Performance & Final Submission Phase

Project Documentation

Team Id	NM2023TMID04415
Project Name	Block Chain Technology For Electronic Health Records

Abstract:

Objectives:

To describe the IMI EHR4CR project which is designing and developing, and aims to demonstrate, a scalable, widely acceptable and efficient approach to interoperability between EHR systems and clinical research systems.

Methods:

The IMI EHR4CR project is combining and extending several previously isolated state-of-the-art technical components through a new approach to develop a platform for reusing EHR data to support medical research. This will be achieved through multiple but unified initiatives across different major disease areas (e.g. cardiovascular, cancer) and clinical research use cases (protocol feasibility, patient identification and recruitment, clinical trial execution and serious adverse event reporting), with various local and national stakeholders across several

countries and therefore under various legal frameworks.

Results:

An initial instance of the platform has been built, providing communication, security and terminology services to the eleven participating hospitals and ten pharmaceutical companies located in seven European countries. Proof-of-concept demonstrators have been built and evaluated for the protocol feasibility and patient recruitment scenarios. The specifications of the clinical trial execution and the adverse event reporting scenarios have been documented and reviewed.

Conclusions:

Through a combination of a consortium that brings collectively many years of experience from previous relevant EU projects and of the global conduct of clinical trials, of an approach to ethics that engages many important stakeholders across Europe to ensure acceptability, of a robust iterative design methodology for the platform services that is anchored on requirements of an underlying Service Oriented Architecture that has been designed to be scalable and adaptable, EHR4CR could be well placed to deliver a sound, useful and well accepted pan-European solution for the reuse of hospital EHR data to support clinical research studies.

Graphical abstract:

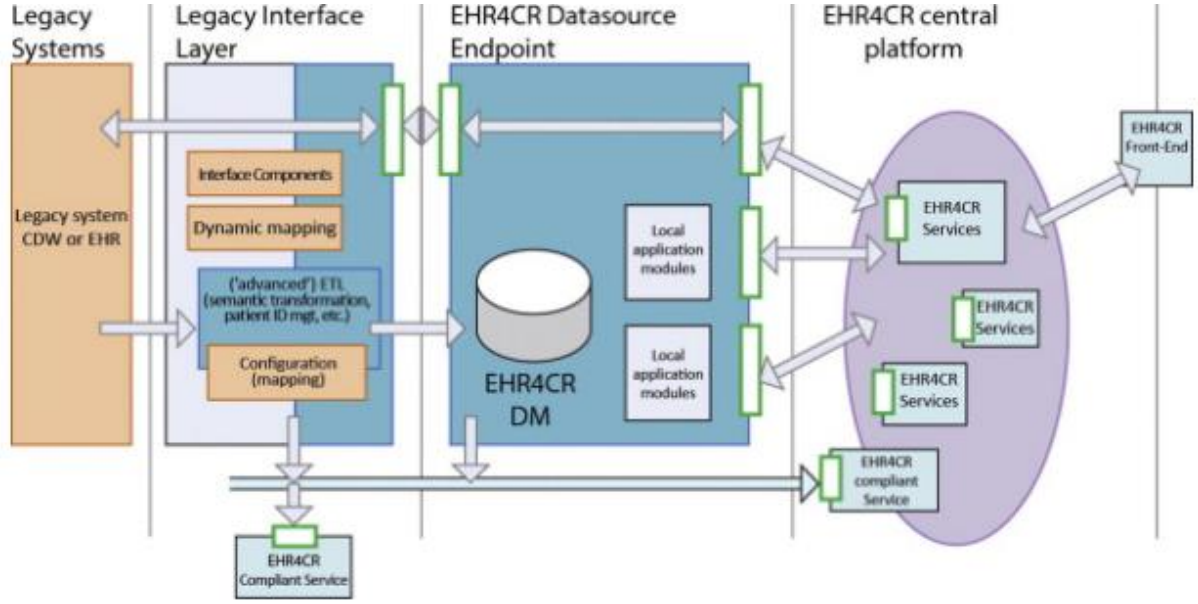

Fig. 1. Simplified view of the EHR4CR platform.

Platform architecture for PFS and PRS:

The current architecture description focuses on the Protocol Feasibility Scenario (PFS) and Patient identification and Recruitment Scenario (PRS). The main components involved in the protocol feasibility scenario are (see Fig. 2):

- Protocol feasibility tools in the form of a workbench for studying non-identifiable distributed patient data. Note that these tools focus on authoring and managing (computable) eligibility criteria queries rather than providing functionality for clinical trial protocol authoring.

