The Office of the National Coordinator for Health Information Technology

Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies

FINAL REPORT

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EXECUTIVE SUMMARY

Introduction

Clinical data registries store patient health data and often focus on a single disease, condition, or procedure. Clinical registries can provide health care professionals and researchers with first-hand information about people with certain conditions, both individually and as group over time, to increase understanding of that condition. These registries are also used to achieve objectives such as discovering new therapies and finding new techniques to diagnose diseases.[1] Registries can also be used to monitor the performance of medical devices to improve patients' health. The data stored in these registries can be used by researchers and clinicians to help improve patient's quality of care and outcomes. These data are particularly useful in conducting patient-centered outcomes research (PCOR).

Women's Health Technologies CRN Federal Partners

- Food and Drug Administration
- National Library of Medicine, National Institutes of Health
- Office of the National Coordinator for Health Information Technology

However, populating, maintaining, and utilizing these registries can be time and cost-intensive, not only for the organizations that collect, manage, and analyze the datasets but also for the hospitals and medical practices that provide data. Furthermore, existing mechanisms for accessing registry data to conduct PCOR often requires a complex process to extract a patient's data from these registries.

Coordinating clinical data registries can help researchers design studies that reflect combinations of multiple therapies and allow for linking data across registries, which can facilitate PCOR. For example, although there have been advancements in the treatment of pelvic floor disorders, uterine fibroids, and conditions requiring female sterilization, there is a lack of evidence regarding long-term effectiveness of these treatments and studies that analyze the effectiveness of different treatment combinations as is seen in the real world.[2,3,4] Relevant data are often stored in non-standardized formats limiting how they can be used for research that aims to be conducted across registries. Such studies are pertinent when noting that the lives of millions of women rely on the effectiveness and safety of medical devices and technologies. Accordingly, in 2017, the Office of the National Coordinator for Health Information Technology (ONC), Food and Drug Administration (FDA), and the National Library of Medicine (NLM) launched the Developing a Strategically Coordinated Registry Network (CRN) for Women's Health

[1] NIH Clinical Research Trials And You. 2019. Retrieved from https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries

[2] Chughtai B, Mao J, Buck J, Kaplan S, Sedrakyan A. Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: Population based cohort study. BMJ. 2015;350. doi:10.1136/bmj.h2685

[3] Chughtai B, Barber MD, Mao J, Forde JC, Normand ST, Sedrakyan A. Association Between the Amount of Vaginal Mesh Used With Mesh Erosions and Repeated Surgery After Repairing Pelvic Organ Prolapse and Stress Urinary Incontinence. JAMA Surg. 2017; 152(3):257-263. doi:10.1001/jamasurg.2016.4200

[4] Walter JR, Ghobadi CW, Hayman E, Xu S. Hysteroscopic Sterilization With Essure: Summary of the U.S. Food and Drug Administration Actions and Policy Implications for Post-marketing Surveillance. *Obstet Gynecol*. 2017; 129(1):10-19. doi:10.1097/AOG.0000000000001796

Technologies project to address these challenges and expand on opportunities to conduct robust PCOR.[5] This project was funded by the PCOR Trust Fund administered by the Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE). The project goal was to establish a strategically coordinated registry network for women's health technologies and develop tools for collecting data for registries by leveraging clinical data and create applications for capturing patient-reported outcomes. Each participating agency led a sub-project that contributed to this goal. This report focuses on the activities and results from the ONC-led sub-project.

ONC Project Activities

The ONC project used a phased approach to achieve the following ONC project goals:

- Conducting an environmental assessment;
- Defining the actors and capabilities required to implement the coordinated registry network;
- Identifying and harmonizing data elements across the women's health registries;
- Leveraging existing interoperable health standards; and
- Creating and testing capabilities that are important to a functional coordinated registry network.[6]

This project resulted in the development of a Health Level Seven International (HL7®) Fast Healthcare Interoperability Resource (FHIR®) Implementation Guide that provides guidance regarding the capture and exchange of women's health data by registries.[7]

Results

Two women's health registries pilot tested the implementation guide and provided feedback regarding the implementation of a coordinated registry network. The American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) tested up to six network capabilities.[8] Table 1 describes these capabilities and attributes them to the specific actors that are needed within a functioning coordinated registry network.[9]

[5] HHS ASPE. Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technology. 2018, March/April. Retrieved from https://aspe.hhs.gov/developing-strategically-coordinated-registry-network-crn-womens-health-technology

[6] https://www.healthit.gov/topic/scientific-initiatives/pcor/coordinated-registry-network-womens-health-technologies-crn

[7] HL7. WHT CRN FHIR Implementation Guide. 2019. Retrieved from https://build.fhir.org/ig/HL7/coordinated-registry-network/profiles.html

[8] American Urogynecologic Society (AUGS). 2018, March/April. Retrieved from https://www.augs.org/about

[9] Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). 2018, March/April. Retrieved from https://sufuorg.com/about.aspx

Table 1. CRN Actors and Capabilities Tested

Actors	Capabilities
CRN Instrument and Metadata Repository	• Publish a CRN Instrument (i.e., a form or questionnaire to collect data from patients) • Retrieve the instrument, render the instrument, and collect the necessary data
External CRN Data Collection System	• Retrieve, render, and auto-populate the CRN Instrument and collect additional data • Retrieve and render the CRN Instrument and collect data and transform data into FHIR
Women's Health Registry	• Receive CRN Instrument and collected data • Receive CRN Instrument, collected data, and other FHIR Resources

Conclusion

Through the development and testing of the implementation guide, the project successfully created an interoperable framework, with reusable tools that can enable linkage among national clinical registries related to women's health technologies. This framework has the capability to advance research efforts to develop an interoperable data network infrastructure to maximize efficiency, advance PCOR, and improve patient-centered outcomes.

INTRODUCTION

The Developing a Strategically Coordinated Registry Network (CRN) for Women's Health Technologies project (referred to in this report as the Women's Health Technologies CRN project) was launched in 2017 to create a strategically coordinated registry network for women's health technologies. This project was funded by the Patient-Centered Outcomes Research (PCOR) PCOR Trust Fund administered by the Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE). The Food and Drug Administration (FDA) envisioned this interagency project to build on the FDA National Evaluation System for health Technology (NEST) objective to "more efficiently generate better evidence for medical device evaluation and regulatory decision-making."[10] A natural partnership with the Office of the National Coordinator for Health Information Technology (ONC) formed as this project supported the ONC mission to "improve the health and well-being of individuals and communities through the use of technology and health information," specifically by enhancing the nation's health information technology (IT) infrastructure. In total, three partnering federal agencies conducted complementary projects aimed at building an interoperable data network linking existing clinical data registries from clinical care delivery systems while using national health standards to collect claims data, clinical data from electronic health record (EHR) systems, and patient-reported outcomes (PROs). This report discusses the objectives, project activities, and findings from the ONC-led sub-project.

Clinical data registries store patient health data and often focus on a single disease, condition, or procedure. Clinical registries can provide health care professionals and researchers with first-hand information about people with certain conditions, both individually and as groups over time, to increase understanding of that condition. These registries are also used to achieve objectives such as discovering new therapies and finding new techniques to diagnose diseases.[11] Registries often focus on collecting data for a single purpose, which can range from a specific disease, condition, or procedure, to monitoring the performance of a medical device. Data in a clinical registry help advance health care in many ways. The curated data sets, methods, and tools developed by a registry can be used for PCOR, quality benchmarking, coverage decisions, or regulatory purposes.[12]

Registries that focus on a single purpose are time and cost-intensive for the organizations that collect, manage, and analyze the data as well as the provider organizations that share data. To populate these registries, data that are captured at the point-of–care are re-entered into a clinical research data repository and then consolidated and transformed for analysis and research purposes. This process requires extensive data validation and normalization to ensure accurate and effective evaluation. Study designs may be limited by these constraints leading to research findings that address the effects of one

[10] FDA. National Evaluation System for Health Technology (NEST). 2018, March. Retrieved from https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm301912.htm

[11] NIH Clinical Research Trials And You. 2019. Retrieved from https://www.nih.gov/health-information/nih-clinical-research-trials-you/list-registries

[12] The Office of the National Coordinator for Health Information Technology (ONC). Patient Centered Outcomes Research. 2019, October. Retrieved from https://www.healthit.gov/topic/scientific-initiatives/building-data-infrastructure-support-patient-centered-outcomes-research

particular therapy (i.e., a single medication or device), rather than a combination of two or more therapies, which is more reflective of what takes place during the course of clinical care.

Coordinating clinical data registries can help researchers design studies that reflect the combinations of multiple therapies and lead to improved patient-centered outcomes. Linking data across clinical data registries can enrich the PCOR data infrastructure. Coordinated registries could also support manufacturers' efforts to address public health concerns, provide a basis for post-market surveillance of medical devices, and support medical device innovation.[13] For example, although there have been advancements in the treatment of pelvic floor disorders, uterine fibroids, and conditions requiring female sterilization, there is a lack of evidence regarding long-term effectiveness of these treatments and studies that analyze the use of different treatment combinations as is seen in the real world.[14,15,16] Data relevant to these conditions may be collected by registries, however they are often stored in non-standardized formats limiting how they can be used for research that aims to be conducted across registries. Such studies are pertinent when noting that the lives of millions of women rely on the effectiveness and safety of medical devices and technologies. A coordinated women's health registry can provide data that allow researchers to evaluate the performance of commonly used devices and technologies in women's health. In addition, such a coordinated registry could facilitate government product safety initiatives and help update research studies.

Women's Health Technologies CRN Project Partners

The Women's Health Technologies CRN project was an interagency project that included clinical and informatics experts from three federal partners, three of which led individual sub-projects. Figure 1 illustrates the project's organizational structure**.** Multi-stakeholder clinical working groups were formed to lend their expertise regarding three conditions unique to women's health: pelvic floor disorders, uterine fibroids, and female sterilization. An informatics working group was established to inform the project and collaborate on cross-functional activities that included:

- harmonizing a standard set of data elements across the three clinical conditions;
- leveraging unique device identification and the Global Unique Device Identification Database (GUDID);
- developing standards to extract the core datasets captured in routine care and for use in the coordinated registry network; and
- conducting feasibility pilots to evaluate the ability of the coordinated registry network to address clinical questions.

[13] Food and Drug Administration (FDA). Postmarket Requirements (Medical Devices). 2018, March/April. Retrieved from https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/default.htm

[14] Chughtai B, Mao J, Buck J, Kaplan S, Sedrakyan A. Use and risks of surgical mesh for pelvic organ prolapse surgery in women in New York state: Population based cohort study. BMJ. 2015; 350. doi:10.1136/bmj.h2685

[15] Chughtai B, Barber MD, Mao J, Forde JC, Normand ST, Sedrakyan A. Association Between the Amount of Vaginal Mesh Used With Mesh Erosions and Repeated Surgery After Repairing Pelvic Organ Prolapse and Stress Urinary Incontinence. JAMA Surg. 2017; 152(3):257-263. doi:10.1001/jamasurg.2016.4200

[16] Walter JR, Ghobadi CW, Hayman E, Xu S. Hysteroscopic Sterilization With Essure: Summary of the U.S. Food and Drug Administration Actions and Policy Implications for Post-marketing Surveillance. *Obstet Gynecol*. 2017; 129(1):10-19. doi:10.1097/AOG.0000000000001796

Health information technology (health IT) standards, such as standards stewarded by Health Level Seven International® (HL7®), were an important to support interoperability across various data sources via software applications and application programming interfaces (APIs).

