Deliverable 6.4:
Final report of EHR4CR Tools and services

Version 1.0
Final
22 March 2016

Project acronym: EHR4CR
Project full title: Electronic Health Records for Clinical Research
Grant agreement no.: 115189
Budget: 16 million EURO
Start: 01.03.2011 - End: 28.02.2015
Website: www.ehr4cr.eu

Coordinator:
Managing Entity:

The EHR4CR project is partially funded by the IMI JU program
## Document description

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<th>Deliverable no:</th>
<th>6.4</th>
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<td>Final report of EHR4CR Tools and services</td>
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<tr>
<td>Description:</td>
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<tr>
<td>Status:</td>
<td>FINAL</td>
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<tr>
<td>Version:</td>
<td>1.0</td>
</tr>
<tr>
<td>Date:</td>
<td>22/03/2016</td>
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<tr>
<td>Deadline:</td>
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<tr>
<td>Editors:</td>
<td>M. Cuggia, Pascal Van Hille, Eric Renault</td>
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1 Objective of the Deliverable 6.4:
This document aims to review and recap the activities of the work package 6 and the work achieved during the period of the project, according to the initial description of work. Full technical and functional description of the system are available in the deliverable 6.1 (PFS), 6.2 (PRS) and 6.3 (CTE and ADE).
2 Summary of the WP6 objectives:

The objective of this WP was to design and implement end-to-end solutions that address the requirements of the different EHR4CR scenarios (clinical trial protocol feasibility, patient recruitment, clinical trial execution and drug safety monitoring).

This Work Package was build on the semantic interoperability services (WP 4) and the data protection services (WP 5) and is comply with the EHR4CR architecture (WP 3). It provides end users tools and services to perform the 4 scenario described in the project:

- Protocol feasibility study (PFS)
- Patient Recruitment Study (PRS)
- Clinical trial execution (CTE)
- Adverse Effect Report (AER)

WP 6 specified the functional and technical process flows based on the detailed WP 1 scenarios and implement them based on generic components delivered by the other technical WPs on the EHR4CR architecture.

Initially, the wp6 tasks was organized to develop low level and end-users components:

Low level components developed in Task 6.4 to 6.6 were dedicated to provide reusable functionalities for end user components and for each scenario (Task 6.1 to 6.3).

2.1 Description of work and commentaries about tasks and actions.

We recap here the objective and the work expected for each task. In italic, we provide commentaries and explanations about what has been actually achieved in the period of the project.

2.2 End user WP6 components

2.2.1 Task 6.1 Clinical Trial Protocol Feasibility Services (PFS)

- The PFS components were designed according the requirements defined in WP1. 
  Actually, these requirements contained detailed descriptions of the expected functionalities that has facilitated the system design and implementation by WP6 partners.
- Service Specification
  - Specification of solution components and end-to-end process flow, building upon architecture (WP 3), semantic interoperability (WP 4) and data protection (WP5).
  - General technical requirements and good practice principles were discussed and were chosen with WP3 (e.g Languages and framework, Service Oriented Architecture).
  - Define and refine requirements of other services defined in this WP (WP6), such as the Criteria Authoring and Management Services, the Criteria Matching Services, and the Data Visualization and Reporting Services
  - For PFS scenario: CAMS and CMS functionalities were included in the 2 end-user components:
    - The study manager tool dedicated to manage users and studies
The PFS query workbench dedicated to manage eligibility criteria and perform query from the platform.

- Service Development
  - Development of end-to-end service; apply iterative process with increasing complexity of IE criteria.
  - For that, a close cooperation between WP4 teams (semantic services) and WP5 teams (security) allowed to fully integrate end users’ tools developed by WP6 partners with middleware components (orchestrator, mapping services) and models (eligibility end user model with ECLECTIC processing model).
  - Service testing; unit testing and integration testing: PFS end-users services were tested, deployed and fully successfully evaluated by WP7 partners (local sites and pharma partners).

### 2.2.2 Task 6.2 Patient Recruitment Services (PRS)

- Analyse requirements as defined in WP 1
  - This scenario was much more complex than PFS and aimed to
    - (i) perform local recruitment of patients reusing query results performed on local clinical data warehouse to spot eligible patient, and to ensure recruitment process involving several actors (Patients, Principal investigator (PI), Treating physician (TP), Data Relational manager (DRM)).
    - (ii) to provide to the Study managers and to the central platform updated information about the local recruitment process.
- Service Specification
  - Specification of solution components and end-to-end process flow, building upon architecture (WP 3), semantic interoperability (WP 4), and data protection (WP5).
  - Requirements and elements of expected functionalities provided by WP1 helped WP6 partners to propose a global view (vertical slice) to WPG2 describing a technical and functional architecture for PRS.
  - Define and refine requirements of other services defined in this WP (WP6), such as the Criteria Authoring and Management Services, the Criteria Matching Services, and the Data Visualization and Reporting Services
- Service Development
  - Development of end-to-end service; apply iterative process with increasing complexity of eligibility criteria
  - In PRS Scenario, end user’s tools were developed, reusing parts of PFS scenario (especially the central and local workbench) to transform PF study to PR study. The study management tools and the central workbench were updated. A local workbench dedicated to PFS was fully designed and implemented to perform all the recruitment workflow between actors.
  - Data visualization tools (local and central dashboard) were also developed to monitor the recruitment process.
- Service testing; unit testing and integration testing
• Tools and services for PRS were tested, deployed and fully evaluated by local sites and WP7 partners. It turned out that each site had its own organization and recruitment process. That is the reason why PRS components were designed to be weakly coupled with legacy systems and to be adapted to each organization.

