



Patient-Centered Outcomes Research (PCOR) Trust Fund Coordinated Registry Network (CRN)

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Agenda

- Introductions
- Patient-Centered Outcomes Research (PCOR)
- Women's Health Technology (WHT) Coordinated Registry Network (CRN) Project Overview
- WHT CRN ONC Pilot Testing
- WHT CRN App Demo
- CRN Capstone
- Questions

Patient-Centered Outcomes Research (PCOR)

- Produce new scientific evidence that informs and supports the health care decisions of patients, families, and their health care providers
- Through Assistant Secretary for Planning and Evaluation (ASPE) and the Patient-Centered Outcomes Research Trust Fund (PCORTF) support intradepartmental projects that build data capacity for PCOR



Project Partners

- Food and Drug Administration (FDA)
- National Library of Medicine (NLM)
- Office of the National Coordinator for Health Information Technology (ONC)
- Weill Cornell Medicine/Institute for Health Technologies and Interventions
- Medical Device Epidemiology Network (MDEpiNet)



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Background

- Registries provide key infrastructure that can be used for quality improvement & evaluation of patient care & outcomes
- Most are single purpose registries
- Time and cost-intensive to maintain
- Point-of-care data is often transformed for the analysis and research purposes
- Limits on study designs to one particular therapy (i.e., medication or device), rather than a combination of two or more therapies

Birth of the CRN Concept

Recommendations for a National Medical Device Evaluation System

Strategically Coordinated Registry Networks to Bridge Clinical Care and Research



BRIDGING UNMET CLINICAL CARE AND CLINICAL RESEARCH NEEDS WITH STRATEGICALLY COORDINATED REGISTRY NETWORKS

Report from the National Medical Device Registry Task Force & The Medical Devices Epidemiology Network

Mitchell W. Krocoff, Sharon Lise Normand, Fred Edwards, Theodore Lystig, Eve Ross, Elise Berliner, Kristi Mitchell, James Tchong, David Blaser, Ralph Brindis, Jack Cronenwett, Pamela Gavin, Linda Harrison, Amy Helwig, Kristin Larsen, William

VIEWPOINT

Bridging Unmet Medical Device Ecosystem Needs With Strategically Coordinated Registries Networks

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Molecular Sciences and Informatics Center, Weill Cornell Medical College, New York, New York

In June 2014, the Medical Devices Epidemiology Network (MDET) (a not-for-profit Public-Private Partnership, on behalf of the U.S. Food and Drug Administration Center for Devices and Radiological Health (CDRH)), convened the Medical Device Regulatory Task Force (MDRTF) (see Appendix in the Supplement). The task force was launched to address the CDH's commitment "to strengthen the medical device post-market surveillance system using existing resources and create new ones as needed to develop a regulated system that efficiently and effectively achieves its basic functions, from timely identification of potential signals to facilitating premarket device clearance and approval. The MDRTF included formal stakeholder representation and was mandated to review the following and to:

The MDRTF recognized that most existing registries were not health-focused (H-F), and that we need to contain all the elements necessary for device evaluation, including device and procedural details, patient descriptions, or long-term outcomes. However, the MDRTF recognized that such limitations could be mitigated through interoperability solutions that strategically link complementary registries and data sources to create an ecosystem for a full life cycle response to a health care device under evaluation. The MDRTF formed this structure: the strategically coordinated registries network, or CRN - with the recognition that many key elements in such networks exist in EHRs, administrative claims data, or mobile devices and are not registries per se. The MDRTF recommends strategies, efforts, and the process to construct the national system and registry development and a hub-and-spoke model to create a true continuum of care. The MDRTF will pursue development of a dual-purpose leveraging of existing administrative data resources and existing third-party models such

Strategically Coordinated Registry Networks (CRN) Principles:

- Link complementary sustainable registries/e-repositories (Professional society registries, EHRs, Claims data, PCORI- CDRNs)
- TPLC approach as a true continuum leveraging "real world" evidence
- "Dual purpose" existing national, regional or other large scale efforts

CRNs - Typical Domains

1

CRN REGISTRIES

(registry section of
CRN)

2

CRN CLAIMS

(administrative claims
data linked to registry)

3

CRN EHR

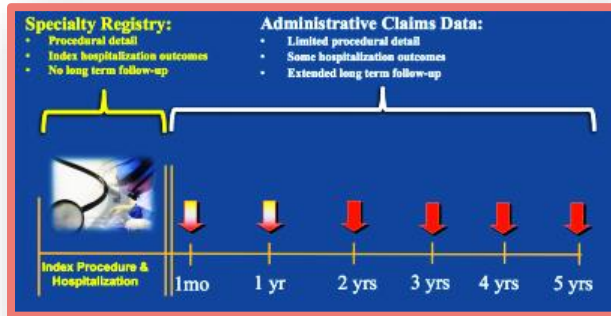
(electronic health
records data to
augment the data)

4

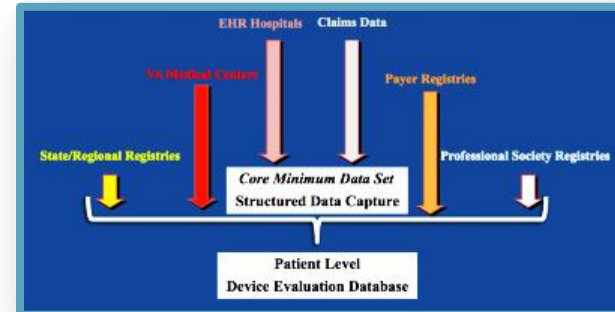
CRN PATIENT

(patient generated
data)

