Crn FHIR IG Proposal

Approved 2018-08-08
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Womens Health Technology Coordinated Registry Network

Owning work group name
BR&R

Committee Approval Date:
2018-06-12

Contributing or Reviewing Work Groups
• O&O
• CIC

FHIR Development Project Insight ID
1426

Scope of coverage
The project is relevant to the following Women's Health Registries which include
• COMPARE-UF,
• PFDR,
• CREST !!!,
• AUGS,
• SUFU and other Sterilization Registries.

These registries will be monitoring Women's Health on the use of devices and implants and other procedures for conditions such as Uterine Fibroids, Pelvic Floor Disorders, Mesh treatments and other sterilization therapies related to Women's Health.

The IG is going to use the following resources to enable CRN work
• Questionnaire
• QuestionnaireResponse
• Device
• US Core profiles

IG Purpose
A landscape analysis of women’s health related registries have identified the lack of standardization in the capturing and exchange of data elements that can be used for multiple outcome research related use cases. The ability to link and query multiple registries will increase the effectiveness of the registries when used by researchers. In order to make this feasible, an interoperable standards-based platform is essential so that one can administer instruments*, collect data and exchange data from EHRs and other Health IT systems with Registries. In order to achieve this the following specific needs have been identified: â€¢ Identify and define data elements in a common format that will be used for defining the instrument. â€¢ Identify and outline the mechanisms to create data collection instruments based on standards. â€¢ Identify and outline the mechanisms to administer the instrument and collect the data. â€¢ Identify and outline the mechanisms to store and exchange the captured data with Registries and other Researchers. â€¢ Identify and outline mechanisms that can be used to link registries to increase the efficiencies and effectiveness.

Content location
https://github.com/HL7/coordinated-registry-network

Proposed IG realm and code
us/womens-health-registries

Maintenance Plan
The current funding for the project expires in September 2019.
The intention is to follow the US Core Model, where the IG is developed and piloted by the various registries and then working with BR&R and CCRF transfer the ownership of the IG to the relevant HL7 WG as it has long term implications and can be used by registries in general beyond Women's Health Registries.

**Short Description**

The purpose of the IG to provide the necessary guidance to use FHIR to build registries specific to monitoring Women's Health.

**Long Description**

A landscape analysis of women’s health related registries have identified the lack of standardization in the capturing and exchange of data elements that can be used for multiple outcome research related use cases. The ability to link and query multiple registries will increase the effectiveness of the registries when used by researchers. In order to make this feasible, an interoperable standards-based platform is essential so that one can administer instruments*, collect data and exchange data from EHRs and other Health IT systems with Registries. In order to achieve this the following specific needs have been identified:  
- Identify and define data elements in a common format that will be used for defining the instrument.  
- Identify and outline the mechanisms to create data collection instruments based on standards.  
- Identify and outline the mechanisms to administer the instrument and collect the data.  
- Identify and outline the mechanisms to store and exchange the captured data with Registries and other Researchers.  

The involved parties identified specific needs to achieve this common platform, especially registries that administer instruments* and exchange data with other registries.

Involved parties:
- FDA
- ONC

**Expected implementations**

Registry Pilots expected.
- AUCs
- SUFU etc.

**Content sources**

SDC FHIR IG profiles for Questionnaire and QuestionnaireResponse as needed.  
US Core profiles for clinical data as applicable and needed.

**Example Scenarios**

- WHT Registries would like to collect various data elements related to Uterine Fibroids for women who have specific device implants over a period of time and use it for research purposes.

**IG Relationships**

Reuse the SDC FHIR IG profiles for Questionnaire and QuestionnaireResponse as needed.

Reuse the PRO FHIR IG APIs for Administering an instrument and collecting data.

Reuse the US Core profiles for clinical data as applicable and needed.

**Timelines**

Ballot for Comment in September 2018 Cycle

STU Ballot in January 2019 Cycle

The project timelines are driven by the registries planning to establish their infrastructure for data collection. Some of them have established infrastructure but are evaluating efficient mechanisms to use data collected during clinical care by EHRs. The IG will provide a target infrastructure for these registries that are getting setup from an interoperable technology stand point. Lack of an official IG impacts the infrastructure planning for pilots and downstream activities.  

The pilots are expected to start in the later part of the year and provide feedback to be incorporated into the IG prior to September 2019 at which point a robust IG is expected to exist that is implemented by many of the registries.
When IG Proposal Is Complete

When you have completed your proposal, please send an email to FMGcontact@HL7.org

FMG Notes

- Would like the non-data element piece broken out into a separate implementation guide in the future. This is consistent with proposed FDA direction.