

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

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