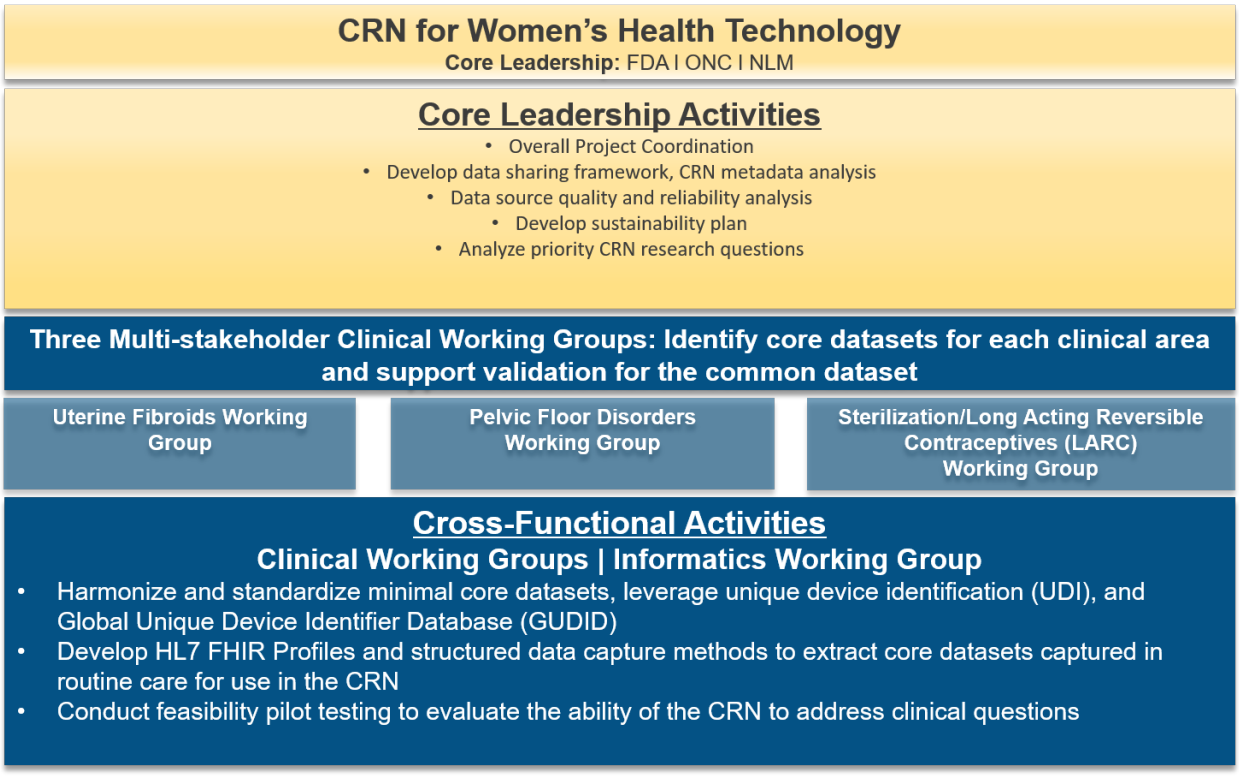

Figure 1. Women's Health Technologies CRN Project Organization

Project Goals

The interagency project partners each led complementary and interdependent sub-projects that supported the overall project goals. These goals included:

- Establish a coordinated registry network focused on women's health technologies
- Develop tools for registries to facilitate the collection of data relevant to women's health
- Demonstrate that data in these registries could be used to do the following:
    - Evaluate the effectiveness, quality of life, and safety associated with differing treatment options;
    - Provide a framework for clinical studies to be conducted within the registry network, including industry-sponsored studies required to fulfill the FDA's request for post-market surveillance; and
    - Allow health care providers to monitor surgeon volume, patient outcomes, and quality measures required to meet Centers for Medicaid & Medicare Services (CMS) Physician

Quality and Reporting Systems (PQRS) certification requirements.[17]

ONC PROJECT

Objectives

To meet the goals of the interagency project, ONC set out to accomplish the following objectives through its sub-project:

- Develop an implementation guide that provides the technical specifications needed to collect the data elements identified by the multi-stakeholder clinical working groups as relevant to women's health
- Identify a harmonized, interoperable mechanism to link existing registries to each other and other major data networks to support longitudinal follow-up and assessment of patient care across therapeutic areas
- Develop tools to efficiently extract clinical data from EHR systems and enter data into the coordinated registry network, leveraging existing standards that are widely available and supported by industry, such as the HL7 Fast Healthcare Interoperability Resources® (FHIR®) specification[18]
- Pilot test the technology in a test or production environment and use the findings to help refine the technology or standards

Key Activities

The following summarizes key activities conducted for this project.

Key Informant Interviews. Key informant interviews were conducted to identify the current capabilities of women's health registries, including how data were captured, stored, and shared. The findings from these interviews informed the development of two models that outline the different actors and capabilities required to implement a women's health technologies coordinated registry network.

Identify and Harmonize Data Elements. The project team determined there was a need to define an interoperable collection of data elements and to establish a standard method of exchanging these data elements. Interagency partners collaborated with stakeholders in the clinical working groups to identify and harmonize the selected data elements that are collected across registries. The harmonization effort included identifying the structured definitions, vocabularies, concepts, and value sets (semantics) for each data element. Both HL7 and the Clinical Data Interchange Standards Consortium standards were considered for data exchange. HL7 FHIR R4 was selected to meet metadata needs for data element definition.

[17] CMS. *Physician Quality Reporting System (PQRS) Overview*. 2019, October. Retrieved from https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/PQRS_OverviewFactSheet_2013_08_06.pdf

[18] HL7. Fast Healthcare Interoperability Resources (FHIR) Release 4. 2019. Retrieved from http://hl7.org/fhir/summary.html

Develop an Implementation Guide to Guide the Creation of a Women's Health Technologies coordinated registry network. ONC mapped the selected data elements to FHIR resources. This mapping was used to create and test the Women's Health Technologies CRN FHIR Implementation Guide.[19] This implementation guide includes descriptions of the actors, systems, capabilities, and specified conformance requirements required for implementing Women's Health Technologies coordinated registry network registry capabilities. The Women's Health Technologies CRN FHIR Implementation Guide built upon nationally-recognized and vendor-supported specifications, namely US Core, HL7 FHIR, the HL7 FHIR Structured Data Capture (SDC) Implementation Guide, and the SMART on FHIR app launch framework. [20,21,22] The Women's Health Technologies CRN FHIR Implementation Guide can be used an example by registry organizations that are interested in implementing capabilities of coordinated registry networks. The implementation guide provides guidance for infrastructure development that supports interoperability and registry linkages.

Pilot Test the Implementation Guide. Two organizations pilot tested components of the Women's Health Technologies CRN FHIR Implementation Guide. Information from this pilot testing was used to inform further development of the implementation guide and lessons learned are documented in this report.

KEY INFORMANT INTERVIEWS

Key informant interviews were conducted with representatives from stakeholder organizations focused on women's health and related technologies. These stakeholder organizations are listed in Table 2. In addition, participants from the three project clinical working groups were interviewed. Interviewees volunteered resource materials such as publications, web links, data dictionaries, and other points of contact to inform subsequent project activities.

Table 2. Organizations Represented in Key Informant Interviews

Organization/Work Group	Organization Website
The American College of Obstetricians and Gynecologists (ACOG)	https://www.acog.org/
The American Urogynecologic Society (AUGS)	https://www.augs.org/
Comparing Options for Management Patient-Centered Results for Uterine Fibroids (COMPARE-UF)	http://compare-uf.org/
Pelvic Floor Disorders Registry (PFDR)	https://www.augs.org/clinical-practice/pfd-research-registry/
Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)	https://sufuorg.com/about.aspx

[19] HL7. WHT CRN FHIR Implementation Guide. 2019. Retrieved from https://build.fhir.org/ig/HL7/coordinated-registry-network/profiles.html

[20] HL7. FHIR US Core Implementation Guide (IG) v3. 2019. Retrieved from https://www.hl7.org/fhir/us/core/

[21] HL7. FHIR SDC Structured Data Capture Implementation Guide (IG) STU2. 2019, December. Retrieved from http://hl7.org/fhir/us/sdc/

[22] SMART Health IT. 2018. Retrieved from https://smarthealthit.org/an-app-platform-for-healthcare/about/

Findings

Findings that emerged from the key informant interviews are described below.

Variation in Registry Operational Capabilities

The range of maturity and capability across the registries offered different perspectives of the opportunities and challenges each registry experienced. Registries that were currently operational were collecting data and designing studies. In some cases, data from more than 500 studies were collected and analyzed for various conditions related to women's health for more than a decade. Others were in the early stages of establishment without comparable capabilities. The established registries have navigated changes to procedures, data elements, instruments, and other aspects of data collection. Newer registries were concerned about funding challenges, effectively recruiting patients, leveraging standards for data collection, and selecting the appropriate technologies to support registry functions. There was variation among the technologies and systems used by the registries, which included electronic portals, standalone mobile applications (apps) integrated with an EHR, open-source web-based software, Microsoft Excel or Access, and third-party vendors that store data in the cloud. Integration with an EHR varied regardless of how old the registry was. Overall most registries lacked the necessary infrastructure these systems to support interoperability and to link to other registries.

Lack of Core Data Elements

Each registry collected different data elements based on their specific use case for women's health. The number of data elements captured ranged from 200 to more than 700 data elements. Some of the newer registries were still identifying data elements. At the time the interviews took place, there did not exist a core set of data elements that are common across the registries. Additionally, each registry had data definitions and data dictionaries in different formats and with varying levels of semantic compatibility. These variations highlighted the need for harmonization of data elements to enable interoperability.

Variation in Data Collection Techniques and Processes

In addition to the differences in definitions and the number of elements, the instruments data collection instruments used also varied. The interviews revealed that most of the registries used research coordinators in varying capacities. Research coordinators played a vital role in connecting with patients before an intervention or a surgery to discuss data collection and obtain informed consent for enrollment. They also facilitated data collection during the surgery or intervention and post-surgery, following up with patients at regular intervals. There were also significant variations in data collection methods. For example, some registries used custom-developed portals while some used stand-alone apps to collect data. Some used systems such as Research Electronic Data Capture (REDCap) and Dorsata while others manually extracted clinical data from EHR systems to populate registry systems. There were also reported instances where telephone and in-person interviews were conducted to collect the data for subsequent entry into registry systems. These variations reflected the differing technical capabilities of registries, where some have the necessary infrastructure and tools to automate data collection while others did not. The data collection techniques and processes were originally designed to meet the unique needs of each registry, therefore there was minimal need for standardization of data and data collection approaches. These variations made the infrastructure across registries less interoperable, adding complexity to the project task of creating a registry network.

Low Adoption of Technical Standards

The interviews highlighted that health care data standards were not widely used to define data elements, collect structured (i.e., machine-readable) data, and store data. While many registries were aware of relevant regulations from federal agencies such as FDA and ONC, data collection processes generally did not include the use of standards for either structure or semantics. Interviewees expressed several reasons for low adoption of standards, including:

- Lack of awareness of existing standards
- Complexity of the standards
- Changes to data elements or terminology already in use are time-consuming
- Lack of a single standard to address all of a registry's needs

Few Data Linkages and Need for Common Technical Infrastructure Across Registries

The interviews revealed that there was minimal linkage of data across registries. While some organizations administering multiple registries had tried developing a common infrastructure for re-using data across the registries, experience was insufficient to determine its effectiveness. A coordinated network of registries would require a common technical infrastructure to enable these linkages.

Need for Standardized Data Access APIs

The interviews also revealed that data access APIs were not well-defined across the registries. While there were strict privacy protections or necessary security controls limiting data access, there were no consistent data access and sharing approaches across registries. In some cases, the entire database was shadowed and accessed, while in others, data was exported and pushed to federal agencies or accessed only by personnel within the organization directly from the database.

Areas for Consideration

Interview findings helped identify areas for consideration in the creation of an effective coordinated registry network.

Patient Engagement and Enrollment

The effectiveness of a registry depends on the ability to enroll patients, obtain informed consent to collect data, and use the collected data for approved research purposes. Registries have identified reaching the right patients at the right time and educating them about the importance of data collection and usage for research as increasingly difficult. Registries use patient outreach, marketing, seminars, education sessions, referrals, and other techniques to enroll patients. There may be relevant lessons learned from effective approaches used in other research initiatives to recruit and enroll participants. For example, the NIH *All of Us* Research Program is employing a platform to enroll one million or more people living in the United States to accelerate research and improve health.[23] A similar, common infrastructure for patient enrollment could be created to include appropriate materials through a coordinated registry network that individual registries could use.

[23] National Institutes of Health (NIH). *All of Us* Research Program. 2018, May. Retrieved from https://allofus.nih.gov/

Common Core Data Elements for Women's Health

Every registry interviewed identified the need for data definition to begin any registry activity. Even established registries have to perform this activity repeatedly as they add new use cases. Data collected cannot be interoperable across registries without standardization and normalization since their activities are independent. Data definitions can improve the interoperability of data collected across registries tremendously producing the base for a linked coordinated registry network. Further aligning these data elements with other existing relevant federal regulations from FDA, CMS, and ONC improves the likelihood of data being available in a structured form. Defining a common set of core data elements applicable to women's health that all registries could implement was identified as a way to make an immediate impact.

Standardized and Interoperable Data Collection Tools

As identified previously, data collection techniques and processes vary across the registries. A common set of tools that could be used by the registries as a starting point to build a technical infrastructure for data collection would help better align the disparate efforts. For example, a tool that can create and administer instruments and collect responses in a standardized manner would be a core part of the technology required for each registry. Data collection tools built using health data standards such as FHIR can enable interoperable exchange of data. An implementation guide that provides guidance regarding the standard representation of the instrument and the collected data could be useful for implementers. This could create and promote a reference implementation (i.e., the standard from which all other implementations and corresponding customizations are derived) that is open source and can be used by the registries to save time, effort, and improve the overall interoperability of the data collected and exchanged.

Data Collection Burden on Patients, Providers, and Research Coordinators

One of the major challenges identified from the interviews is patients' reluctance to respond to lengthy questionnaires or surveys. Collecting these data is also time-intensive for providers and research coordinators. A set of data collection tools could help streamline the registry's data collection infrastructure, but would not reduce the data entry burden. Reusing data from other sources by integrating with other systems that are part of care delivery and already have some of the data needed for a given registry may reduce some of the data collection burden. For example, patient demographics, medical history, procedures, and other related data collected as part of routine care should not have to be collected a second time using a registry data collection instrument. Instead, the instrument should be pre-populated with data previously collected during the course of clinical care so that only additional data need to be obtained.

Additionally, data collection conducted during routine patient follow-up post-intervention should focus on questions expected to provide important insight into outcomes of interest rather than spending time and effort collecting demographic data or data that could be sourced and populated from other interoperable systems. Questionnaire forms developed using standards such as FHIR and SMART on FHIR provide a common architecture that reduces the data entry burden as they can leverage interoperable networks to automatically populate routinely collected data.