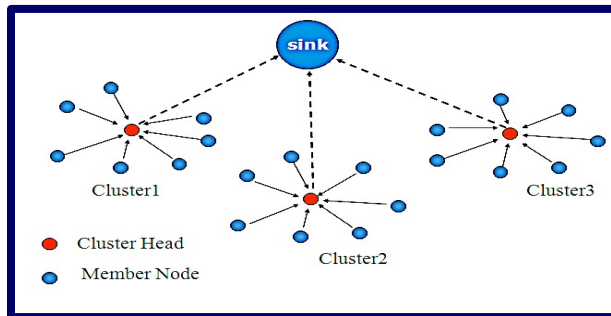
CRNs Data Sharing Solutions



A. Linked complementary data sources



B. Multiple source structured data extraction

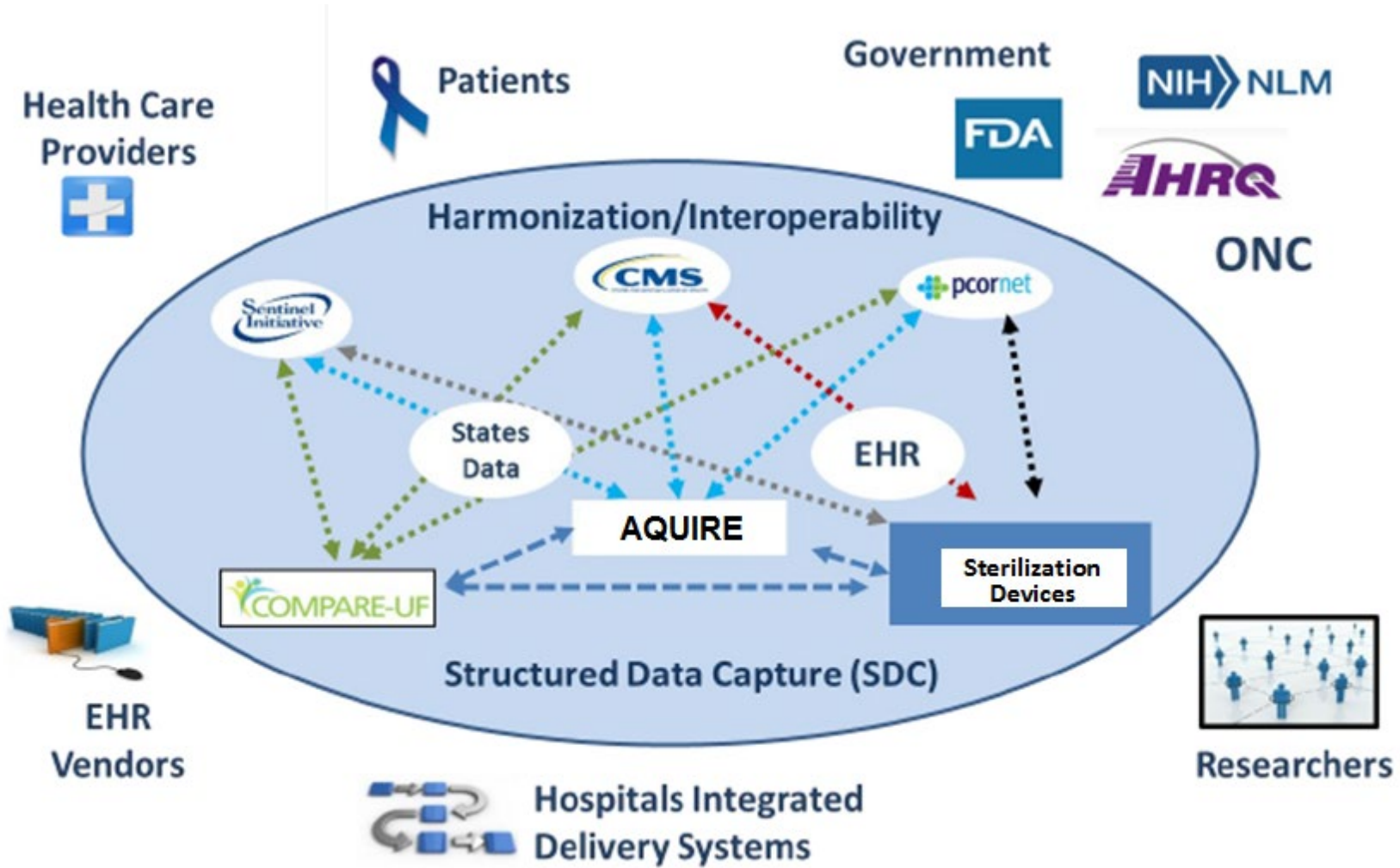


C. Distributed data networks



D. Combining data networks

Women's Health CRN



Women's Health Technologies (WHT) Coordinated Registry Network (CRN)

- RWE *networks* present greater opportunities than single-use registries
- The WHT-CRN facilitates PCOR focused on women's health by connecting RWE including existing registries and several other federal data sources (e.g., Sentinel, claims data, PCORnet)
- Promotes HL7 FHIR and structured data capture (SDC) standards for data collection and exchange

WHT CRN Project Goals



Coordinated

Comprehensive approach to improve evaluation of women's health technologies across care settings



Harmonized

Create interoperable platform to link existing registries to each other and to other major data networks



Efficient

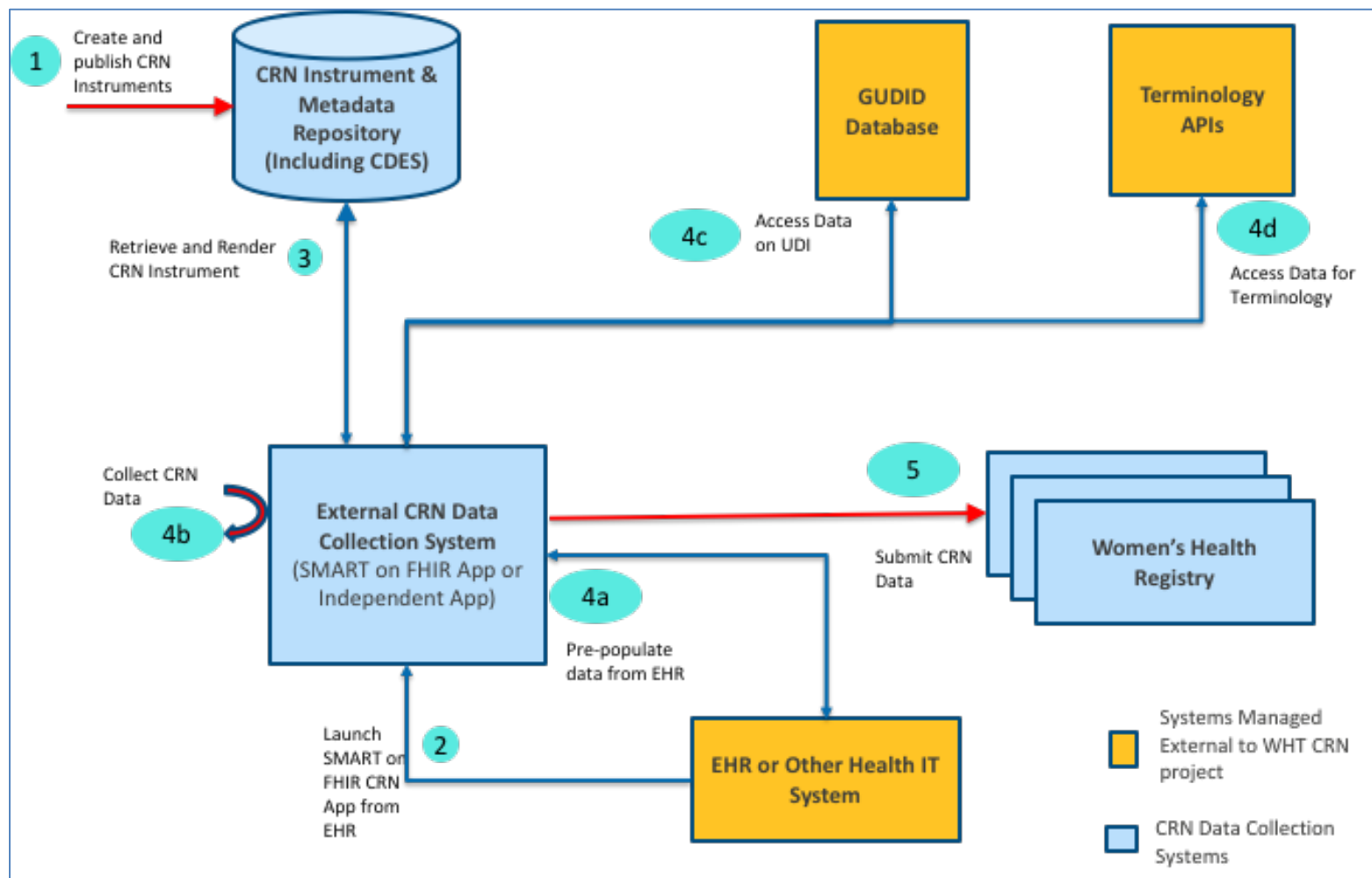
Develop tools to efficiently collect data in the registries and extract/link data from claims and EHR into the CRN



