to complement the ethical inputs referred to above. To enable wide adoption by EHR vendors, and quality assurance of the EHR4CR platform within hospitals, the project developed robust governance through accreditation and certification programmes for establishing best practices [21]. Considering that the EHR4CR platform has considerably evolved since its inception, and given its conclusive pilot testing, it has now reached the commercialization phase and is being scaled up across Europe. Since EHR4CR solutions have been designed to enhance and speed up current practices, it is predicted that they will transform clinical research environments, and generate substantial benefits for all stakeholders involved [2,22]. Consequently, building a business ecosystem and creating sustainable business models are essential in order to successfully implement new technologies in healthcare, and to maximise the value that they can bring to health systems, healthcare organisations, care professionals, patients, care givers, citizens, and to society [23–27].

The main objective of our study was to design a comprehensive multi-stakeholder business ecosystem and to assess the financial sustainability of exploiting the EHR4CR platform from the perspective of an EHR4CR service provider. This paper describes the methodology used to ensure that EHR4CR solutions are deployed and exploited in a sustainable manner in Europe, and beyond.

2. Materials and methods

2.1. Market analyses

At the start of the project, a multidisciplinary Business Modelling Innovation Task Force (BMI-TF) was established to guide the design of a business model for the deployment and sustainable exploitation of the EHR4CR platform. The BMI-TF consisted of up to 15 senior representatives from EHR4CR consortium partners who were invited to participate based on their expertise and interest in business modelling (i.e. academic experts, specialists in EHR research and quality labelling, senior clinical research scientists from 6 participating pharmaceutical companies, clinical research organisations, representatives of patient organisations), including business modelling and health economics experts (designated subcontractors to the project). Over the duration of the project, the BMI-TF met every quarter for a total 12 multidisciplinary workshops. The purpose of these workshops was to co-develop the EHR4CR ecosystem and to design and align the components of a sustainable business model (i.e. definition of the strategic plan, vision, mission and core values, multi-stakeholder value chain, value propositions adapted by stakeholder group, sustainability strategies, business model framework, and market assumptions for conducting advanced business model simulations). Before each BMI-TF workshop, an agenda and reading material were prepared and disseminated to the participants in order to optimise the outcomes. During the multidisciplinary workshops, strategic input was gathered through plenary and breakout sessions using small group discussions and interactive posters. After each workshop, the discussions were synthesised, and again disseminated to the BMI-TF members for further input until the next quarterly workshop. An evaluation of each workshop was conducted so to monitor progress and ensure continuing improvement. In order to gather additional market insights from the primary sponsors of clinical trials, the BMI-TF also organised a total of 3 annual strategic forums with senior clinical research pharma executives who were personally invited by each participating EHR4CR pharmaceutical partner involved in the BMI-TF. The objectives of the strategic forums were