REDHot OMOP: Facilitating Semantic Interoperability in REDCap with FHIR and the OMOP CDM

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Background

Insufficient interoperable data exchange when conducting observational research.[1,2] One of the leading clinical research informatics (CRI) tools for observational research is Research Electronic Data Capture (REDCap). As the REDCap community has expanded beyond Vanderbilt University to an international consortium of over 3,200 partners, addressing issues of data interoperability has gained considerable importance.[3] The Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) serves as a solution for organizations across the globe to conduct systematic analysis of disparate databases. Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®) has become a well-trusted standard for facilitating data-exchange at the electronic health record (EHR) level.[4] There have been recent efforts to combine each of these three resources: REDCap and OMOP, at institutional levels[2]; REDCap and FHIR, through the consortium;[5,6] and OMOP and FHIR, from Georgia Tech.[7] Further, at the start of 2021, there was an announcement of an official partnership between HL7 and the OHDSI network, who maintains OMOP, to provide a Single CDM for sharing information in clinical care and observational research.[8] To our knowledge, however, there is no prior work that leverages all three resources, REDCap, FHIR, and OMOP, into one system. An exemplary use case for such a system would be performing chart reviews to enhance existing data.

When a group conducts a chart review for retrospective analysis, information will be collected in electronic case report forms, such as REDCap forms.[9,10] The various entities generating case report forms inevitably augment the data with some amount of clinical knowledge, whether that be the potential for an adverse event or more suitable diagnosis.[11,12] Then, when researchers seek to review various sources of information for a retrospective observational research study, the main concerns are: "How do we get the information from the case reports into the data model?" and "How do we address a lack of standardization in the collection and processing the data collected in reports from disparate sources?" In response to those concerns, we have conceptualized a new tool called *REDHot OMOP*, a Substitutable Medical Applications Reusable Technologies (SMART) on FHIR[13] application, which will leverage the benefits of FHIR and OMOP to be the conduit of clinical data standardized in a format tailored toward improving translational and observational research endeavors.

Methods

Since REDCap operates on and can be expanded via open-source components, thanks to the REDCap Consortium[3], it appeared reasonable to leverage existing resources[6,7] as a foundation and fill in any remaining gaps with REDHot OMOP. Figure 1 describes the system architecture that connects with REDHot OMOP. REDHot OMOP exists as the conduit in a system that will allow researchers to leverage customizable, interoperable, as well as FHIR and OMOP compliant, REDCap form data.

The pipeline works as follows: **(1)** users enter information of any data type into a REDCap form **(1a)** with any free-text input being captured in a specialized field, augmented by REDCap's Ontology Provider service. The Ontology Provider is linked to a local FHIR Terminology Service through an External Module developed by a team from the Commonwealth Scientific and Industrial Research Organisation (CSIRO) in Australia. The FHIR Terminology Service **(1b)** returns a list of potential codes, based on a pre-defined list of values (FHIR ValueSet Resource) from local code system selected by the form designer in advance, from which the user can select the most appropriate choice. Once the form is complete, **(2)** the form report is exported via the REDCap application programming interface (API) into Redmatch, a CSIRO tool that transforms REDCap form reports with user-defined mapping rules. After the user loads the report and assigns appropriate values, **(3)** Redmatch converts the REDCap data into FHIR Resources and sends them to REDHot OMOP. The FHIR Resources with the local codes are stored in REDHot OMOP and the data associated with the

Resources are **(4a)** sent to OMOPonFHIR, a HL7 API (HAPI) FHIR server, which will make the information OMOP compliant. OMOPonFHIR **(4b)** maps the input codes to their OMOP equivalents using an internal translation service, stores the data in a local OMOP database, and returns all viable mappings to REDHot OMOP. Subsequently, REDHot OMOP **(5a)** provides the user with a representation of the REDCap data in both custom and all mappable OMOP codes for covariate analysis or visualization. As an additional route, REDHot OMOP can also **(5b)** connect with an EHR, if it is established in an institution, or external application via the SMART on FHIR platform. With the

SMART on FHIR integration enabled, findings from REDCap forms or the OMOP instance can be utilized to assist in clinical decision support (CDS) or integrated into a mobile app. To close out the data loop, if enabled by the institution **(6)** information can be extracted from the EHR and be associated with a participant in a research study using REDCap's Clinical Data Pull, which can connect to major EHR systems such as Epic and Cerner, among others, on a continuous basis.