Targeted

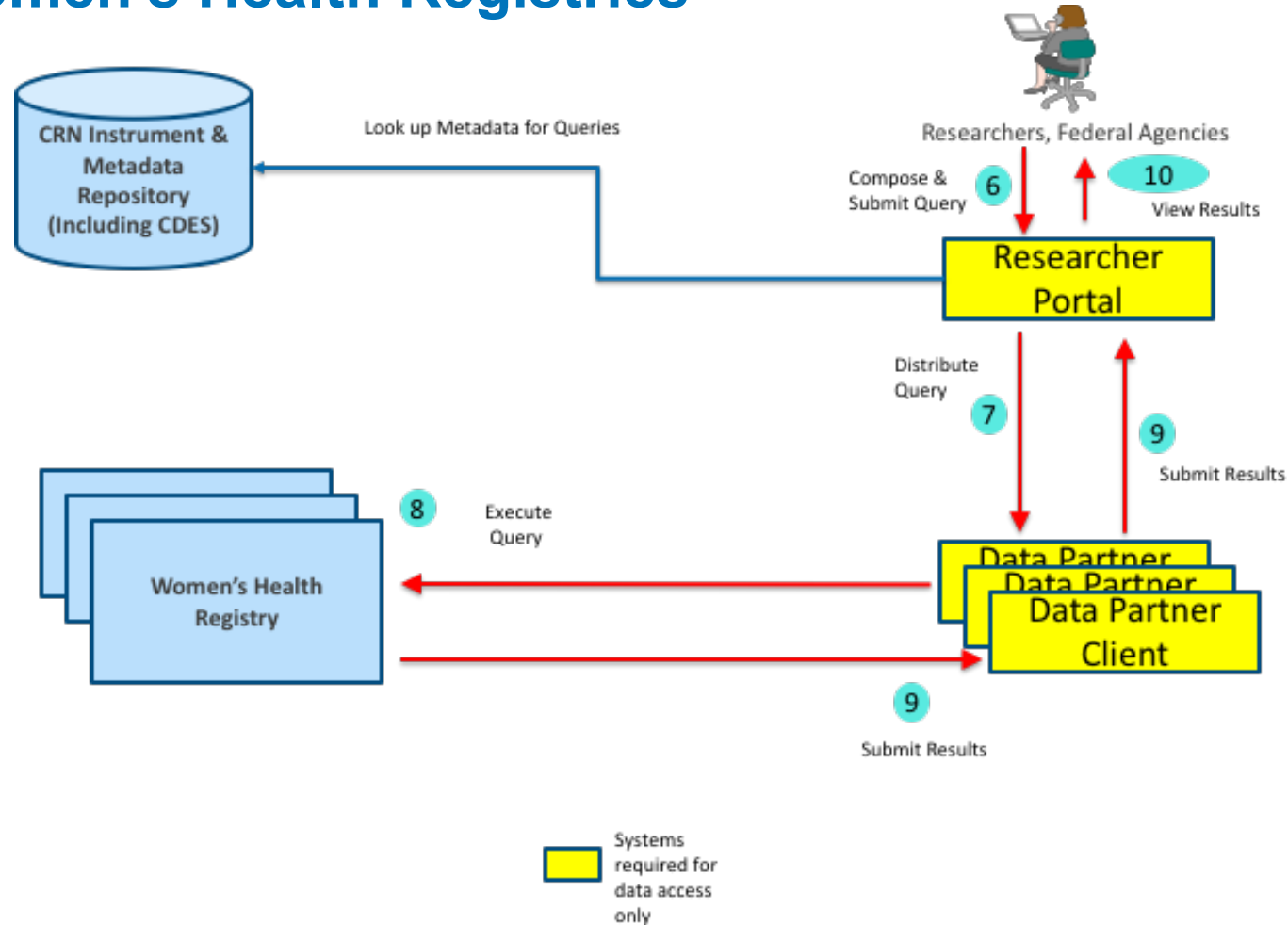
Address performance of devices and therapies for treatment of uterine fibroids, pelvic floor disorders and female sterilization

Abstract Model for Collecting WHT CRN Data



The abstract model, actors and the data flow for WHT CRN data collection.

Example Model for Accessing Data from Women's Health Registries



The abstract model, actors and the data flow to access collected data from registries.

Women's Health Technologies CRN HL7 CRN Implementation Guide

- Develop a structured framework for data sharing and interoperability among participating data sources and clinical sites
- Reuse existing tools standards and resources to link individual patients across disparate datasets allowing for detailed analysis of clinical outcomes related to device exposures
 - US Core, Structured Data Capture, Patient Reported Outcomes, DAF for Research
- Test the capture/exchange of data to support the study of women's health technology issues, by incorporating preliminary data elements into HL7 FHIR profiles
 - Patient characteristics
 - Procedural or treatment details
 - Unique Device Identifier (UDI)
 - Patient outcomes involving uterine fibroids, pelvic floor disorders and female sterilization devices
- Evaluate the completeness of the HL7 FHIR resources

Women's Health Technologies Pilot Approach

- Stand up FHIR servers on Amazon web services (AWS) American Urogynecologic Society (AUGS) and MDEpiNet High-performance Integrated Virtual Environment (HIVE) platforms
- Develop FHIR app for pelvic organ prolapse (POP)/ stress urinary incontinence (SUI)/ long-acting reversible contraceptives (LARC), test and make available on mobile and connected devices
- Work with clinical team to determine/refine/finalize the data elements for terminology in preparation for storing in the instrument repository (for other conditions)
- Gather clinician feedback on app design and usability
- Update and refine app based on feedback

Women's Health Technologies CRN

Pilot 1- Background & Overview

- American Urogynecologic Society (AUGS) Women's Health Registry
 - AQUIRE (AUGS Quality Improvement Registry) serves as a quality reporting tool with benchmarking and outcome tracking.
- AUGS Project Team
 - Charles Rardin, MD, MDEpiNet Physician Lead
 - Volunteer lead for the WHT CRN
 - Colleen Skau, PhD, Research and Quality Programs Manager
 - Staff point person for the WHT CRN
 - Michelle Zinnert, CEO
 - Provides oversight and strategic support
- AUGS Organization
 - AUGS represents more than 1,900 members dedicated to treating female pelvic floor disorders including incontinence and pelvic organ prolapse.
 - Members include surgeons, advance practice providers and trainees at various levels.

