Implementation and validation of a standards-based approach to embedding clinical trial functionality in routine EHR systems

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Background

Clinical trials have been in a long-term crisis, in terms of costs and poor recruitment, for the best part of a decade.[1]

There has been a steady move away from paper Case Report Forms (CRFs) towards both electronic maintenance of clinical trial data and electronic data capture systems (EDC).[2]

The Learning Health System (LHS) envisages a health care organisation where routine EHR systems are the direct mediators of both research and knowledge translation activities.[3]

Material and Methods

TRANSFoRm adopts a dual-level modelling approach to maintain semantic interoperability:

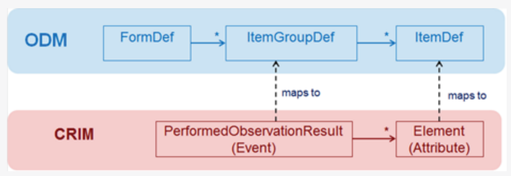
1. Clinical Research Information (CRIM) to guide research workflow
2. Clinical Data Integration Model (CDIM) to describe and define the primary health care domain[4]

The Operational Data Model (ODM) is a research standard for data represenation in CRF.

In order to pre-populate data in the ODM file, a query must be issued through the TRANSFoRm infrastructure to fetch data and return it in the right place in the ODM.

By adding a <QueryId> child element, a unique identifier can be inserted to link the group with a related specific query.

ODM-CRIM Mappings



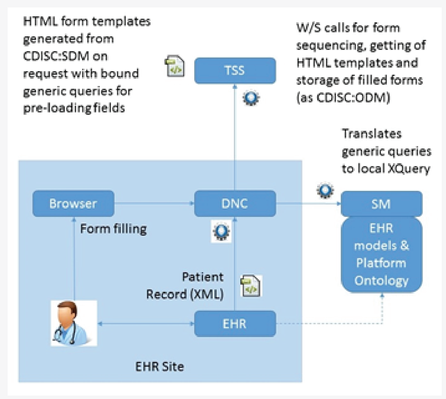
Results

The anchor on the research side is the TRANSFoRm Study System (TSS) which is centrally hosted at a secure location. The TSS holds the study information and protocols, defined via ODM files, as well as acting as the research repository.

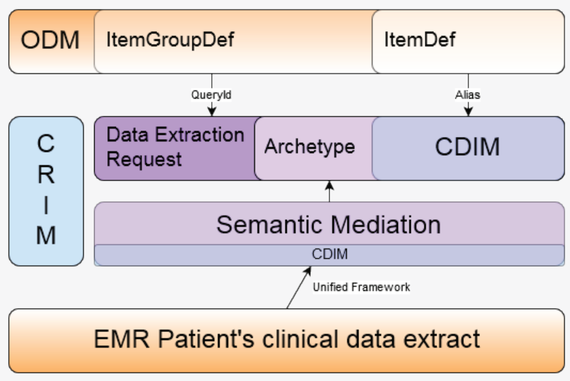
When a patient arrives for a consultation, his existing EHR data is exported by the EHR to the data node connector (DNC) as an XML document. The XML is mapped through the interoperability framework to CDIM to express a common semantic. The DNC then applies the queries to the XML documents to compute eligibility.

The DNC retrieves the appropriate eCRF forms from the study system, transported as HTML forms parameterised for preloading and storage of field values, together with the corresponding ODM document. Once, approved, the form is submitted to the DNC where data is inserted in the ODM file which is sent to the TSS but also to the EHR for auditing purposes.

Overall Architecture



Semantic Links



Conclusion

TRANSFoRm has shown that the process of integrating clinical trial processes and data management into the EHR system can be made simpler and more feasible for EHR vendors, lowering the barriers to adoption and increasing the uptake of the Learning Health System. One virtue of the approach is that it does not require modification of ODM, simply exploiting the existing flexibility of the standard and the ability to specify external bindings.

The approach we outlined is generalizable to other domains as different domain specific models can be specified. We used higher level concepts to ensure future compatibility by using BRIDG for CRIM and building CDIM from middle level ontologies.

Acknowledgment and Contact

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