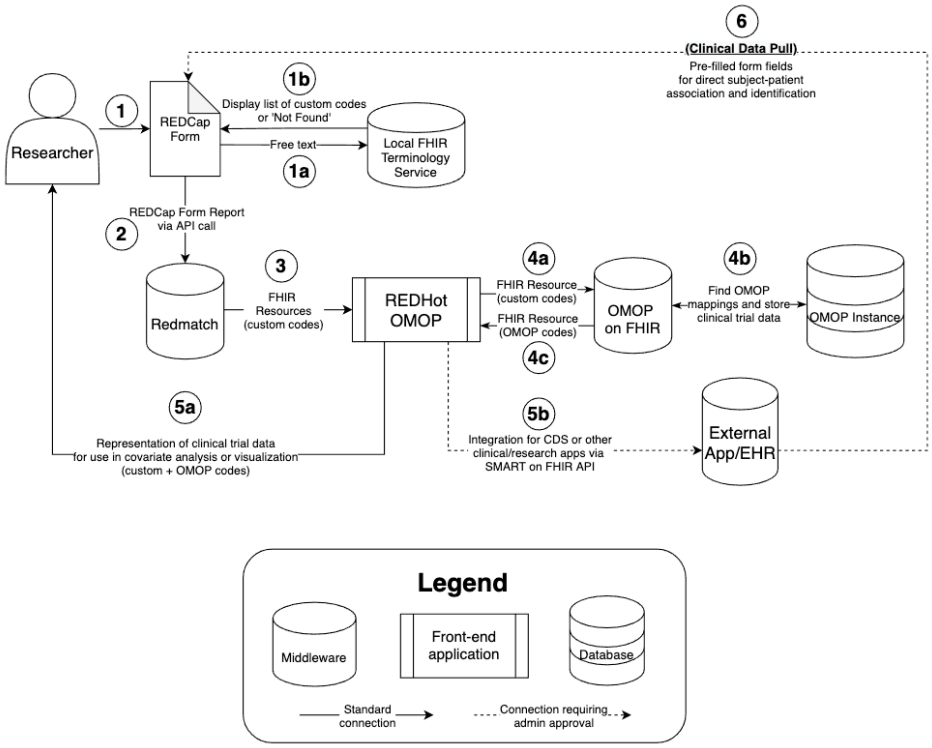

Figure 1. REDHot OMOP Architecture. Example workflow of data as researchers complete REDCap forms.

Conclusion

Standardization and improved interoperability by way of FHIR and OMOP stand at the forefront of informatics solutions. The creation of a system that connects REDCap, FHIR, and OMOP could have lasting implications on CRI and translational research. REDHot OMOP could support interoperable data exchange bidirectionally between observational research and clinical practice and has the potential to foster more robust learning health systems and accelerate existing clinical research practices.

References/Citations

1. Valkenhoef G van, Tervonen T, Brock B de, Hillege H. Deficiencies in the transfer and availability of clinical trials evidence: a review of existing systems and standards. BMC Med Inform Decis Mak. 2012 Sep 4;12:95.
2. Hsu W, Gonzalez NR, Chien A, Pablo Villablanca J, Pajukanta P, Viñuela F, et al. An integrated, ontology-driven approach to constructing observational databases for research. J Biomed Inform. 2015 Jun;55:132–42.
3. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap Consortium: Building an International Community of Software Platform Partners. J Biomed Inform. 2019 Jul;95:103208.
4. Overview - FHIR v4.0.1 [Internet]. [cited 2021 May 25]. Available from: https://www.hl7.org/fhir/overview.html
5. Hey, Your REDCap Is on FHIR! [Internet]. Healthcare Innovation. 2019 [cited 2021 May 30]. Available from: https://www.hcinnovationgroup.com/interoperability-hie/fast-healthcare-interoperability-resources-fhir/article/21111013/hey-your-redcap-is-on-fhir

6. aehrc/redmatch [Internet]. The Australian e-Health Research Centre; 2021 [cited 2021 May 25]. Available from: https://github.com/aehrc/redmatch
7. The FHIR Project at Georgia Tech [Internet]. GT-FHIR2, the OMOP on FHIR Project. [cited 2021 May 25]. Available from: http://omoponfhir.org/
8. HL7 International and OHDSI Announce Collaboration to Provide Single Common Data Model for Sharing Information in Clinical Care and Observational Research – OHDSI [Internet]. [cited 2021 May 25]. Available from: https://www.ohdsi.org/ohdsi-hl7-collaboration/
9. Bellary S, Krishnankutty B, Latha MS. Basics of case report form designing in clinical research. Perspect Clin Res. 2014;5(4):159–66.
10. Nahm M, Shepherd J, Buzenberg A, Rostami R, Corcoran A, McCall J, et al. Design and implementation of an institutional case report form library. Clin Trials Lond Engl. 2011 Feb;8(1):94–102.
11. Siems A, Banks R, Holubkov R, Meert KL, Bauerfeld C, Beyda D, et al. Structured Chart Review: Assessment of a Structured Chart Review Methodology. Hosp Pediatr. 2020 Jan;10(1):61–9.
12. Brennan TA, Localio AR, Leape LL, Laird NM, Peterson L, Hiatt HH, et al. Identification of adverse events occurring during hospitalization. A cross-sectional study of litigation, quality assurance, and medical records at two teaching hospitals. Ann Intern Med. 1990 Feb 1;112(3):221–6.
13. Mandel JC, Kreda DA, Mandl KD, Kohane IS, Ramoni RB. SMART on FHIR: a standards-based, interoperable apps platform for electronic health records. J Am Med Inform Assoc. 2016 Sep 1;23(5):899–908.