Funding Challenges

Another challenge identified by the registries is the lack of funding to develop the necessary infrastructure for the registry. Costs may be reduced by providing reusable data definitions, tools, and standards education, as well as furnishing common core data elements to health IT developers and aligning those

elements with national standards. Coordination across registries, standards development organizations (SDOs), and health IT developers is important to advancing the development and use of health IT standards.

Lastly, governance policies and processes are needed for effective registry operationalization. Creating guidance for governance and providing templates for policies and processes may also help reduce the funding challenges faced by registries.

MODELS OF ACTORS AND INTERACTIONS FOR COLLECTING AND ACCESSING DATA

Two models were developed to identify the specific actors and interactions that were in scope for collecting and accessing women's health technologies coordinated registry network data. These models were developed based on findings from the key informant interviews and built on artifacts shared by participating registries which included existing data dictionaries, use cases and workflow designs, expertise in application design, which reduced data entry burden, and long-term registry plans. One model outlines the steps for collecting data as shown in Figure 2 and the second model outlines the steps for accessing data as shown in Figure 3.

Model for Data Collection

This model focused on collecting specific coordinated registry network data elements from patients undergoing various treatments of interest using a combination of clinical health information systems (i.e., EHRs and independent apps). Figure 2 illustrates the steps for collecting data using CRN Instruments and the actors involved. The CRN Instrument represents a form or questionnaire used to collect data from participating patients and can be designed based on data that needs to be collected and use the data element definitions described in the Women's Health Technologies CRN FHIR Implementation Guide.

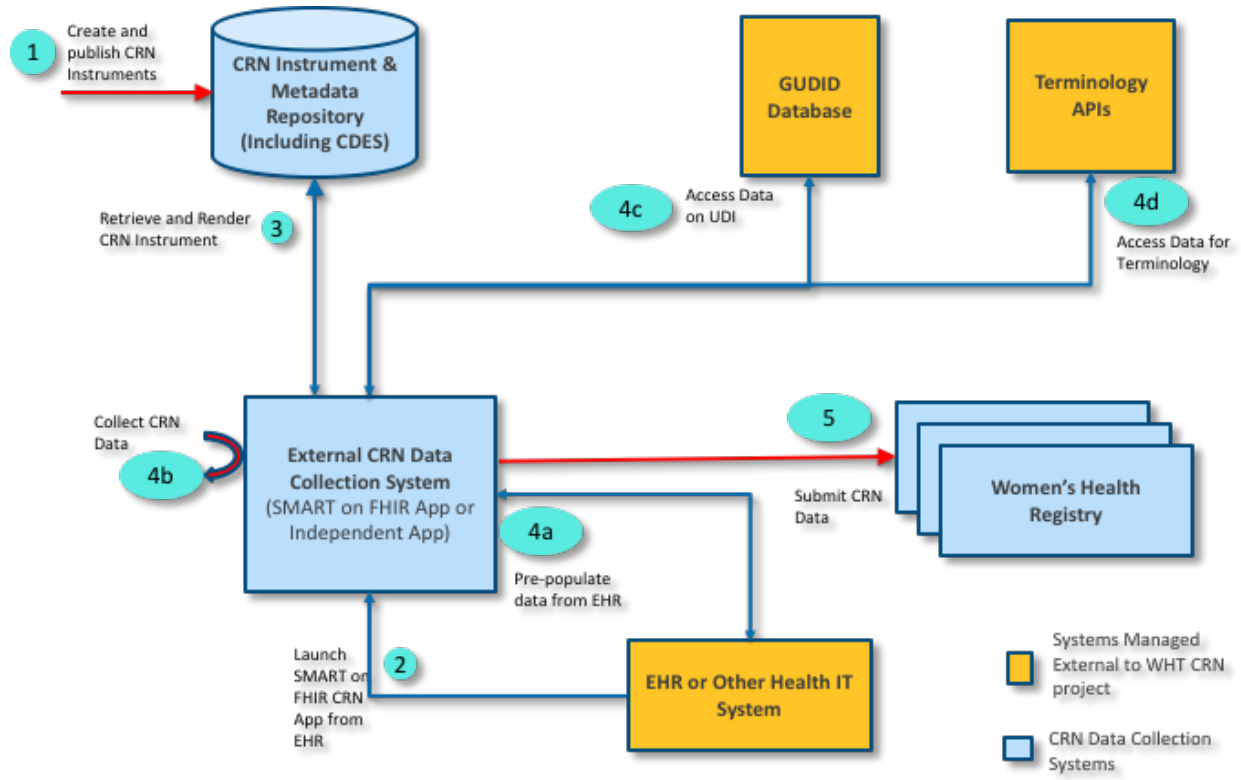

Figure 2. Data Collection Model

Data Collection Steps

Step 1: An organization creates the CRN Instrument along with its metadata and publishes the instrument in the CRN Instrument and Metadata Repository

Step 2: A provider launches the External CRN Data Collection System app from an EHR or other health IT system. This step is optional when there is no EHR or other health IT system connected to the External CRN Data Collection System

Step 3: The External CRN Data Collection System accesses the CRN Instrument from the CRN Instrument and Metadata Repository and renders the instrument for data collection

Step 4a: The External CRN Data Collection System may optionally pre-populate fields in the CRN Instrument using data from the EHR

Step 4b: The provider or patient enters additional data required to be filled out in the CRN Instrument

Step 4c: The External CRN Data Collection System pulls relevant device-related information from the GUDID database and can auto-populate the CRN Instrument based on the UDI information entered

Step 4d: The External CRN Data Collection System uses the terminology API to validate data entered into the CRN Instrument where appropriate

Step 5: The External CRN Data Collection System sends the information collected to participating registries as appropriate

Data Collection Actors

The following actors are part of the data collection model (as shown in Figure 2).

CRN Instrument and Metadata Repository. The CRN Instrument and Metadata Repository is a system that stores the CRN Instruments along with their metadata. The repository provides API access to health IT systems to retrieve the instruments for administration. The repository may be hosted by an organization (i.e., specific registry), a federal agency (i.e., NIH), a network (i.e., CommonWell®), or an independent organization providing coordinated registry network services.[24]

EHR or Other Health IT Systems. The EHR or other health IT systems are used by providers to deliver care. They can capture and store health information about the patient that is relevant to the Women's Health Technologies CRN project and administer CRN Instruments to a patient as part of routine care.

External CRN Data Collection System. The External CRN Data Collection System is an independent application and is external to the EHR or other health IT system used for care delivery. There are many different variations of these systems, such as independent health IT systems that have no connection to an EHR (e.g. tablets with CRN modules used to collect coordinated registry network data with databases to store the data) or third-part apps such as SMART on FHIR apps that can be launched from an EHR with the patient's consent and communicated with the EHR to collect and store coordinated registry network data. These External CRN Data Collection Systems require a mechanism to integrate with the EHR for data from the coordinated registry network to gain wider use. The external systems can be provided to care managers, patients, practitioners, and others, and vary based on policy and workflows between organizations.

Women's Health Registries. The women's health registries collect the data relevant to specific conditions related to women's health and make the data available to researchers and authorized federal agencies.

GUDID Database. The GUDID database system provides access to FDA-approved implantable device information. FDA administers this system, and its data are made publicly available by NLM's AccessGUDID.[25] AccessGUDID serves as a reference catalog for every device with a device identifier. For coordinated registry network workflows, data from the AccessGUDID database is used to populate fields in the CRN Instrument via the Device Lookup API and Parse UDI API. These and other APIs used for accessing the GUDID is available at GUDID Database APIs.[26]

Terminology APIs. Terminology APIs provide code systems and value sets for use in conjunction with the CRN Instrument, ensuring that the data can be validated in real time to avoid errors.

Model for Data Access

[24] CommonWell® Health Alliance (209). Retrieved from https://www.commonwellalliance.org/

[25] NIH National Library of Medicine (NLM). *Access GUDID*. 2019, September. Retrieved from https://accessgudid.nlm.nih.gov/

[26] NIH NLM. Access GUDID Resources. 2019, October. Retrieved from https://accessgudid.nlm.nih.gov/resources/home

This model focused on the process by which researchers would access the data already collected in the registries. **Figure 3** illustrates the model, actors, and the data flow for researchers accessing the collected data from registries.

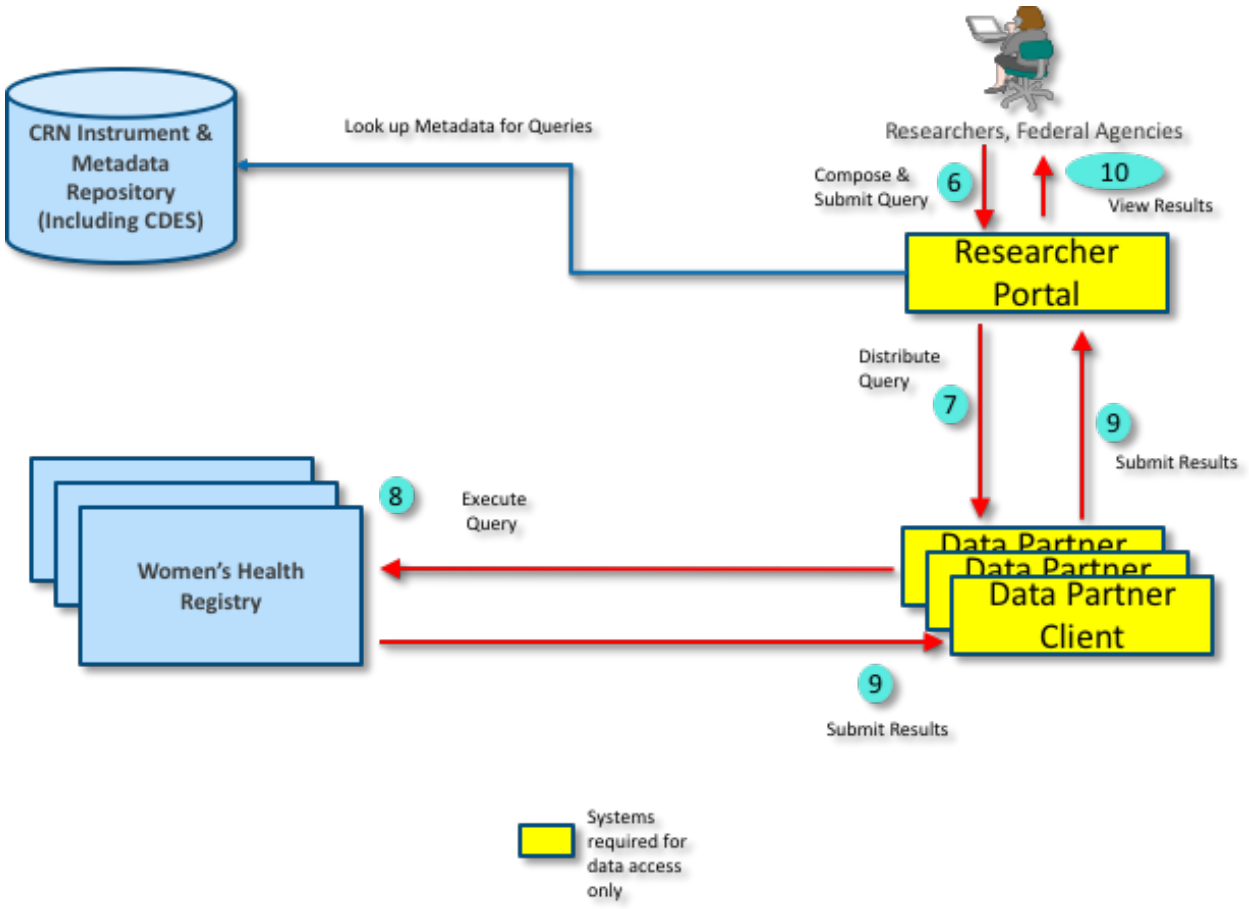

Figure 3. Data Access Model

Data Access Steps

Step 6: A researcher or an authorized user composes a query to access data from the registry and then submits the query for distribution to the various registries. As part of the query composition, the data element definitions were used to create a query

Step 7: The Data Partner Client collaborates with the Researcher Portal to download the queries that are intended for its registry and then queue them for execution

Step 8: The local clinical and research administrators and other systems use the Data Partner Client to execute the query

Step 9: The Data Partner Client compiles the query results and then submits them back to the Researcher Portal after obtaining approval from the local administrators

Step 10: The researcher or authorized user accesses the data retrieved based on the query submitted

Data Access Actors

The following additional actors are part of the data access model shown in Figure 3.

Researcher Portal. The Researcher Portal is a system used by authorized researchers and other personnel to compose and submit queries to various registries that contain women's health data. Once the data are received, the Researcher Portal provides user interfaces for the researchers to view, download, and analyze the collected data.

In terms of policy, it is important to note that researchers and authorized users typically must be approved by the registries before submitting queries and receiving results. In addition, registries may require institutional review board approvals and may restrict the type of data returned (e.g., a registry may only return aggregated data).

Data Partner Client. The Data Partner Client is a specific software module that is instantiated for each Women's Health Registry so that it can coordinate with the Researcher Portal. The client downloads the queries, executes them in the registry infrastructure, compiles the results, and submits the results back to the Researcher Portal.