- An orchestration module allowing distributed execution of eligibility criteria queries.

- Endpoint (data access) services allowing eligibility criteria query execution on local clinical data warehouse facilities.

- Supporting semantic interoperability services (e.g. coding system value mapping), registry services (e.g. for dynamically discovering query endpoints), a message broker and security services (e.g. *single sign-on*).

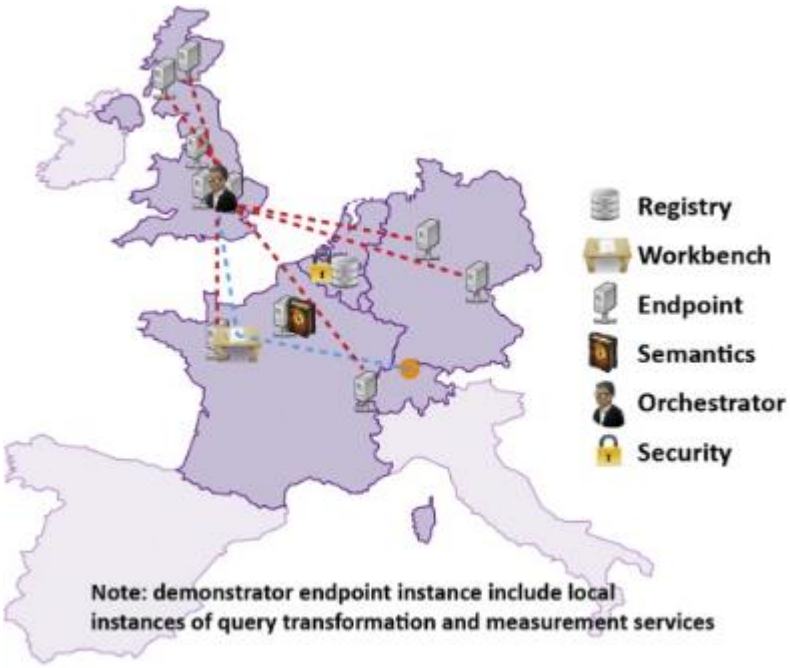

Fig. 2. Overview of the main services of the protocol feasibility scenario.

Similarly to PFS, PRS avoids patient consent-related issues by not exposing patient-level information outside the environment of the clinical sites (Fig. 3). On the local level (within each clinical site), the PRS services support the most stringent requirements encountered amongst the consortium's pilot sites, requiring for instance that a treating physician (or an equivalent role by configuration) notifies each patient who is a potential candidate for recruitment and obtains the patient's approval before

handing over the patient's personally identifiable information to a research investigator for further follow-up. The solution is based on a configurable workflow system that allows for customisation according to local rules and policies. For example, the assignment of the person or group to initially contact a potential candidate patient can be based on departmental information recorded in the clinical data warehouse or other information sources. In addition, tracking of obtained informed consent is an explicit step in the patient's recruitment status tracking system.

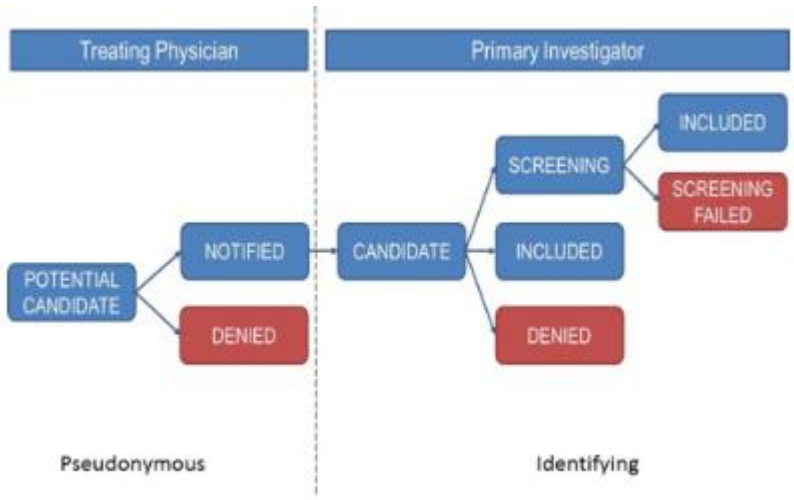

Fig. 3. Patient recruitment status tracking and privacy.