CRN - FHIR Investigation and Implementation Guide

Background

The federal Women's Health Technologies (WHT) Coordinated Registry Network (CRN) project aims to create a set of linked registries focused on women's health through the use of data elements and measures expressed in standard structured definitions. It will also allow for the capability to capture and exchange data using national standards and the ability to support interoperability with other data sources via software apps and application programming interfaces (APIs), including those related to a unique device identifier (UDI). These linked registries would be valuable to researchers to design studies that are reflective of the real-world combination of multiple therapies.

To learn more about the CRN project, download the Environmental Assessment and Pilot Analysis located here.

Scope

Clinical registries record information about the health status of patients and the health care they receive over varying periods of time. Registries can include data on patients receiving treatment involving medical devices. Registries also provide critical infrastructure that can be used for a variety of analyses related to patient care and outcomes. There are clinical conditions that uniquely affect women (e.g., pelvic floor disorders, uterine fibroids, and female sterilization). A consortium of registries focused on women's health using data elements and measures expressed in standard structured definitions with the capability to capture and exchange data via software apps and application programming interfaces (APIs) including those related to a unique device identifier (UDI) would be valuable to researchers beyond what can be accomplished in a single registry. Currently researchers are not able to design studies that are reflective of the real-world combination of multiple therapies. The effort to be undertaken under the statement of work for this coordinated registry network project is leveraging the relationships of the federal partnerships to test the building of an infrastructure examining many clinical conditions that uniquely affect women (e.g., pelvic floor disorders, uterine fibroids, and female sterilization).

From a standards perspective, the project will outline the mechanisms that can be used to capture and exchange

- Common or core data elements related to women's health collected as part of the clinical care delivery eco-system

Specifically, the project will examine how to use the following FHIR Resources and IG's to facilitate collection and exchange of data elements related to women's health using the following:

- Questionnaire
- Questionnaire Response
- Device
- Observations specific to Women's Health
- US-Core profiles and IG
- Structured Data Capture IG

The Questionnaire and Questionnaire Response profiles will likely be used for administering data collection instruments related to women's health. Any extensions that may be necessary for the project will be part of the overall profiles developed. Device Resources will be used to capture UDI and other Device related data and Observation will be used to capture observations collected during the care delivery.

For other clinical data that may be used for auto-population or exchanging CRN data within the context of EHRs the US Core FHIR profiles will be reused.

HL7 Sponsors

Primary: Biomedical Research and Regulation (BR&R) approved on 6/12
Co-Sponsors: Orders and Observation (O&O) approved on 5/3 and Clinical Interoperability Council (CIC) approved on 4/26

HL7 Artifacts

September 2018 Ballot Cycle (Comment Only Ballot)

- Project Scope Statement (PSS): CRN_2018_HL7_Sep_WG_PSS 8-24-2018.docx
- Notice of Intent to Ballot (NIB): http://www.hl7.org/special/committees/tsc/ballotmanagement/ViewPastNIB.cfm?ballot_pool_id=1237
- HL7 Project Summary: http://www.hl7.org/special/committees/projman/searchableprojectindex.cfm?action=edit&ProjectNumber=1426
- CRN FHIR IG Proposal: http://wiki.hl7.org/index.php?title=CRN_FHIR_IG_Proposal
- HL7 FHIR® Implementation Guide: Women's Health Technology Coordinated Registry Network (CRN), Release 1: http://hl7.org/fhir/us/womens-health-registries/2018Sep/
- Baltimore WGM Plenary Slide Presentation: BRR CRN Slide for HL7 9-2018 FINAL.pptx

January 2019 Ballot Cycle

- San Antonio WGM CRN BR&R WG Update: BRR CRN Slide for HL7 Jan-2019.pptx

May 2019 Ballot Cycle (STU 1 Ballot)

- Notice of Intent to Ballot (NIB): CRN NIB Spring 2019 (1).pdf
- FHIR Implementation Guides/Planned Ballots: 2019 May - Ballot Cycle
- HL7 FHIR® Implementation Guide: Women's Health Technology Coordinated Registry Network (CRN), 0.2.0 STU: http://hl7.org/fhir/us/womens-health-registries/2019May/

September 2019 Ballot Cycle

- Atlanta WGM CRN BR&R WG Update: BRR CRN Slide for HL7 Sept 2019.pptx

Implementation Guide Development Workgroup (WG)

We thank everyone for their participation in the CRN HL7 activities and for attending the IG WG calls. Now that we have reconciled all the CRN ballot comments, we have cancelled the IG WG calls and provide any further updates (as necessary) during the HL7 BR&R WG meetings.

Meeting Date	Meeting Artifacts
June 29, 2018	WG Kickoff Presentation Meeting Recording Meeting Notes
July 10, 2018	Meeting Recording Meeting Notes
July 11, 2018	Meeting Recording Meeting Notes
July 17, 2018	Meeting Recording Meeting Notes CRN Working Group Variables FDA Device Data Elements Template
July 24, 2018	Meeting Presentation Meeting Recording
July 31, 2018	Meeting Recording
August 14, 2018	Meeting Recording
August 21, 2018	Meeting Recording Current HL7 Timeline
August 28, 2018	Link to the CRN IG: http://hl7.org/fhir/us/womens-health-registries/2018Sep/ Meeting Recording: Walkthrough of CRN IG Current CRN HL7 Timeline
September 18, 2018	Meeting Notes
October 9, 2018	Meeting Recording Current CRN HL7 Timeline
October 16, 2018	Current CRN HL7 Timeline
October 30, 2018	Current CRN HL7 Timeline Meeting Recording Meeting Notes
November 13, 2018	Current CRN HL7 Timeline Meeting Recording Meeting Notes
December 5, 2018	Current CRN HL7 Timeline Meeting Recording Meeting Notes

December 18, 2018	Current CRN HL7 Timeline Meeting Recording Meeting Notes
January 15, 2019	Current CRN HL7 Timeline Meeting Recording Meeting Notes
January 22, 2019	Current CRN HL7 Timeline Meeting Recording Meeting Notes
January 29, 2019	Current CRN HL7 Timeline Meeting Recording Meeting Notes
February 05, 2019	Current CRN HL7 Timeline Meeting Recording Meeting Notes
March 05, 2019	Current CRN HL7 Timeline Meeting Recording Meeting Notes
March 12, 2019	Current CRN HL7 Timeline Meeting Recording Meeting Notes BR&R WG Notes-Approval of Ballot ****IG WG Meetings will resume in mid-May*****
May 21, 2019	Meeting Recording Meeting Notes
May 28, 2019	Meeting Recording Meeting Notes
June 4, 2019	Meeting Recording Meeting Notes
June 18, 2019	Meeting Recording Meeting Notes
July 2, 2019	Meeting Recording Meeting Notes
July 16, 2019	Meeting Recording Meeting Notes
July 23, 2019	Meeting Recording Meeting Notes
August 6, 2019	Meeting Notes ****CRN Ballot Reconciliations are complete and the IG WG meetings have been cancelled. We thank everyone for their participation*****