The interactions for Figure 3 reflect a previously-funded ONC project that resulted in the Data Access Framework Research (DAF-Research) Implementation Guide.[27]

DATA ELEMENT HARMONIZATION

After outlining the models shown above, the next step in this project was to identify and determine the type of data that should flow between registries. Given the lack of common core data elements across the registries, it was important for the project to harmonize a standard set of data elements. A set of elements collected across various registries was identified using the Delphi process.[28] The data elements were then analyzed and harmonized into a set of common data elements (CDEs), which the NLM team curated into a metadata structure with definitions, data types, and value sets when needed. The final curated list was then incorporated into the Women's Health Technologies CRN FHIR Implementation Guide to guide the implementation of the infrastructure and health IT standards for data collection and exchange.[29]

Identification of Data Elements Using the Delphi Process

The Delphi process was conducted by the MDEpiNet Initiative at Weill Cornell Medicine. The Delphi process is a quantitative technique aimed at generating agreement by soliciting opinions from groups by answering questions in an iterative process. After each round, the responses are summarized and redistributed for discussion in the next round. Agreement is reached through a process of convergence involving identifying common trends and inspection of outliers. To help determine what data elements were in use, the team worked with three FDA clinical working groups (i.e., Sterilization/Long-acting

[27] HL7. FHIR DAF Research Implementation Guide (IG) v2. 2017, March. Retrieved from http://hl7.org/fhir/us/daf-research/STU2/index.html

[28] Better Evaluation. 2019, September. Retrieved from https://www.betterevaluation.org/en/evaluation-options/delphitechnique

[29] HL7. Harmonized Common Data Element Profiles - WHT CRN FHIR IG. 2019, September. Retrieved from http://hl7.org/fhir/us/womens-health-registries/2019May/profiles.html

Reversible Contraceptives, Pelvic Organ Prolapse, and Uterine Fibroids) to complete two rounds of the Delphi process.

For the first Delphi round, a survey was conducted from December 2017 through February 2018. The results were analyzed and discussed in a series of conference calls with the working group co-chairs. Any data element with less than 50% agreement was removed from the list of data elements, and any data element with greater than 50% agreement was retained for the second-round survey.

The entire project team discussed the results and used open response suggestions to achieve agreement on how to proceed. The analysis team incorporated the results of this discussion into the design of the second-round Delphi survey.

The Delphi process was repeated in the second round until agreement was achieved on the final minimum core dataset in August 2018.

Harmonization and Curation of Data Elements

The informatics working group assisted the clinical working groups as they went through the two rounds of the Delphi process to develop initial lists of core data elements. With support from the FDA Oak Ridge Institute for Science and Education Fellows, the informatics working group also performed a frequency analysis to identify the most common concepts across all three clinical groups. The informatics working group and clinical working groups then discussed and further refined the common concepts until a harmonized CDE list was created.

The data element curation highlighted variations among value sets, data formats, and standards in use in the data elements captured by each registry. The working groups identified 30 data elements common across at least two clinical working groups. NLM then curated the data elements for inclusion into the NLM CDE Repository.[30] Curating the harmonized list of data elements required defining the structure, data type, semantics, and vocabularies for each data element. Curating data elements that are collected independently by registries provides semantic interoperability across multiple registries, as they are all mapped to HL7 FHIR Resources.

Since the initial list of CDEs was included in the Women's Health Technologies CRN FHIR Implementation Guide, the CDEs were tested by the two organizations conducting pilot testing as overseen by ONC. The pilot testing resulted in a reference implementation for others to use and build upon. Similarly, the initial CDE list in the NLM CDE Repository is available for other stakeholders interested in joining a coordinated registry network to exchange data regarding women's health technologies to use. This process and the resulting initial curated list of CDEs served to define the data collection instruments. To provide a sample representation of how the CDEs could be structured in an instrument, NLM developed a CRN Instrument in the NIH CDE Repository that represents the initial set of harmonized data elements.[31] The instrument can be exported to a variety of file formats (e.g., JavaScript Object Notation [JSON], Extensible Markup Language [XML], comma-separated values [CSV], and FHIR Questionnaire) for further use and analysis.

[30] NIH NLM. Common Data Elements (CDE) Repository. 2019, September. Retrieved from https://cde.nlm.nih.gov/

[31] NIH NLM. CRN Harmonization Pilot Form. 2019, September. Retrieved from https://cde.nlm.nih.gov/formView?tinyId=XJwYSNJ4I

HL7 PROCESS FOR IMPLEMENTATION GUIDE DEVELOPMENT

The HL7 FHIR standard was selected as the foundational standard to enable data exchange. Table 3 shows the high-level steps involved in creating an implementation guide through HL7. [32] A complete description of the process is provided in the HL7 documentation.[33]

Table 3. Steps to Create an HL7 FHIR Implementation Guide

Step	Purpose
Create a Project Scope Statement (PSS) and obtain approvals	Inform the HL7 community about the project and the type of work to be performed for awareness and collaboration options Identify a primary sponsoring work group that will review and support the development of the implementation guide, and maintaining it after creation through working group meetings
Host working group meetings to create content	Host public working group meetings and calls to create the content changes, brief the community, and reach consensus on the content
Create implementation guide proposals and submit	A FHIR-specific step to provide information to the FHIR Management Group (FMG) for awareness of project details such as implementation guide content and the location and names used for the project
Finalize implementation guide content and submit Notice of Intent to Ballot	Finalize and review the content with the Primary Sponsoring working group and gain approval for balloting in a particular ballot cycle
Submit content for ballot	Publish content for ballot (no changes are made to the implementation guide during the ballot cycle)
Ballot reconciliation	Ballot comments are reviewed and reconciled to address the comments and implement changes. This is also the process for ensuring the ballot has passed with enough affirmative votes for publishing
Publish implementation guide	HL7 publishes the implementation guide as a standard for trial use (STU)
Normative balloting and publishing	Promote the implementation guide from STU to normative by going through the STU to normative ballot and publication process

The HL7 FHIR Standard

The HL7 FHIR standard, along with SMART on FHIR specifications, were selected for this project because they provide a web-based application programing interface (API) approach that could be leveraged for workflow integration with EHRs. The standards are open source, widely accessible, and relatively simple to understand because it is based on widely used XML and JSON formats along with Hypertext Transfer Protocol (HTTP) and OAuth authorization protocol. The ease of implementing FHIR solutions provides an advantage for coordinated registry network implementers to operationalize their capabilities faster.

[32] HL7. FHIR Overview.2019, October. Retrieved from https://www.hl7.org/fhir/overview.html

[33] HL7. FHIR IG Process Flow (209). Retrieved from https://confluence.hl7.org/display/FHIR/FHIR+Implementation+Guide+Process+Flow

Additionally, FHIR is representational state transfer (RESTful) API-based which lends itself to the patient facing-applications required for coordinated registry network data collection.

Existing HL7 Implementation Guides Leveraged

The Women's Health Technologies CRN project's vast scope required multiple software modules with various capabilities to create the necessary infrastructure. These modules and their specifications were created as part of the Women's Health Technologies CRN project. Furthermore, similar software modules that already existed were evaluated to determine their effectiveness in meeting the use case requirements of this project.

The following existing HL7 FHIR Implementation Guides were leveraged to develop the Women's Health Technologies CRN FHIR Implementation Guide and are discussed below:

- US Core
- SDC
- DAF-Research
- PRO

US Core Implementation Guide. The US Core FHIR Implementation Guide contains profiles that are used to access the 2015 Edition data elements that are already captured by clinical care delivery systems such as EHRs.[34] These US Core Profiles have been broadly adopted in the real world due to the Argonaut project, which involved multiple health IT developers, and ONC's 2015 Edition API certification requirements.[35] The US Core FHIR Implementation Guide is based on ONC's 2015 Edition Common Clinical Data Set (CCDS) requirements.

When the data elements required for capture for the Women's Health Technologies CRN project overlapped with the ONC 2015 Edition CCDS, the US Core Profiles and their existing data element definitions were considered because of their broad adoption. In addition, if while capturing the CCDS data the coordinated registry network systems interfaced with FHIR-enabled EHR or Care Delivery Systems, the FHIR APIs were used to auto-populate the instruments with data already collected, reducing the burden on the providers and caregivers.

SDC Implementation Guide. The SDC FHIR Implementation Guide provides a framework on the use of the Questionnaire and QuestionnaireResponse FHIR Resources for multiple use cases. The capabilities described in the SDC FHIR Implementation Guide include the ability to:

- Create instruments for real-world use in an interoperable manner
- Specify display and rendering requirements for instruments
- Pre-populate instruments from existing clinical data
- Convert data collected into FHIR Resources
- Administer adaptive questionnaires
- Associate instruments with research protocols and studies

[34] HL7. FHIR PRO Patient Reported Outcomes Implementation Guide (IG) v0.2.0. 2019, December. Retrieved from http://hl7.org/fhir/us/patient-reported-outcomes/2019May/pro-overview.html

[35] HL7. Argonaut Project. 2019, October. Retrieved from https://argonautwiki.hl7.org/Main_Page

The Women's Health Technologies CRN project required many of these capabilities for real-world implementation. Therefore, the SDC FHIR implementation Guide capabilities could be used for the Women's Health Technologies CRN FHIR Implementation Guide, eliminating the need to re-create similar capabilities from scratch.

DAF-Research Implementation Guide. The DAF-Research FHIR Implementation Guide provides a framework for researchers to access data from multiple data sources by composing and submitting queries for data extraction, monitoring the status of these queries, and retrieving results for the various submitted queries.

The specific capability from the DAF-Research FHIR Implementation Guide that was reused by the Women's Health Technologies CRN FHIR Implementation Guide is the DAF-Research Task Profile. This profile enables a researcher to query multiple registries participating in the coordinated registry network for data and receive the results from multiple registries. The profile provides the mechanism for distributing these queries and getting the data back from the registries.

PRO Implementation Guide. The PRO FHIR Implementation Guide provides a framework to use the Questionnaire and QuestionnaireResponse FHIR Resources for administering Patient-Reported Outcome Measures (PROMs) and for scoring the collected responses.

The Questionnaire, QuestionnaireResponse, Adaptive Questionnaire, and Adaptive QuestionnaireResponse profiles from the PRO FHIR Implementation Guide were incorporated in the Women's Health Technologies CRN FHIR Implementation Guide for instances when PROMs need to be administered for coordinated registry network purposes, therefore eliminating the need to re-create these profiles.

Data Elements in the Women's Health Technologies CRN FHIR Implementation Guide

The Women's Health Technologies CRN FHIR Implementation Guide includes the list of data elements curated by NLM in collaboration with the various registries and Clinical Working Groups. **Table 4** contains the data element lists provided by the working groups and used to help create the final CDE list.[36]

[36] HL7. WHT CRN Overview. 2019, October. Retrieved from https://build.fhir.org/ig/HL7/coordinated-registry-network/crn-overview.html#wht-crn-project-data-elements

Table 4. List of Data Elements Identified by the FDA Clinical Working Groups

FDA Clinical Working Group Name	List of Data Elements Identified for the Women's Health Technologies CRN Project
Long-Acting Reversible Contraceptives (LARC)	LARC Draft Elements [37]
Pelvic Organ Prolapse (POP)	POP Draft Data Elements [38]
Uterine Fibroids (UF)	UF Draft Data Elements [39]

The Women's Health Technologies CRN FHIR Implementation Guide reused profiles that already existed (namely, CDEs were mapped to various profiles). New profiles were created in cases where the data elements could not be directly mapped to existing profiles from other implementation guides, or they were insufficient for the needs of this project. For example, profiles specific to coordinated registry networks such as Device, DeviceDefinition, and Procedure were created for this project and included in the Women's Health Technologies CRN FHIR Implementation Guide.

PILOT TESTING

Pilot testing supports refinement and validation of the implementation approach. Two organizations were engaged to test the models proposed and specifications in the implementation guide. The first was AUGS. The second was a collaboration among three organizations, FDA High-performance Integrated Virtual Environment (HIVE), SUFU, and New York-Presbyterian Hospital (NYP) (HIVE-SUFU-NYP). The two organizations conducted a total of three rapid-cycle development sprints that lasted for approximately ten weeks each.

These established registries aimed to test the six capability statements outlined in the Women's Health Technologies CRN FHIR Implementation Guide in a test or production environment (i.e., clinical or provider setting) (Table 5). [40] The feedback obtained from the organizations conducting pilot testing was used to revise the technical approaches, identify implementation challenges, and provide insights regarding how the proposed approach can be scaled to a national level and applied by other registries.

Pilot Actors, Capabilities, Success Metrics, and Milestones

The coordinated registry network capability statements outline conformance requirements for each actor within a real-world system, including specific profiles, operations, security mechanisms, and search parameters that need to be supported. Each organization that conducted pilot testing selected one or more actors and then implemented the requirements for the specific actors as part of their testing. Success metrics and milestones for each capability were developed to monitor the progress. Table 5 lists each real-world system (Actor) involved in the workflow of collecting and sharing clinical care data on

[37] LARC Draft Elements. 2019. Retrieved from https://drive.google.com/file/d/17h-EFoae123Sfr4YexFsEEM8xzcPRElF/view
[38] POP Draft Data Elements. 2019. Retrieved from https://drive.google.com/file/d/1Wo0aMvGkfBsamzaO7lBKftkfKZZoDqo5/view
[39] UF Draft Data Elements. 2019. Retrieved from https://drive.google.com/file/d/1TTAgkFzDEcVJbfrYI4fQChjokaYTbYEz/view
[40] HL7. FHIR WHT CRN IG: Capability Statements for the IG. 2019, October. Retrieved from http://hl7.org/fhir/us/womens-health-registries/2019May/capstatements.html

women's health. Each actor has specific capabilities assigned to it that are necessary within that workflow, and each subsequent capability for each actor expands on the previous capability.