Women's Health Technologies CRN Pilot 2- Background & Overview

- High-performance Integrated Virtual Environment (HIVE)
 - HIVE is a regulatory data aggregation and analytics platform
 - It is an ETL (extract, transform, load) and Data warehousing tool
- The Society of Uroynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU)
 - Foundation dedicated 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
- New York-Presbyterian Hospital (NYP)
 - Non-profit academic medical center affiliated with both Columbia University Vagelos College of Physicians and Surgeons and Weill Cornell Medical College
- HIVE/SUFU/NYP Project Team
 - Vahan Simonyan Ph.D., Project Lead

CRN-Actors, Capabilities and Designated Pilot Site

Actors	Capabilities	Pilot Site
CRN Instrument and Metadata Repository	1. Ability to publish a CRN instrument.	AUGS
External CRN Data Collection System	2. Ability to retrieve the instrument, render the instrument and collect the necessary data.	AUGS
	3. Ability to retrieve, render and autopopulate the CRN instrument and collect additional data.	SUFU/HIVE/NYP
	4. Ability to retrieve, and render the CRN instrument and collect data and transform data into FHIR Resources.	SUFU/HIVE/NYP
Women's Health Registry	5. Ability to receive CRN instrument and collected data.	SUFU/HIVE/NYP
	6. Ability to receive CRN instrument, collected data and other FHIR Resources.	SUFU/HIVE/NYP

Women's Health Technologies CRN Sprint 1

#	Capability	
1	Ability to publish a CRN instrument	<p>Created Case Report Forms (CRFs) of previously-established POP data elements</p> <p>Created FHIR Server</p>
2	Ability to retrieve the instrument, render the instrument and collect the necessary data.	<p>Created SMART on FHIR app and completed client implementation</p>

Women's Health Technologies CRN Sprint 2

#	Capability	
3	Ability to retrieve, render and auto-populate the CRN instrument and collect additional data.	<p>SMART on FHIR app</p> <ul style="list-style-type: none"> • Modified and deployed the app for the HIVE ecosystem • New questionnaires were added to the ecosystem based on data elements <p>Provisioned the HIVE servers for deployment</p> <ul style="list-style-type: none"> • HIVE servers were prepared and equipped for deployment with HAPI FHIR server
4	Ability to retrieve, render and auto-populate the CRN instrument and collect data and transform data into FHIR Resources	<p>Creation of Auto-population Instrument</p> <ul style="list-style-type: none"> • Creation of an API to auto-populate from FHIR API • Translate data to FHIR resources <ul style="list-style-type: none"> • Observation & Procedure • Added the ability to auto-populate the Questionnaire resource • Added the ability to extract from the QuestionnaireResponse resource

Women's Health Technologies CRN Sprint 3

#	Capability	
5	Ability to retrieve, render and auto-populate the CRN instrument and collect additional data.	<p>Added the SUI module</p> <p>Revamped some of the questionnaire interface based on feedback</p> <p>Modified the app structure based on clinician feedback</p> <p>Performed more testing with GUDID</p>
6	Ability to retrieve, render and auto-populate the CRN instrument and collect data and transform data into FHIR Resources	<p>Unified the questionnaire layout across SUI and POP</p>

Women's Health Technologies CRN Sprint Lessons Learned

Sprint 1

- Allow more time for back-end development of Case Report Forms
- Establishing reasonable expectations for the timeline
- Infrastructure of registry can limit implementation

Sprint 2

- Lack of EHR test environments and availability make it difficult to evaluate technical progress

Women's Health Technologies CRN Sprint Lessons Learned

Sprint 3

- FHIR resources developed on previous efforts can be effectively utilized for registries
 - SDC IG (Questionnaire, QuestionnaireResponse, Populatable Questionnaire, Extractable Questionnaire)
 - PRO IG (Adaptive Questionnaire, Adaptive QuestionnaireResponse)
- The same FHIR infrastructure can be used to collect data across multiple conditions (e.g. POP and SUI) with minimal changes to the infrastructure (through condition-specific questions)
- A structure such as HIVE could host a number of registries and take advantage of the common components to achieve efficiencies at scale

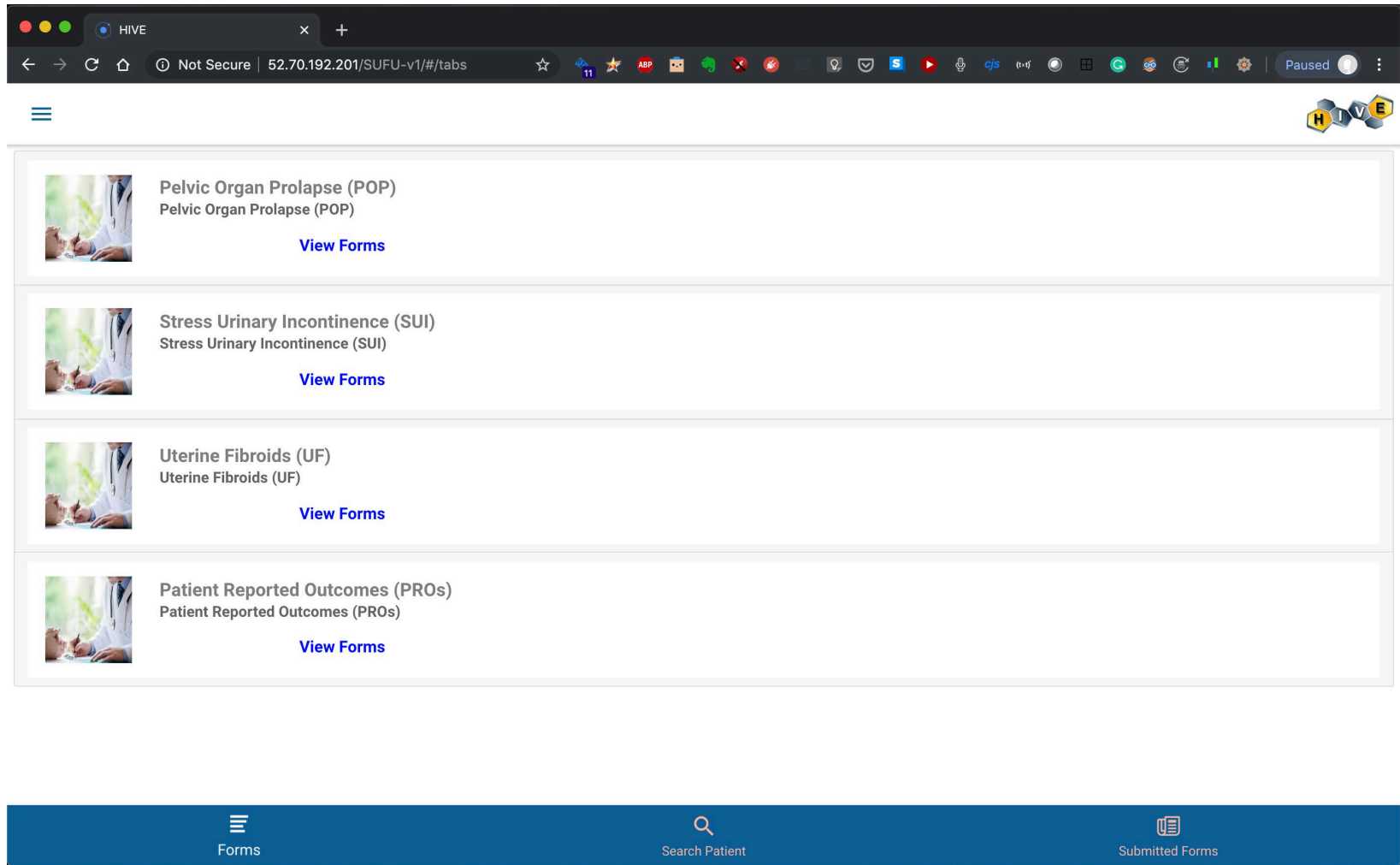
Women's Health Technologies CRN Additional Lessons Learned