2.2.3 Task 6.3 Clinical Trial Data Capture Services (DCS)

• Analyse requirements as defined in WP 1.
• These services actually cover the two last scenario addressed and that were merged during the project (Clinical Trial Execution (CTE) and Adverse Effect Reporting (AER)).
• CTE and AER were quite challenging since they aimed to automatically capture patient data for ongoing clinical trials or for post marketed studies. In this scenario users of each sites were supposed to enter information in the local electronic health system the EHR4CR system was supposed to extract transform patient datasets from legacy systems (either directly from the EHR or from the local clinical data warehouse) and load them into targeted e-CRF systems.

• Service Specification
  o Specification of solution components and end-to-end process flow, building upon architecture (WP 3), semantic interoperability (WP 4), and data protection (WP5)
  o Define and refine requirements of other services defined in this WP (WP6) – such as the Criteria Authoring and Management Services, the Criteria Matching Services, and the Data Visualization and Reporting Services
  o Specify solution for data transform from existing EHR systems, via platforms to corresponding CDM systems
  o Define specification for mapping and collection of data elements from existing EHR systems into CRF’s; this mapping and collection will be performed within the local EHR systems, and this Task will provide the corresponding requirements

Based on WP1 requirements, WP6 has provided a full description of the functional and technical architecture to address both CTE and AER. This architecture supposed to interoperate with legacy systems and to have a full involvement of EHR and e-CRF vendors in the project, that was unfortunately the case.

Moreover, this last scenario occurred at the end of the project and supposed to have access to development resources that were no more available during the 1 year extension of the project.

These are the main reasons why this DCS component was not technically implemented. However, this service was design to reuse parts of existing component and it implementation should be feasible if vendors are involved and agree to open them system and if necessary research and development resources are available.
2.3 Low level services of WP6 components:

As mentioned above, regarding to the initial description of works, low levels services such as CAMS, CMS and VIZ were regrouped and redefined in the different components provided during the project. We illustrate for each task what has been done for each scenario.

2.3.1 Task 6.4 Eligibility Criteria Authoring and Management Services (CAMS)

- Analyse requirements as defined in WP 1 and based on requirements from other services in this WP (WP6)

- Service Specification
  - Specification of solution components and end-to-end process flow, building upon architecture (WP 3), semantic interoperability (WP 4), and data protection (WP5)
  - Define interaction with other services defined in this WP (WP6)
  - Define and design criteria authoring tools
  - Define query formats and languages to be used by the query mechanism (together with WP 4). Define intermediate formalism and criteria patterns
  - Define methods (manuals and/or automated) for transforming free-text eligibility criteria to the intermediate formalism

- Service Development
Development of end-to-end service; apply iterative process with increasing variety and complexity of source data elements

- Service testing; unit testing and integration testing

This component was included in the Study manager tool and the central and local query workbenches used for PFS and PRS.

2.3.2 Task 6.5 Criteria Matching Services (CMS)

- Requirements analysis: analyse requirements as defined in WP 1 and based on requirements from other Services in this WP (WP6)
- Service Specification
  - Specification of solution components and end-to-end process flow, building upon architecture (WP 3), semantic interoperability (WP 4), and data protection (WP5)
o Define interaction with other services defined in this WP (WP6).

o Design and implementation of the “local” query execution component (relying on WP 4 components)

- Service Development

o Development of end-to-end service; apply iterative process with increasing variety and complexity of source data elements

- Service testing; unit testing and integration testing

CMS services was actually embedded in the technical layer between the GUI components of the query work bench, and the semantic layers component including the ECLECTIC model and the interoperability services (mapping services and query orchestrator). The graphical representation of the criteria is translated into Eclectic representation and then transform through the semantic services to query performed at the local endpoints. Aggregated information about population of interested which match the set of criteria are sent from the endpoint to the data viz component (see below).

For PFS, only aggregated data is sent from local site to the central platform
For PRS, aggregated data and status of pre-screened patients is sent to central workbench. Individual data of pre-screened patients is sent to the local workbench to support the recruitment process.

2.3.3 Task 6.6 Data Presentation and Visualization (VIZ)

- Requirements analysis: analyse requirements as defined in WP 1, and based on requirements from other Services in this WP (WP6)

- Service Specification

  o Specification of solution components and end-to-end process flow, building upon architecture (WP 3), semantic interoperability (WP 4), and data protection (WP5)

  o Define interaction with other services defined in this WP (WP6)

- Service Development

  o Development of end-to-end service; apply iterative process with increasing variety and complexity of source data elements.

  o Develop or integrate required visualization capabilities (e.g. geo-visualization, timeline visualization)

- Service testing; unit testing and integration testing

Different components for visualization and data presentation were developed for each scenario.

For PFS scenario: aggregated data of population of interest are displayed by site, age, and sex, for all criteria or per criteria.
data viz component for PFS scenario

PRS Workflow viz tool (local workbench)
### Recap of the deliverable and milestones and status

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