Table 5. Pilot Capabilities, Success Metrics, and Milestones

Actors	Capabilities Required	Success Metrics	Milestones
CRN Instrument and Metadata Repository	1. Ability to publish a CRN Instrument	• Ability to publish a CRN Instrument using FHIR APIs • Ability to publish the different types of CRN Instruments (basic, populatable, extractable, adaptive)	• Set up of a FHIR server • Populate the server with the various CRN Instruments • Implement the various search parameters
External CRN Data Collection System	2. Ability to retrieve the instrument, render the instrument, and collect the necessary data	• Ability to retrieve and render a basic CRN Instrument • Ability to collect data manually for a basic CRN Instrument • Ability to post the collected data to a registry	• Implement a FHIR client • Render the Questionnaire Resource • Collect data • Validate collected data with the GUDID database • Validate collected data with Terminology Server • Create QuestionnaireResponse • Publish the QuestionnaireResponse to the registry
External CRN Data Collection System (cont.)	3. Ability to retrieve, render, and auto-populate the CRN Instrument and collect additional data	• Ability to retrieve and render a CRN Instrument that can be auto-populated • Ability to collect data manually to auto-populate a CRN Instrument • Ability to post the collected data to a registry	• Implement a FHIR client • Render the Questionnaire Resource • Auto-populate data from EHR using SMART on FHIR app protocols • Collect additional data • Validate collected data with the GUDID database • Validate collected data with Terminology Server • Create QuestionnaireResponse • Publish the QuestionnaireResponse to a registry

Actors	Capabilities Required	Success Metrics	Milestones
External CRN Data Collection System (cont.)	4. Ability to retrieve and render the CRN Instrument and collect data and transform data into FHIR resources	• Ability to retrieve and render a basic CRN Instrument • Ability to collect data manually for a basic CRN Instrument • Ability to post the collected data to a registry • Transform collected data into other FHIR Resources • POST other FHIR Resources to registry	• Implement a FHIR client • Render the Questionnaire Resource • Collect data • Validate collected data with the GUDID database • Validate collected data with Terminology Server • Create QuestionnaireResponse • Publish the QuestionnaireResponse to a registry • Transform QuestionnaireResponse to other FHIR Resources • POST other FHIR Resources to registry
Women's Health Registry	5. Ability to receive CRN Instrument and collected data	• Ability to receive collected data from a CRN Data Collection System • Ability to expose Collected data via FHIR APIs	• Set up a FHIR Server • Create the POST APIs for Questionnaire and QuestionnaireResponse • Accept the POST Requests • Security: Create a method for clients to authenticate before POST; the recommendation is to use the SMART Backend Services, and other options are welcome • Create APIs to expose the collected data for retrieval by Researchers

Actors	Capabilities Required	Success Metrics	Milestones
Women's Health Registry (cont.)	6. Ability to receive CRN Instrument, collected data, and other FHIR Resources	• Ability to receive collected data from a CRN Data Collection System • Ability to expose collected data via FHIR APIs • Ability to expose other FHIR Resources via FHIR APIs	• Set up a FHIR Server • Create the POST APIs for Questionnaire and QuestionnaireResponse • Accept the POST Requests • Security: Create a method for clients to authenticate before POST; the recommendation is to use the SMART Backend Services, and other options are welcome • Create APIs to expose the collected data for retrieval by Researchers • Create APIs to accept other FHIR Resources via POST and PUT • Create APIs to expose the collected data via other FHIR Resources for retrieval by Researchers

Pilot Project Descriptions

The following sections provide background on each pilot organization and a summary of their approach.

PILOT SITE 1: AUGS

AUGS was founded in 1979 and is a nonprofit organization representing professionals dedicated to treating female pelvic floor disorders. The organization has 1,900 members that include practicing physicians, nurse practitioners, physical therapists, nurses, other health care professionals, and researchers from many disciplines. AUGS is the primary source of clinical and scientific information and education in female pelvic medicine and reconstructive surgery for its members and other constituents.

The AUGS AQUIRE registry is a national urogynecology-focused registry open to all physicians. AQUIRE serves as a quality reporting tool with benchmarking and outcome-tracking.

AUGS pilot tested capabilities 1 and 2 (Table 5) and used the POP surgery data elements identified during the Delphi process. Those data elements were implemented in a module within AQUIRE that was interoperable with other resources and potentially with other registries.

AUGS worked with ONC to set up a FHIR server and create a SMART on FHIR-capable app. The AUGS clinical team helped finalize the data elements for terminology and stored them in an instrument repository. They then populated the app with the POP data elements and instrument repository data. The CRN Instruments were successfully called via the FHIR server in both basic and auto-populated forms. AUGS then formalized the AQUIRE module as a point of data entry for providers and called information from AccessGUDID based on the UDI. AUGS expects to continue building on this work by adding functionality to the AQUIRE registry allowing it to send patients instruments. Although the developed

infrastructure was not ready for production deployment, clinicians were able to use and provide feedback by accessing the test environment.

PILOT SITE 2: HIVE-SUFU-NYP

HIVE, SUFU, and NYP collaborated to examine the feasibility of implementing capabilities as defined in the Women's Health Technologies CRN FHIR Implementation Guide, with each organization contributing expertise to the pilot. HIVE was responsible for the infrastructure, SUFU was responsible for setting up the registry, including the governance and policies, and NYP provided clinical and other subject matter experts to test the app. These pilot team members are briefly described below.

- HIVE is a distributed computing environment supported and continuously developed by FDA. HIVE is used for healthcare IT and biological research data, e.g., preclinical, clinical, post-market, adverse events, and metagenomic. HIVE provides a distributed data retrieval system, archival capabilities, and computational environment architecture that implements a unified API to search, view, and manipulate data of all types. HIVE simplifies the introduction of new data types, thereby minimizing the need for database restructuring, and streamlines development of new integrated information systems.
- SUFU is a foundation created to improve the art and science of urology through basic and applied clinical research in urodynamics and neurourology, voiding function and dysfunction, female urology, and pelvic floor dysfunction, and to disseminate and teach these concepts. SUFU members include surgeons, urologists, advance practice providers, and trainees at various levels.
- NYP Hospital is a nonprofit academic medical center in New York City that is affiliated with Columbia University Vagelos College of Physicians and Surgeons and Weill Cornell Medical College.

HIVE-SUFU-NYP approached the pilot by first standing up a FHIR server on the MDEpiNet HIVE platform. They replicated and customized the FHIR app created by ONC and AUGS for POP data elements, then tested and made the app available on mobile devices and other connected devices. The team worked with SUFU's clinical team to determine, refine, and finalize the data elements for terminology in preparation for storing them in the instrument repository for use with other conditions. HIVE-SUFU-NYP then gathered clinician feedback on the design and usability of the app that was used to update and refine the app.

HIVE-SUFU-NYP piloted capabilities 1-6, as shown in Table 5. They incorporated and implemented the work done by AUGS and customized it as necessary. The HIVE-SUFU-NYP pilot team built a FHIR infrastructure that could address multiple areas of women's health (e.g., POP, SUI, and UF). Through the implementation of capability 3, the app used APIs from the AccessGUDID database (specifically, the Device Lookup API and Parse UDI API) to auto-populate fields in the instrument used for data collection. The implementation of capability 4 translated the QuestionnaireResponse resource data that was made available through capability 2, into granular FHIR Resources such as Observations, Conditions, AllergyIntolerance, and MedicationStatement. This made the data available for different use cases within the registry. The HIVE-SUFU-NYP implementation of capabilities 5 and 6 resulted in creation of FHIR APIs for data to be accessed by outside stakeholders such as researchers and federal stakeholders.

During this project this registry was not fully operational. Therefore deployment of the technology developed was not tested in a production environment as HIVE-SUFU-NYP was in the process of establishing its workflows and data collection and usage procedures. However, the infrastructure was tested to determine its suitability for production purposes and ascertained to be sufficient. Additionally,

while this project resulted in the infrastructure needed to link registries HIVE-SUFU-NYP was unable to locate another FHIR-enabled registry to link to.

SMART on FHIR Capable App

As noted in the pilot project descriptions, a SMART on FHIR capable app was used to render the CRN Instruments from the instrument repository and compile the data.[41] The app was able to publish various types of CRN Instruments. The app's structured framework is flexible and was built to collect the following information:

- Patient Demographics
- Medical History
- Surgical History
- Device Information (including retrieval from GUDID) for devices used in the procedures
- Short Term Follow Up Information
- Long Term Follow Up Information

Implementing a prototype app, similar to the one tested for this project, would require more information from physicians regarding specific workflow needs and the specific data elements that should be made mandatory for each implementation. The feedback must then be translated into the CRN Instrument using appropriate data elements for the capabilities to be implemented in production. For examples of the specific data/forms used for each organization that conducted pilot testing please refer to Appendix B.

As shown in Figure 4, the apps for the different conditions addressed by the Women's Health Technologies CRN project can be launched from the same web site.

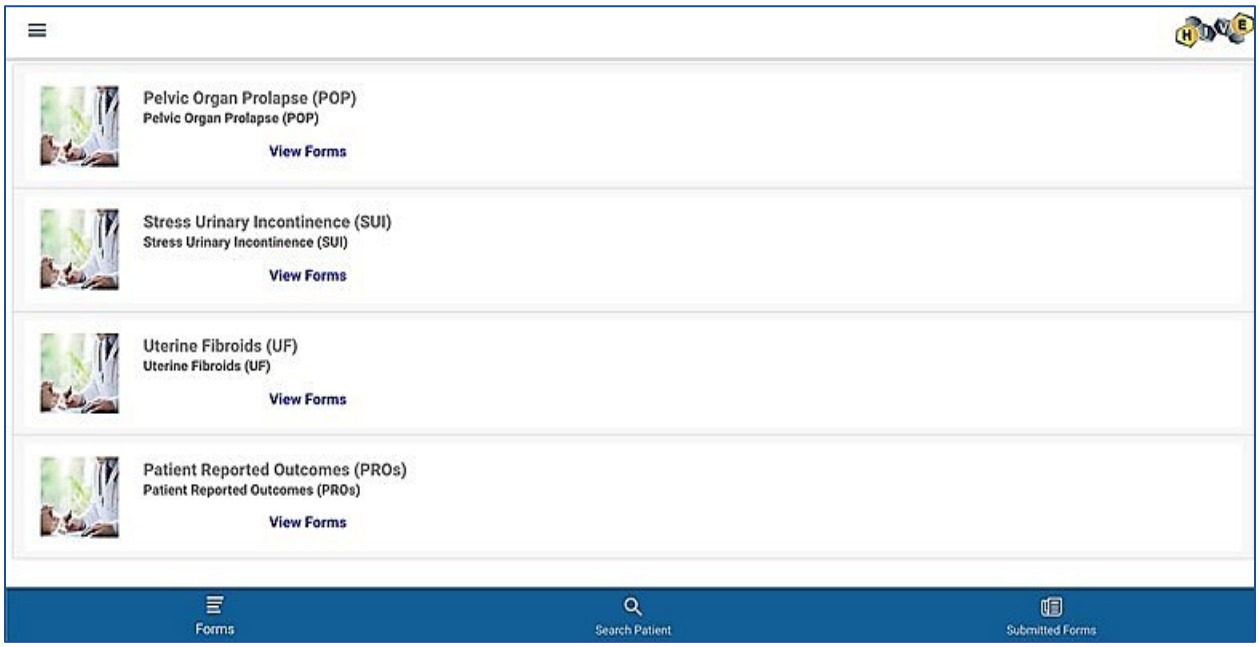

Figure 4. CRN App Form Selection Homepage

[41] Coordinated Registry Network source code. 2019. Retrieved from https://github.com/onc-healthit/crn

As shown in Figure 5, a user can choose any section to initiate data collection. The forms for POP and SUI have the same structure.

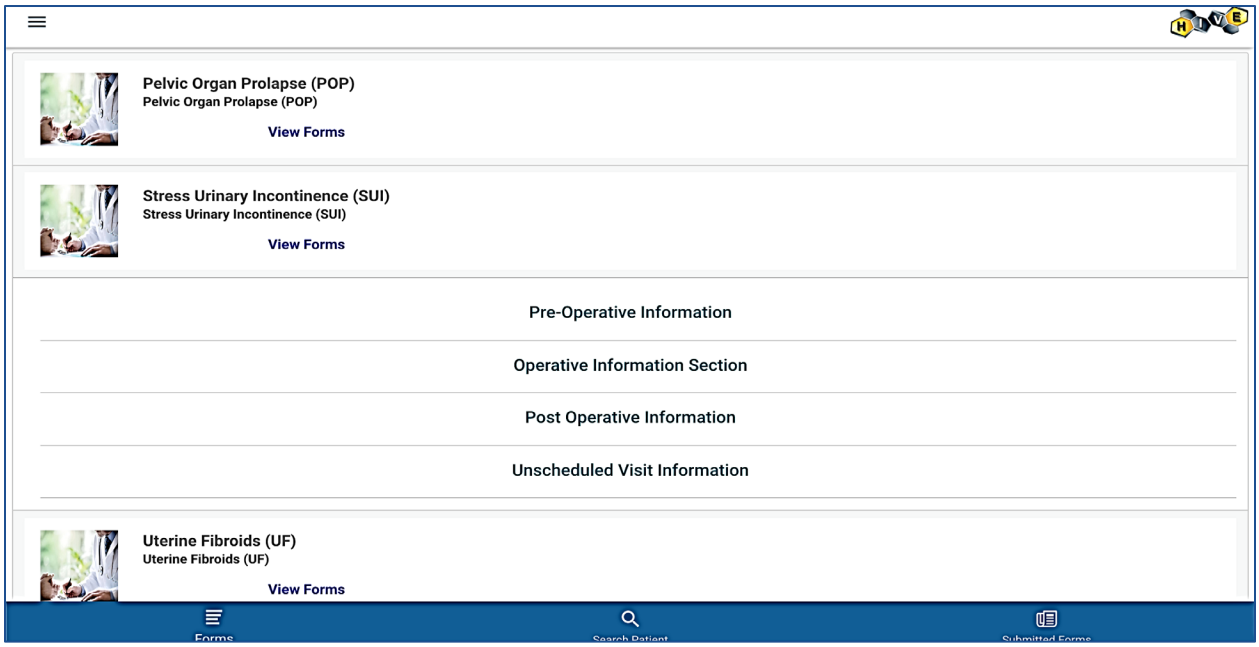

Figure 5. CRN App SUI Selection Homepage

The pre-operative information section (a portion of which is shown in Figure 6) has demographic and other information.