- Properly specifying skip logic
 - Worked with the technical team to simplify the skip logic used by removing multiple nesting levels making the questionnaire(s) easier to use
- Organizing production implementation and workflows
 - Data collection and workflow vary from organization to organization
 - WHT CRN IG has been updated to provide implementers some guidance around workflows
- Mapping data elements successfully can implement capabilities to reduce clinician burden







CRN App Demonstration

Women's Health Technologies CRN Form Selection

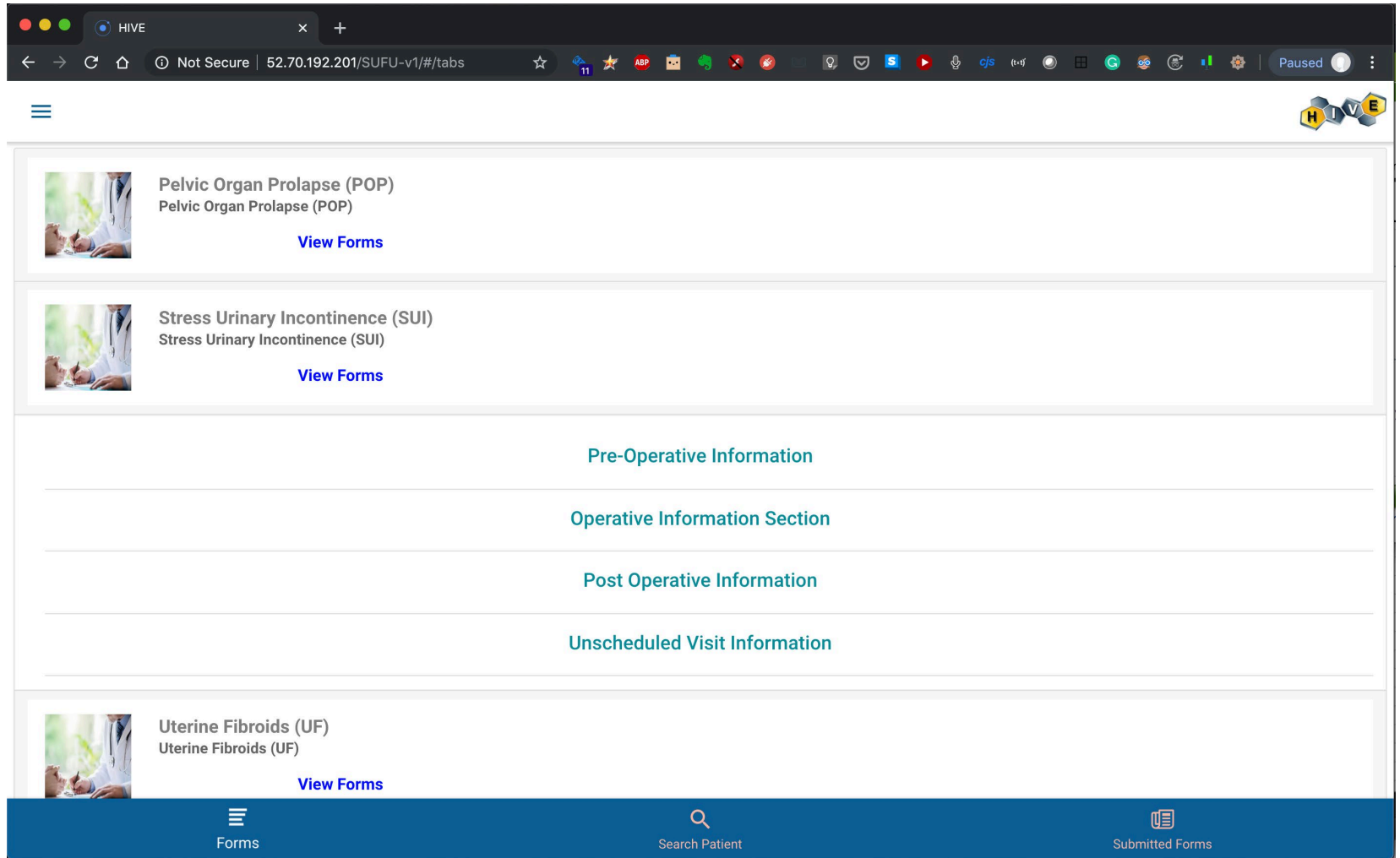


Browser: HIVE | 52.70.192.201/SUFU-v1/#/tabs | Not Secure | Paused

-  **Pelvic Organ Prolapse (POP)**
Pelvic Organ Prolapse (POP)
[View Forms](#)
-  **Stress Urinary Incontinence (SUI)**
Stress Urinary Incontinence (SUI)
[View Forms](#)
-  **Uterine Fibroids (UF)**
Uterine Fibroids (UF)
[View Forms](#)
-  **Patient Reported Outcomes (PROs)**
Patient Reported Outcomes (PROs)
[View Forms](#)

Navigation Bar: Forms | Search Patient | Submitted Forms

Women's Health Technologies CRN SUI Selection



The screenshot shows a web browser window with the URL 52.70.192.201/SUFU-v1/#/tabs. The application interface includes a top navigation bar with a hamburger menu and a HIVE logo. The main content area features three primary sections, each with a medical image and a 'View Forms' link:

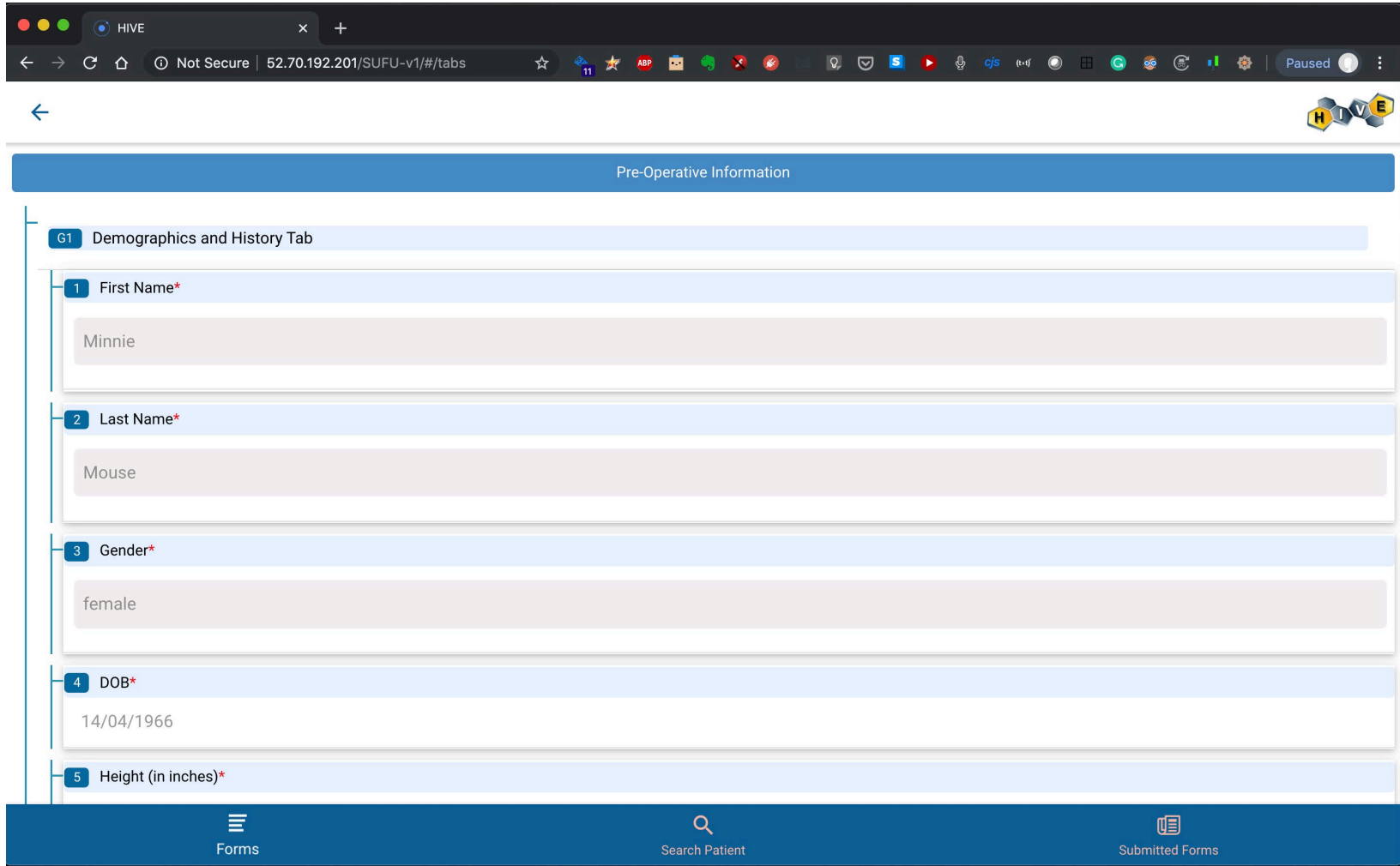
- Pelvic Organ Prolapse (POP)**: Pelvic Organ Prolapse (POP) - View Forms
- Stress Urinary Incontinence (SUI)**: Stress Urinary Incontinence (SUI) - View Forms
- Uterine Fibroids (UF)**: Uterine Fibroids (UF) - View Forms

Below these sections is a list of information categories:

- Pre-Operative Information
- Operative Information Section
- Post Operative Information
- Unscheduled Visit Information

The bottom navigation bar contains three icons: Forms, Search Patient, and Submitted Forms.