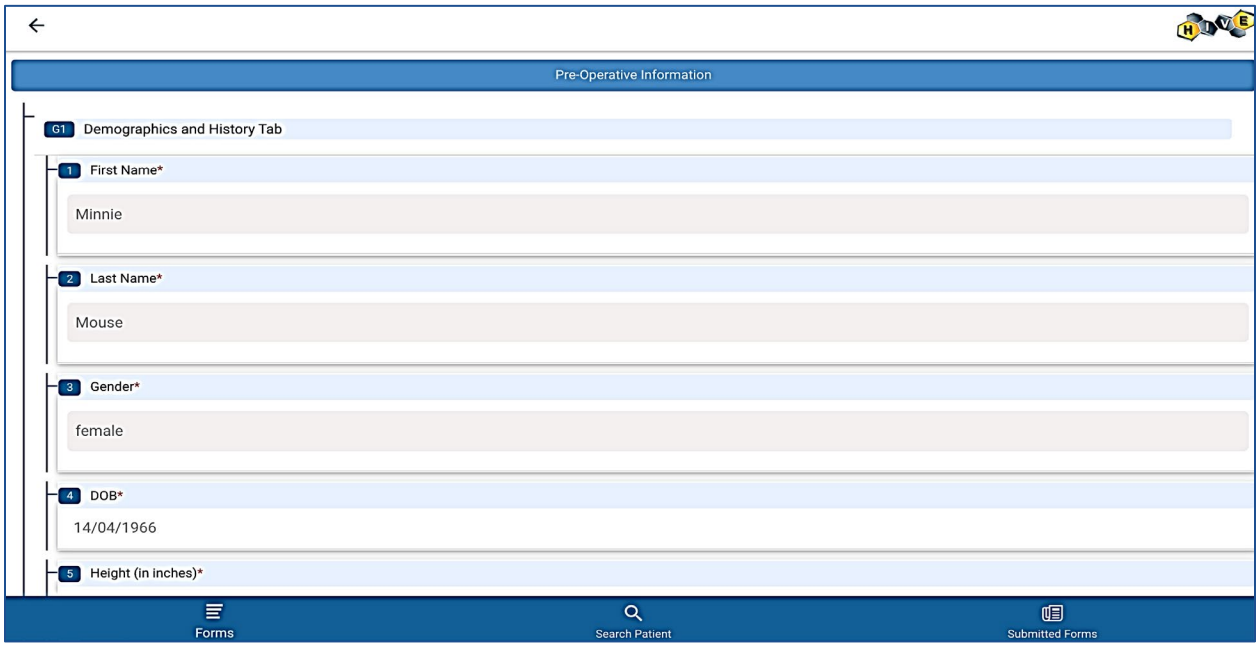

Figure 6. CRN App SUI Data Entry Screen

FDA envisioned a women's health technologies coordinated registry network as a way to coordinate and inform other coordinated registry networks within its Center for Devices and Radiological Health (CDRH). Of particular importance to FDA during this project was the use of the unique device identifier (UDI) in machine-readable format. While this project describes the infrastructure needed to scan and capture the UDI, it also focused on developing the registries infrastructure to be able to pull associated UDI data from the GUDID.[42]

The operative information section includes a section on device UDIs, as shown in Figure 7. If a UDI is entered on the form, a call is made to the GUDID database and the available information regarding the device is used to populate the form.

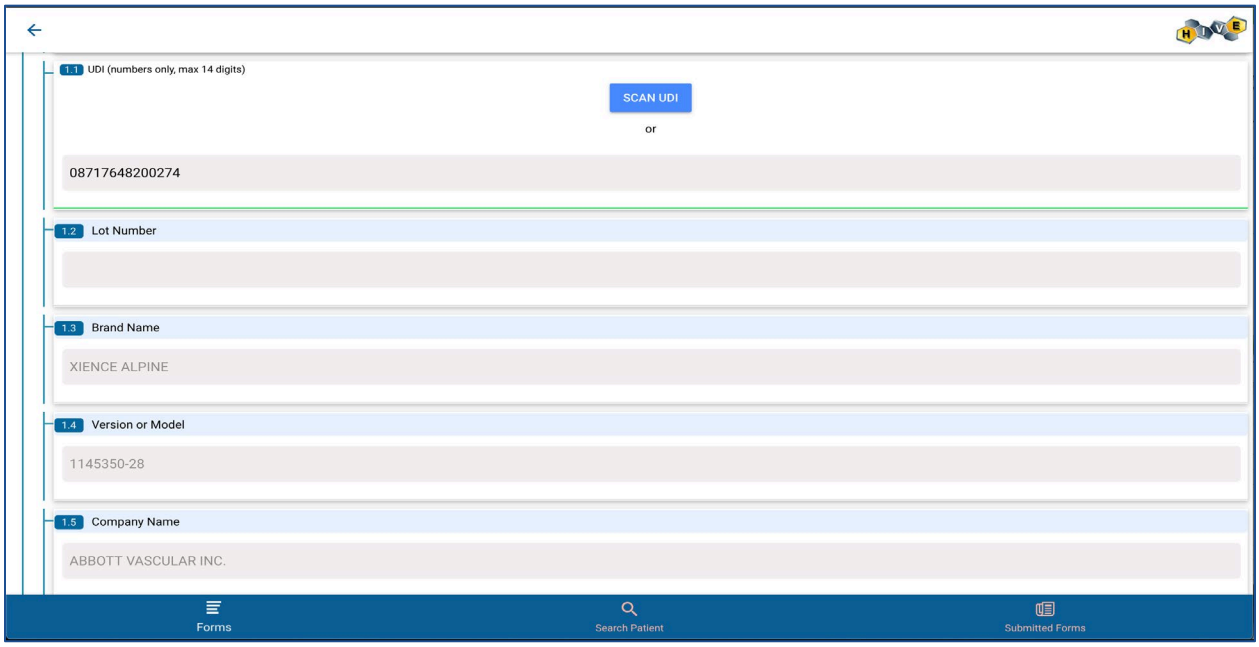

Figure 7. CRN App SUI UDI/GUDID Entry Page

To test the ability to enter a device identifier and pull additional information from the GUDID database, both pilots used sample device identifiers. The device information screens relayed this data to the users.

Pilot Project Results

After completing the rapid-cycle development sprints, each organization was able to achieve the success metrics outlined for each coordinated registry network capability, as noted in Table 6 and Table 7.

[42] FDA. Global Unique Device Identification Database (GUDID). 2019, September. Retrieved from https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid

Table 6. AUGS Pilot Success Metrics

No.	Capability	Milestones	Success Metrics
1	**Ability to publish a CRN Instrument**	• Set up a FHIR server • Populate the server with the various CRN Instruments • Implement the various search parameters	☒ Ability to publish a CRN Instrument using FHIR APIs ☒ Ability to publish the different types of CRN Instruments (☒ basic, ☒ populatable, extractable, adaptive)
2	**Ability to retrieve the instrument, render the instrument, and collect the necessary data.**	• Implement a FHIR client • Render the Questionnaire Resource • Collect data • Validate collected data with GUDID database • Validate collected data with Terminology Server • Create QuestionnaireResponse • Post the QuestionnaireResponse to a registry	☒ Ability to retrieve and render a Basic CRN Instrument ☒ Ability to collect data manually for a Basic CRN Instrument ☒ Ability to post the collected data to a registry

Table 7. HIVE/SUFU/NYP Pilot Success Metrics

No.	Capability	Milestones	Success Metrics
1	**Ability to publish a CRN Instrument**	• Set up a FHIR server • Populate the server with the various CRN Instruments • Implement the various search parameters	☒Ability to publish a CRN Instrument using FHIR APIs ☒ Ability to publish the different types of CRN Instruments (☒ basic, ☒ populatable, ☒ extractable, adaptive)
2	**Ability to retrieve the instrument, render the instrument, and collect the necessary data.**	• Implement a FHIR client • Render the Questionnaire Resource • Collect data • Validate collected data with GUDID database • Validate collected data with Terminology Server • Create QuestionnaireResponse • Post the QuestionnaireResponse to a registry	☒ Ability to retrieve and render a Basic CRN Instrument ☒ Ability to collect data manually for a Basic CRN Instrument ☒Ability to post the collected data to a registry

No.	Capability	Milestones	Success Metrics
3	**Ability to retrieve, render, and auto-populate the CRN Instrument and collect additional data.**	• Implement a FHIR client • Render the Questionnaire Resource that can be auto-populated • Auto-populate data from EHR using SMART on FHIR App protocols • Collect additional data • Validate collected data with GUDID database • Validate collected data with Terminology Server • CREATE QuestionnaireResponse • POST the QuestionnaireResponse to a registry	☒ Ability to retrieve and render a Populatable CRN Instrument ☒ Ability to collect data manually for a CRN Instrument to auto-populate it ☒ Ability to post the collected data to a registry—POST being done with a FHIR Server as will be done with operational FHIR registries
4	**Ability to retrieve, render and auto-populate the CRN Instrument and collect data and transform data into FHIR Resources**	• Implement a FHIR client • Render the Questionnaire Resource • Collect data • Validate collected data with GUDID database • Validate collected data with Terminology Server • CREATE QuestionnaireResponse • POST the QuestionnaireResponse to a registry • Transform QuestionnaireResponse to other FHIR Resources • POST other FHIR Resources to registry	☒ Ability to retrieve and render a Basic CRN Instrument ☒ Ability to collect data manually for a basic CRN Instrument ☒ Ability to post the collected data to a registry—POST being done with a FHIR Server as will be done with operational FHIR registries ☒ Transform collected data into other FHIR Resources ☒ *POST* other FHIR Resources to registry
5	**Ability to receive CRN Instrument and collected data**	• Set up a FHIR Server • Create the POST APIs for Questionnaire and QuestionnaireResponse • Accept the POST Requests • Security: Create a method for clients to authenticate before POST, the recommendation is to use the SMART Backend Services Other options are welcome • Create APIs to expose the collected data for retrieval by Researchers	☒ Ability to receive collected data from a CRN Data Collection System ☒ Ability to expose Collected data via FHIR APIs

No.	Capability	Milestones	Success Metrics
6	**Ability to receive CRN Instrument and collected data and other FHIR resources**	• Set up a FHIR Server • Create the POST APIs for Questionnaire and QuestionnaireResponse • Accept the POST Requests • Security: Create a method for clients to authenticate before POST, the recommendation is to use the SMART Backend Services Other options are welcome • Create APIs to expose the collected data for retrieval by Researchers • Create APIs to accept other FHIR Resources via POST and PUT • Create APIs to expose the collected data via other FHIR Resources for retrieval by Researchers	☒ Ability to receive collected data from a CRN Data Collection System ☒ Ability to expose collected data via FHIR APIs ☒ Ability to expose other FHIR Resources via FHIR APIs

Pilot Project Lessons Learned

AUGS

As the first site to utilize the initial list of CDEs, establish a FHIR server, and create a SMART on FHIR capable app, AUGS had several lessons learned during the testing of these coordinated registry network capabilities. These insights are listed below followed by a summary of lessons learned.

AUGS Lessons Learned

New CRN Instruments were created for this project, limiting time for developers to spend on back-end development. The developers were unable to develop and map the appropriate FHIR resources to the data elements in the CRN Instruments until the instruments were created. A more efficient process is to re-use instrument questions from previous registry efforts. The detailed discussions with clinicians during the Delphi process helped to inform questions used for the instruments. However, the creation of the instrument without incorporating previously developed questions required adaptability from the clinicians. Additionally, the burden of data entry was indicated after the implementation of the forms, which necessitated changing the forms to make many of the questions optional. Care managers wanted to follow up with the same patient as part of their workflows. This required a change in the app to accommodate this feedback

The workflow could not be optimized until testing was complete and the CRN Instrument questions reordered and reworked.

Identifying an appropriate project timeframe. AUGS found the 10-week time frame was not sufficient to create instruments, create a SMART on FHIR app, and develop the new infrastructure while executing capabilities 1 and 2. More time allotted for the project may have limited setbacks.

Clinician and user buy-in is important to participation. Clinician feedback was not available for the initial design of the forms, therefore, feedback was incorporated post-implementation of the app. Clinician engagement could be enhanced by leveraging clinical care data using FHIR (and other standards) to capture and exchange data electronically within registries. Also, using tools such as the SMART on FHIR app to facilitate data collection could provide value for the clinicians and result in increased registry participation.

The infrastructure of a registry could limit their capabilities to conduct an implementation. The lack of infrastructure at the onset of the sprint to capture and exchange data electronically limited the number of capabilities AUGS was able to test.

The collection and use of UDI were a challenge for AUGS. Manual collection of UDI was difficult, time-consuming, and the packaging with the UDI on it was not always easily accessible. It would be beneficial to collect the UDI with a barcode scanning app. At times, there was also a lack of a unique identifier, which resulted in the lot number being the most specific information collected.

HIVE-SUFU-NYP

HIVE-SUFU-NYP tested capabilities 1-6. HIVE-SUFU-NYP re-used the work developed by AUGS on capabilities 1 and 2. The redeployment of the SMART on FHIR app and associated infrastructure to other platforms such as HIVE, and the re-use of the Questionnaire and QuestionnaireResponse resources developed by AUGS, were useful for the HIVE-SUFU-NYP pilot. The same forms were used as AUGS and successfully demonstrated how the app and the forms can be reused in their registry. This may have also eased the ability to focus on and accommodate clinician feedback on the usability of the app in terms of buttons used, pick-lists used, and certain design features or orientations to make the app more user-friendly.

HIVE-SUFU-NYP Lessons Learned

Apps to reduce provider burden needed improvement. Apps were developed to reduce the burden providers experienced from entering the same data in multiple locations. However, it was found that more examples for the app were needed to make vocabularies and value sets more realistic to their various scenarios.

Variance in data collection and workflow from organization to organization needs to be considered. Coordinating and integrating various systems within the registries required guidance regarding how the data was collected and used. The Women's Health Technologies CRN FHIR Implementation Guide was updated to provide implementers with guidance regarding workflows.

Re-use of FHIR resources. The SDC and PRO FHIR implementation guides developed by other ONC projects were reused or built upon to apply to the collection and transfer of women's health data. The same FHIR infrastructure could be used to collect data across multiple conditions (e.g., POP and SUI) through condition-specific questions with minimal changes to the infrastructure. However, the lack of another registry with the same technical capability still presents a barrier. A structure such as HIVE could host multiple registries and take advantage of the common components to achieve efficiencies at scale.

Reducing provider burden. HIVE-SUFU-NYP demonstrated that mapping data elements successfully offered capabilities to reduce provider burden. The mapping of data elements from the GUDID API to the instruments facilitated verifying the capture of UDI information. Providers entering the identifier would

have the remaining device information auto-populated from the GUDID database, reducing clinician burden of having to manually enter the information.

Common Themes

In addition to the lessons learned that were specific to each organization, the following themes were common to the experience of both sets of organizations.

Instrument Design

The design of the instrument for data collection played an integral part in being able to use the data collection app effectively. This design affected how the instrument was rendered and how easy it was to fill out. For example, the instrument design specified how choices should be displayed (radio choice with multiple options, checkbox, dropdowns, free form text/date fields, etc.). An initial lesson learned was that existing instruments submitted by the pilot organizations were not easily translated to the format needed to create a CRN Instrument because they were lists of questions that did not take into consideration user experience. For this project, user testing was conducted, and the resulting feedback from clinicians was incorporated into the CRN Instrument design to produce a more user-friendly and effective display for collecting data. Organizations seeking to translate their existing instruments into capture methods using software apps should incorporate user testing into the design plan.

Skip Logic

Skip logic is an essential part of CRN Instruments to reduce the data entry burden for patients and providers. Skip logic is skipping questions that do not apply to the responder. Properly formulating skip logic simplified the instrument and its usage. Some of the existing instruments provided by the pilot organizations contained multiple nested levels of skip logic. The pilot organizations and the technical teams collaborated to simplify the skip logic by removing multiple nesting levels, making the instruments easier to use. Additionally, workflow charts were useful tools that clearly outlined how skip logic flow should occur.

Testing Using Sandboxes

AUGS and HIVE-SUFU-NYP currently do not use EHRs for registry data collection. Instead, they have separate data collection systems where data is entered manually and submitted to the registries. The frequency of data entry and submission varies based on policy and research needs, as the data collected is not part of other mandatory reporting program requirements. One of the mechanisms recommended for implementing the coordinated registry network capabilities is to use a SMART on FHIR app for data collection, which can auto-populate data in the CRN Instrument and leverage data from the EHR. However, the organizations conducting pilot testing did not have an EHR environment integrated with their registry to use for collecting data and their production systems did not support SMART on FHIR protocols. The lack of EHR test environments made it difficult to evaluate technical progress.

A health IT sandbox is a virtual testing environment that mimics a live EHR production environment, but is populated with sample data. The organizations that participated in pilot-testing were able to use two publicly-available sandboxes for testing: Logica, previously known as the Health Services Platform Consortium; and ONC's Standards Implementation & Testing Environment (SITE). These sandboxes supported testing of the Women's Health Technologies CRN FHIR Implementation Guide concepts and capabilities by demonstrating how select fields in the instrument could be auto-populated. Some of the fields that were auto-populated include demographic data elements, condition, and procedure data elements. The design of the data collection app relies on the availability of specific data elements in EHRs.

Future pilot testing should to identify ahead of time if integrated EHRs are available to provide data for auto-population. If the data elements are not available, then the user interface can be designed to collect only the available data necessary data by using skip logic and other controls.

Production Implementation and Workflows

In addition to instrument design, other crucial aspects of production implementation included data collection methods and real-world workflows. Workflows differ among organizations and systems. For example, if data are collected once a month and the data collection app is scheduled to collect data every day, the same data would get reported multiple times. The workflows which include creating the necessary orders, such as notifying users when data will be collected, and the actual collection of data must be coordinated across systems. Currently, the Women's Health Technologies CRN FHIR Implementation Guide does not prescribe workflow coordination but does include some guidance regarding workflows to help implementers.

Collecting Device Information Using GUDID Database and APIs

The SMART on FHIR capable app was used to test the ability to collect data about devices implanted in women. The pilot organizations verified UDI information capture by entering the example device identifiers and then populating the remainder of the information from the GUDID database using the GUDID APIs. The APIs worked well, and the UDI fields such as Device Name, Brand Name, Manufacturer, and Dates, were populated automatically without user involvement. This demonstrated that by scanning or identifying a device identifier, the remaining information could be auto-populated for the data elements identified in the Device and Device Definition profiles. This finding validated the need for mapping data elements from the GUDID API to the CRN Instrument before administration. The lesson learned was to ensure that the instruments are designed with the appropriate data elements and FHIRPath expressions to populate data from the GUDID database automatically during administration. The FHIRPath expressions provide the app with the information needed to determine which data elements must be auto-populated using information from the GUDID database.

CONCLUSION

This project identified various complexities involved in enabling data collection for registries, exchanging data collected with researchers, and linking data across registries. These complexities must be addressed incrementally to build the standards and infrastructure required for seamless data exchange among women's health registries. The activities below describe specific issues identified and how to best address them based on lessons learned from this project.

Definition and Harmonization of Data Elements Across Registries

Currently, every registry has a set of data elements that it is collecting or intending to collect. These data elements overlap significantly with other registries collecting data for similar conditions. However, there is limited reuse of data definitions and data element representations shared across registries. This increases the inconsistency and complexity for implementers to build technology for linking registries. The Delphi process used for this project helped to define and harmonize a set of data elements across a few registries. These data definitions were used in creating the Women's Health Technologies CRN FHIR Implementation Guide, which helped build a strong semantic infrastructure for the pilots.

There are a few ongoing efforts in the health care industry to help with that lack of harmonized data. These efforts and the data elements being defined should be coordinated with future versions of the Women's Health Technologies CRN FHIR Implementation Guide.

Common Reporting Framework for Registries

The availability of a common reporting framework would help with launching and implementing for registries more rapidly. Such a framework should consist of:

- Policy templates for data collection and use including guidance on privacy controls for protecting patient data
- Standards-based data exchange mechanisms leveraging the Women's Health Technologies CRN FHIR Implementation Guide
- Reference implementations (e.g., web applications that provide working examples of FHIR interfaces that can be downloaded and run in a local environment) leveraging the data collection app developed by the Women's Health Technologies CRN project

The Women's Health Technologies CRN FHIR Implementation Guide defines standards-based data exchange mechanisms using FHIR and provides reference implementations that can be leveraged by registries. These artifacts should be promoted across registries to jump-start their data collection operations using interoperable mechanisms. The Women's Health Technologies CRN Implementation Guide should be maintained and periodically updated as the FHIR standard evolves.

Reusing Data Collected in Clinical Care and Reducing Provider Burden

Registry data collection is currently very labor-intensive and typically consists of separate systems that are not integrated with clinical workflows. This current structure makes registry data prone to data entry errors, missing data, and capturing data multiple times, which burdens patients and providers. The Women's Health Technologies CRN FHIR Implementation Guide provides a framework using SMART on FHIR apps to reuse data collected from clinical care to auto-populate instruments used for data collection. The Women's Health Technologies CRN FHIR Implementation Guide framework can be leveraged in the future as EHRs become more interoperable using SMART on FHIR protocols and can contribute data to registries via SMART on FHIR data collection apps. This reduces provider burden while increasing data quality by eliminating duplication and errors in data entry.

Linking of Data Across Registries

The current women's health registry ecosystem has minimal ability to exchange data across registries. However, it would be beneficial for researchers to leverage data from multiple registries. Doing so requires the ability to link and harmonize data across registries. In addition to using these data elements, registries can use the standards and tools developed by the ONC Patient Matching, Aggregating, and Linking project to link data across registries.[43] The linking of the data elements across registries was not accomplished in this project because the registries for the pilots are currently building data collection capabilities and have not engaged in data exchange with other registries. Standardization of data and querying capabilities through the use of the FHIR standard would enable researchers to leverage multiple registries to discover relationships among conditions and treatments. These functions are complex and

[43] ONC. Patient Matching, Aggregating, and Linking (PMAL). 2018. Retrieved from https://www.healthit.gov/topic/scientific-initiatives/pcor/patient-matching-aggregating-and-linking-pmal

have not been addressed uniformly. This is an area for continuing work and should be pursued in future phases of the Women's Health Technologies CRN project.

Summary

There is a growing opportunity for registries to leverage health IT standards to reuse clinical data, more efficiently capture data that is critical to research, and share data across complimentary registry partners. The Women's Health Technologies CRN project successfully created an interoperable framework with reusable tools that can enable linkage among national clinical registries related to women's health technologies and that may be leveraged for other types of registries. The Women's Health Technologies CRN FHIR Implementation Guide, which provides guidance for organizations interested in implementing a coordinated registry network, was developed and informed by pilot testing conducted in parallel.

Appendix A: Glossary and Acronyms

Term	Definition
ACOG	The American College of Obstetricians and Gynecologists
AHRQ	Agency for Healthcare Research and Quality
API	Application programming interface, particular sets of rules and specifications that software programs can follow to communicate with each other directly
AQUIRE	AUGS's Urogynecology Quality Registry
ASPE	Assistant Secretary for Planning and Evaluation
AUGS	American Urogynecologic Society
CCDS	Common Clinical Data Set
CDC	Centers for Disease Control and Prevention
CDE	Common data element
CDRH	Center for Devices and Radiological Health
CMS	Centers for Medicare & Medicaid Services
COMPARE-UF	Comparing Options for Management Patient-Centered Results for Uterine Fibroids
CRN	Coordinated registry network
CSV	Comma-separated values
DAF-Research	Data Access Framework for Research developed technical standards for accessing, querying, and aggregating EHR data for multiple patients across multiple organizations using a standard mechanism.
Dorsata	A platform for the creation and distribution of pathway-based, EHR-integrated application
EHR	An electronic health record is an electronic version of a patient's medical history that is maintained by the provider over time and may include all of the key administrative clinical data relevant to that person's care.
ERP	Epidemiology Research Program
FDA	Food and Drug Administration
FHIR®	Fast Healthcare Interoperability Resources (FHIR) is standard for exchanging healthcare information electronically. FHIR was created and is maintained by HL7.
FMG	FHIR Management Group
GUDID	Global Unique Device Identification Database
HHS	U.S. Department of Health and Human Services
HIVE	High-performance Integrated Virtual Environment
HL7®	Health Level Seven International is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services
HTTP	Hypertext Transfer Protocol (HTTP)
Interoperability	The ability of computer systems or software to exchange and make use of information
IT	Information technology
JSON	JavaScript Object Notation
LARC	Long-Acting Reversible Contraceptives
LHS	Learning Health System