Women's Health Technologies CRN SUI Data Entry Screen

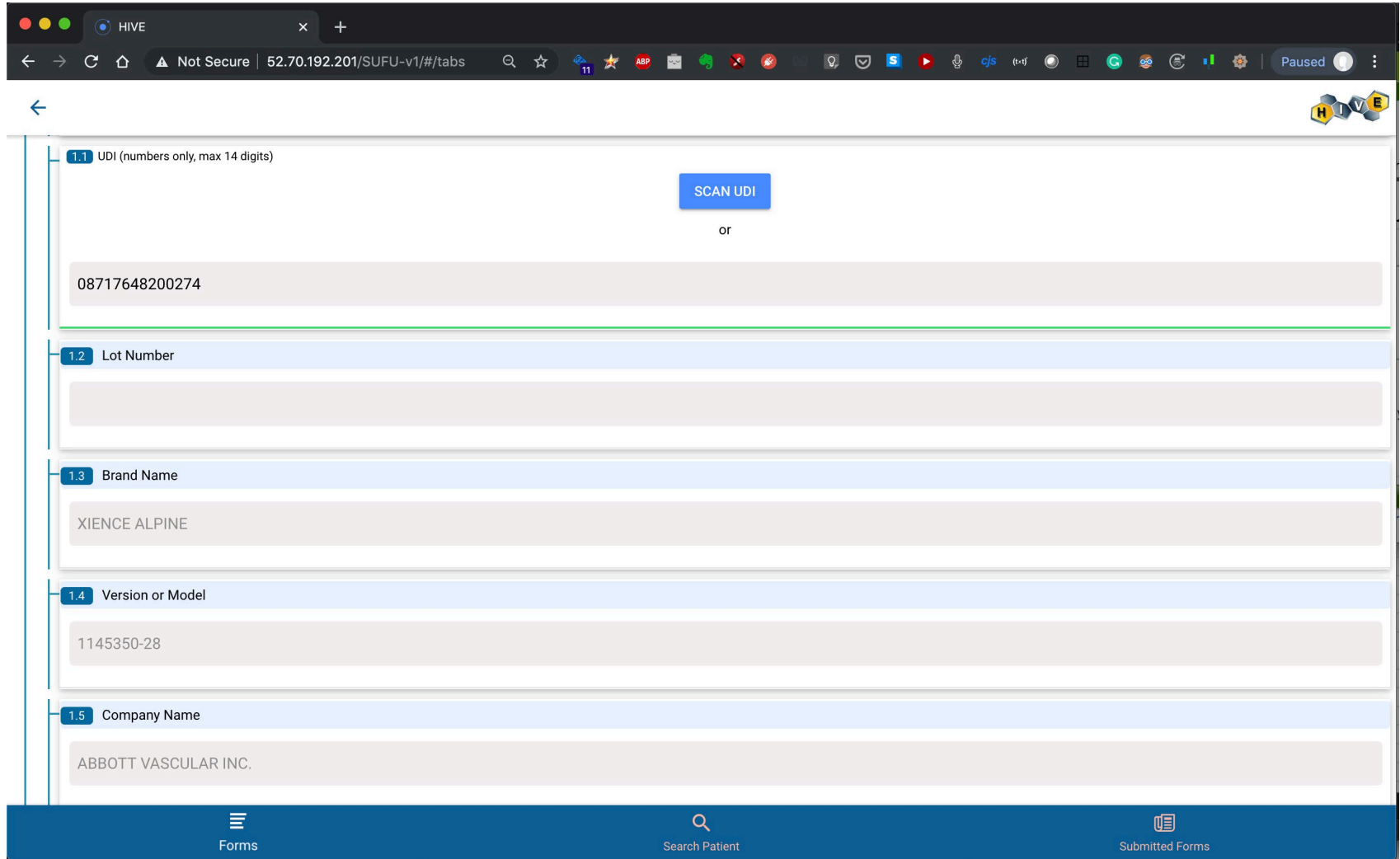


The screenshot shows a web browser window with the URL 52.70.192.201/SUFU-v1/#/tabs. The page title is 'Pre-Operative Information'. The form is titled 'G1 Demographics and History Tab' and contains five numbered fields:

- 1 First Name*: Minnie
- 2 Last Name*: Mouse
- 3 Gender*: female
- 4 DOB*: 14/04/1966
- 5 Height (in inches)*: (empty)

The bottom navigation bar includes icons for 'Forms', 'Search Patient', and 'Submitted Forms'.

Women's Health Technologies CRN SUI UDI/GUDID Entry



1.1 UDI (numbers only, max 14 digits)

SCAN UDI

or

08717648200274

1.2 Lot Number

1.3 Brand Name

XIENCE ALPINE

1.4 Version or Model

1145350-28

1.5 Company Name

ABBOTT VASCULAR INC.

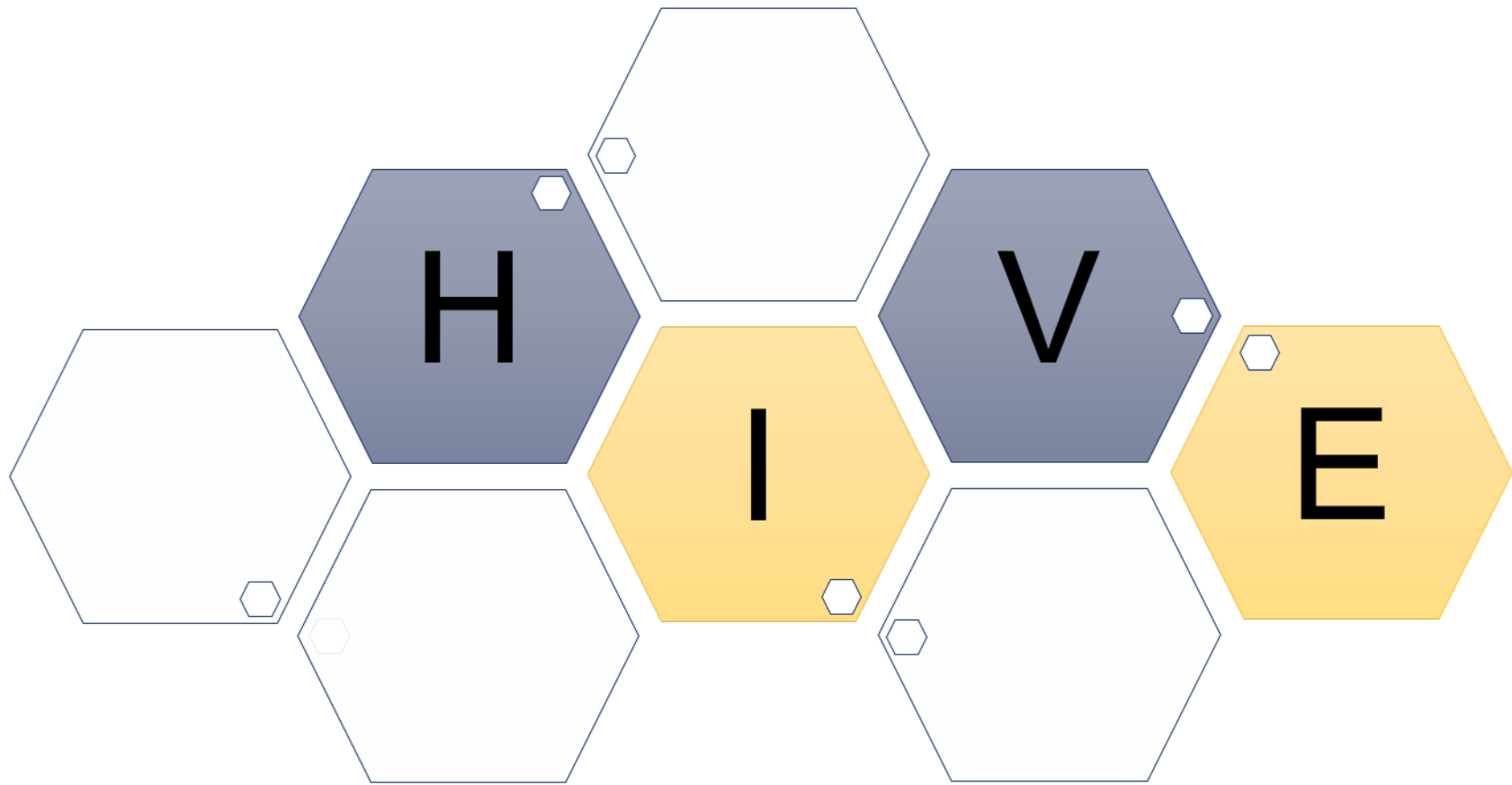
Forms Search Patient Submitted Forms

Women's Health Technologies CRN Recommendations

- Promote the IG capabilities and pilot implementations to other Women's Health Registries
- Further harmonize data elements across Women's Health Registries and update IG
- Generalize the CRN FHIR IG as a common registry reporting framework
- Participate in HL7 WGs to update the CRN FHIR IG periodically as the FHIR standard evolves
- Ensure future PCOR initiatives leverage the CRN FHIR IG where applicable
- Integration of the SMART on FHIR app within EHR ecosystem
- Expand clinician participation
 - Promote the increase in value of registries, particularly standards-based registries
 - Demonstrate value of UDI collection