Term	Definition
MDEpiNet	Medical Device Epidemiology Network Initiative
NIH	National Institutes of Health
NLM	National Library of Medicine
NYP	New York-Presbyterian Hospital
ONC	Office of the National Coordinator for Health Information Technology
PCOR	Patient-centered outcomes research
PCORnet	Patient-Centered Outcomes Research Network
PCORTF	Patient-Centered Outcomes Research Trust Fund was established in 2010 under the Patient Protection and Affordable Care Act
PFDR	Pelvic Floor Disorders Registry
POP	Pelvic organ prolapse
PRO	Patient-reported outcome is any report of the status of a patient's health condition directly reported by the patient without interpretation of the patient's response by a clinician or anyone else.
PROMs	Patient-Reported Outcome Measures are the data collection instruments used to measure PROs. They are designed to provide a standardized way to collect such outcomes.
PSS	Project scope statement
REDCap	REDCap is a secure web application for building and managing online surveys and databases.
RESTful	Representational state transfer
SDC	Structured Data Capture
SDO	Standards Development Organization
SITE	Standards Implementation & Testing Environment
SMART on FHIR	Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR is a set of open specifications to integrate apps with EHRs, portals, health information exchanges, and other health IT systems
STU	Standard for trial use
SUFU	Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction
SUI	Stress urinary incontinence
UDI	Unique device identifier
UF	Uterine fibroids
Women's Health Technologies CRN FHIR Implementation Guide	The Women's Health Technologies Coordinated Registry Network Fast Healthcare Interoperability Resources Implementation Guide
XML	Extensible Markup Language

Appendix B-1: Pilot Organization Data Collection Form: Postoperative Factors: Short Term Follow Up (0-30 Days)

1. Was the patient seen/evaluated within 30 days after surgery? (Y/N) If Y then:
    a. Follow-Up Date (date)
    2. Did the patient have postoperative complications within 30 days of surgery (includes events while in the hospital)? (Y/N) If Y then: ----→ Q1
        a. Select all complications that occurred (can select more than one): --→ G1 enabled When Q1--Y
            i. Cardiovascular (If selected then select one or more of the following) -→ Q2 with CheckBox
                1. Select all applicable conditions ---→ Q3 enabled when Cardiovascular is Checked …
                2. AMI
                3. Non-ST elevation MI
                4. CVA
                5. TIA
                6. Cardiac Arrest

                Add additional choice (Any or N/A or Other) and just use Cardiovascular as questions with 5 choices + additional choice discussed. In this case the options can be displayed to the user…before they select CardioVascular.

            ii. Pulmonary (If selected then select one or more of the following)
                1. Prolonged intubation (past the PACU)
                2. ICU admission
                3. Reintubation
            iii. Systemic infection (If selected then select one or more of the following)
                1. Pneumonia (confirmed)
                2. SIRS
                3. Septic shock
                4. Sepsis
                5. Pyelonephritis
                6. Urosepsis
            iv. VTE (If selected then select one or more of the following)
                1. DVT
                2. PE
            v. SSI (If selected then select one or more of the following)
                1. Superficial SSI
                2. Deep SSI
                3. Organ space SSI
            vi. UTI (If selected then select one or more of the following)
                1. Culture proven

2. Initiation of antibiotics for empiric treatment (w/in 30 days)

vii. C Diff colitis

viii. Bleeding (If selected then select one or more of the following)
   1. Blood transfusion with 3 days of index surgery
   2. Hematoma requiring imaging or further management
   3. IR drainage
   4. Surgical evacuation

ix. GI (If selected then select one or more of the following)
   1. Postoperative ileus
   2. SBO

x. Organ Injury (If selected then select one or more of the following)
   1. Ureteral injury
   2. Bladder injury and/or perforation
   3. Bowel Injury
   4. Other
   5. Please describe treatment (free text box)

xi. Fistula

xii. Peripheral nerve injury

xiii. Vaginal cuff dehiscence

xiv. Suture exposure/erosion (If selected then select one or more of the following)
   1. Into vagina
   2. Into viscera

xv. Mesh exposure/erosion (If selected then select one or more of the following)
   1. Into vagina
   2. Into viscera

xvi. Foreign body left during procedure

xvii. Other

xviii. Death

xix. If yes to any of the above, Clavien-Dindo Scale for the most severe complication (short text box; this scale can have the following scores: I, II, IIIa, IIIb, IVa, IVb, or V)

3. Was the patient readmitted to the hospital overnight within 30 days of surgery? (Y/N)
4. Did the patient return to the OR for POP surgery-related complication within 30 days of surgery? (Y/N)

Appendix B-2: Pilot Organization Data Collection Form: Postoperative Factors: Device Information

1. Surgeon enters UDI-DI either manually or by using barcode scanner
    a. UDI (numbers only, max 14 digits)
2. If available, surgeon enters Lot number
    a. Lot number (alpha-numeric text box, max 14 digits)
3. System calls AccessGUDID to pull the following information:
    a. Button (?) that says Fetch Details
    b. Brand Name: (text box)
    c. Version or Model: (text box)
    d. Company Name: (text box)
    e. Device Description: (text box)
    f. Primary Device Identifier Number: (Number)
    g. What MRI safety information does the labeling contain?: (text box)
    h. Device required to be labeled as containing natural rubber latex or dry natural rubber. (Y/N)
    i. Device labeled as "Not made with natural rubber latex". (Y/N)
    j. For Single-Use (Y/N)
    k. Kit (Y/N)
    l. Combination Product (Y/N)
    m. Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) (Y/N)
    n. GMDN: (text box for name, not description; can contain more than one GMDN, comma separated)
    o. FDA Product Code: (text box)
    *Not all of this information is available for all devices
4. Additional device information questions NOT connected to UDI:
    a. Type of sutures used (dropdown box with the following options)
        i. Absorbable
        ii. Permanent
        iii. Both
    b. Suture capturing device used (text box)

Appendix B-3: Pilot Organization Data Collection Form: Postoperative Factors: Long Term Follow Up (>90 Days)

1. Follow-Up Date (date)
2. Has the patient had any complications related to POP surgery since the index procedure? (Y/N)
    a. Select all applicable complications:
        i. Vaginal scarring
        ii. Vaginal shortening
        iii. Suture exposure/erosion (If selected then select one or more of the following)
            1. Into vagina
            2. Into viscera
        iv. Mesh exposure/erosion (If selected then select one or more of the following)
            1. Into vagina
            2. Into viscera
        v. Urinary or bowel symptoms/problems
        vi. Difficulty emptying bladder/urinary retention
        vii. Pelvic pain
        viii. Dyspareunia if sexually active (de novo or worsening)
        ix. Pelvic infection/abscess
        x. Bone infection
        xi. Sinus tract infection
        xii. Organ injury/fistula
        xiii. Ureteral injury
        xiv. If yes to any of the above, Clavien-Dindo Scale for the most severe complication (short text box; this scale can have the following scores: I, II, IIIa, IIIb, IVa, IVb, or V)
3. Does the patient report symptomatic recurrence including seeing or feeling a bulge? (Y/N)
4. Does the patient have anatomic recurrence beyond the hymen (Y/N)? If Y, then:
    a. POP-Q stage (Roman numeral 0-IV)
    b. Compartment with greatest anatomic prolapse (short text box)

Appendix B-4: Pilot Organization Data Collection Form: Medical History

1. Total number of pregnancies (integer) If answer>0 then:
    a. Vaginal Births (integer)
    b. C-sections (integer)
2. Co-morbidity index
3. Has the patient been diagnosed with diabetes (Y/N)?
4. Use of tobacco or nicotine-containing products:
    a. Never
    b. Former
    c. Current—Every day
    d. Current—Not every day
    e. Unknown
5. Is the patient postmenopausal (Y/N)?
6. Is the patient sexually active (Y/N)? If Y then:
    a. Does the patient have pain with sexual activity?
        i. Rarely
        ii. Sometimes
        iii. Frequently
        iv. Always
7. Does the patient report urinary incontinence (Y/N)? If Y then (can select more than one):
    a. Stress urinary incontinence
    b. Urgency urinary incontinence
    c. Other
8. Does the patient report defecatory dysfunction (Y/N)? If Y then (can select more than one):
    a. Chronic constipation
    b. Fecal incontinence
    c. Other
9. Does the patient currently use estrogen (Y/N)? If Y then:
    a. Vaginal estrogen
    b. Systemic estrogen
    c. Other
10. Does the patient report vaginal bulge symptoms (Y/N)?

Appendix B-5: Pilot Organization Data Collection Form: Peri-operative Factors: Procedure

1. Surgery Date (date)
2. Did the patient have a concomitant hysterectomy? (Y/N) If Y then:
    a. Type of hysterectomy (dropdown, select one of the following)
        i. Total
        ii. Supracervical
    b. Hysterectomy approach (dropdown, select one of the following)
        i. Abdominal
        ii. Vaginal
        iii. Laparoscopic
        iv. Robotic-assisted
    c. Was the hysterectomy for the indication of prolapse? (Y/N)
3. Did the patient have a concomitant anti-incontinence procedure? (Y/N) If Y then (dropdown, select one of the following)
    a. Midurethral sling
    b. Burch procedure
    c. Peri-urethral bulking agent
    d. Pubovaginal sling
4. Was a vaginal apical vault suspension performed? (Y/N)
    a. Type (short text box)
5. Was an abdominal apical vault suspension performed? (Y/N)
    a. Type (short text box)
6. Was hysteropexy (apical support procedure leaving uterus in place) performed? (Y/N) If Y then:
    a. Approach for hysteropexy (dropdown, select all that apply)
        i. Vaginal
        ii. Abdominal
        iii. Laparoscopic
    b. Material used
        i. Mesh (enter UDI below)
        ii. Native Tissue
        iii. Unknown
7. Was anterior repair performed? (Y/N) If Y then:
    a. Approach for anterior repair (dropdown, select all that apply)
        i. Vaginal
        ii. Abdominal
        iii. Laparoscopic
        iv. Robotic
    b. Material used
        i. Mesh (enter UDI below)
        ii. Native Tissue

iii. Unknown

8. Was enterocele repair performed? (Y/N) If Y then:
    a. Approach for enterocele repair (dropdown, select all that apply)
        i. Vaginal
        ii. Abdominal
        iii. Laparoscopic
        iv. Robotic
    b. Material used
        i. Mesh (enter UDI below)
        ii. Native Tissue
        iii. Unknown
9. Was posterior repair performed? (Y/N) If Y then:
    a. Approach for posterior repair (dropdown, select all that apply)
        i. Vaginal
        ii. Abdominal
        iii. Laparoscopic
        iv. Robotic
    b. Material used
        i. Mesh (enter UDI below)
        ii. Native Tissue
        iii. Unknown
10. Was an obliterative prolapse procedure performed? (Y/N)
11. Was a complication observed during the procedure? (Y/N) If Y then (dropdown, select all that apply):
    a. Bleeding requiring blood transfusion
    b. Urinary Tract Injury (If checked, further dropdown, select all that apply)
        i. Ureteral Injury
        ii. Bladder Injury excluding trocar perforation
        iii. Urethrotomy/Repair
        iv. Mesh Kit Trocar Injury
    c. Vascular Injury
    d. Visceral Organ Injury (If checked, further dropdown, select all that apply)
        i. Bladder
        ii. Small bowel
        iii. Large bowel
        iv. Rectum
    e. Aborted procedure (If checked, further dropdown, select all that apply)
        i. Reason for aborting procedure:
            1. Bleeding
            2. Injury
            3. Device malfunction
            4. Other
    f. Mesh kit/Device Malfunction

   g. Death
   h. Other operative complication/injury
12. Clavien-Dindo Scale for the most severe complication (only appears if Q11=Y; short text box; this scale can have the following scores: I, II, IIIa, IIIb, IVa, IVb, or V)
13. Was the complication related to prolapse surgery? (Y/N; only appears if Q11=Y)
14. Was the procedure unsuccessful or did it result in conversion to another procedure? (Y/N)
15. Did a complication unrelated to the prolapse surgery occur? (Y/N)

Appendix B-6: Pilot Organization Data Collection Form: Peri-operative Factors: Discharge

1. Did reoperation occur during the index hospitalization? (Y/N)
2. Discharge date (date)
3. Discharge Disposition
    a. Home
    b. Visiting nurse association
    c. Skilled nursing facility
    d. Long-term care
    e. Deceased
    f. Other

Appendix B7: Pilot Organization Data Collection Form: Surgical History

1. Has the patient had a hysterectomy? (Y/N) If Y then:
    a. Type of prior hysterectomy
        i. Total
        ii. Supracervical
        iii. Radical
    b. Route of hysterectomy
        i. Vaginal
        ii. Abdominal
        iii. Laparoscopic/robotic
    c. Indication for prior hysterectomy
        i. Prolapse
        ii. Bleeding
        iii. Fibroids
        iv. Cancer
        v. Precancerous condition
        vi. Other
2. Does the patient have existing urogynecologic mesh? (Y/N) If Y then (can select more than one):
    a. Existing mesh for SUI
    b. Existing mesh for prolapse
3. Has the patient had anti-incontinence surgery? (Y/N) If Y then (can select more than one):
    a. Synthetic sling
    b. Autologous sling
    c. Biologic sling
    d. Urethropexy/Burch procedure
    e. Bulking agent
    f. Vaginal native tissue
4. Has the patient had prolapse surgery? (Y/N) If Y then (can select more than one):
    a. Sacrocolpopexy
    b. Non-mesh vaginal apical suspension
    c. Anterior repair without mesh
5. Has the patient had abdominal surgery (Y/N) If Y then:
    a. Type of previous abdominal surgery (free text box)
6. BMI (number up to two decimal places)
7. POP-Q stage (Roman numeral 0-IV)
8. Compartment with the greatest anatomic prolapse (dropdown, can select more than one):
    a. Anterior
    b. Posterior
    c. Apical