High-performance Integrated Virtual Environment



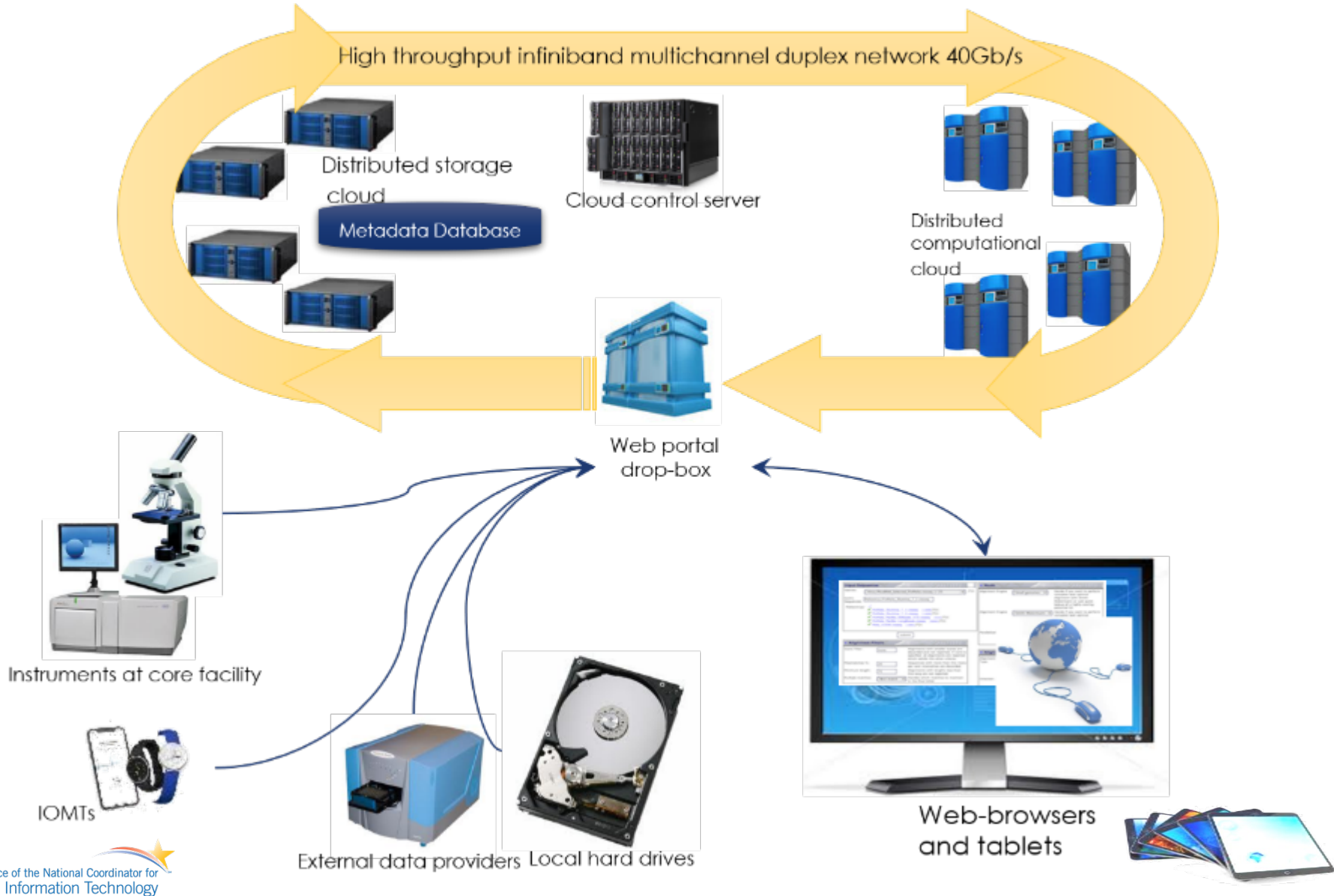
What is HIVE- History of HIVE

- Technology
 - Secure healthcare and biomedical data archival ecosystem
 - Standardization and harmonization framework
 - High-performance analytics
 - Integrator platform
- MDEpiNet-HIVE
 - Patient and physician registry platform
 - Hosting registry & claims data, data linkages
 - Distributed and centralized analytics to support national and international collaborations

HIVE is multicomponent end to end solution architecture

- Security compliant with FDA, National Institute of Standards and Technology
- Integrator platform to bring different data and analytics together
- Tailor made analytics designed around needs
- Visualization made to help in interpretation of data
- Support of the entire hard-, soft-ware and knowledge infrastructure


HIVE Topology



MDEpiNet-HIVE example registry implementation

— Patient:

↳ Patient Id:

 barcodes

↳ Sex: constraint to predefined vocabulary

↳ Date Of Birth: Age: computable fields

↳ Height: built in unit calibrations

↳ Weight: BMI:

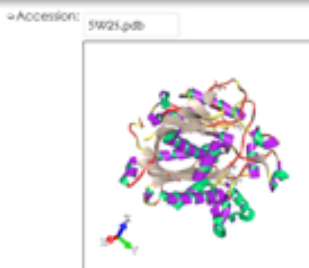
↳ Race: Ethnicity: Country:

Implicit and explicit type definitions : integers, floating numbers, boolean conditions, dates, dictionaries

dynamic vocabularies per country



dynamic annotation on 3d models



ability to integrate pictures and movies taken on mobile devices

Screening Visit:

— Eligibility and Registration:

↳ Date of Visit: *


↳ Date of Consent: *

↳ ICF version:

↳ is patient eligible:

searchable external ontologies: UDI and GUID

— History:



ICD	ICD description
A0220	Localized salmonella infection
A0221	Salmonella meningitis
A0222	Salmonella pneumonia
A0223	Salmonella arthritis

↳ Surgical plan:

Importance of Administrative Data

- Discharge summaries and billing claims contain important information on interventions
- Take advantage of coding algorithms to define mesh based procedures or sterilization implants
- Longitudinal claims data enables evaluation fo long-term reoperations and erosions (via codes)
- Linkages and validation studies are possible

WHT- CRN Domains

1

CRN REGISTRIES

(registry section of CRN)

2

CRN CLAIMS

(administrative
claims data linked
to registry)

3

CRN EHRs

(electronic
health records
data to augment
the data)

4

CRN PATIENT

(patient generated
data)

- FHIR IG piloted in AUGS AQUIRE
- Tool for harmonization of core data elements developed
- (Acessa™) is leveraging the CRF for collecting the data on RF laparoscopic fibroid treatment.
- HiIVE deployed to host the FHIR platform pilots

- Library of ICD -9, ICD-10; CPT, HCPCS codes for all four clinical areas was created
- Several studies were executed using the NY state longitudinal cohorts

- This effort will leverage recently awarded NESTcc – funded project

- Patient champions identified
- A patient facing mobile app to collect the PRO in SUI module

Total : Over 550, 000 records

Moving Forward

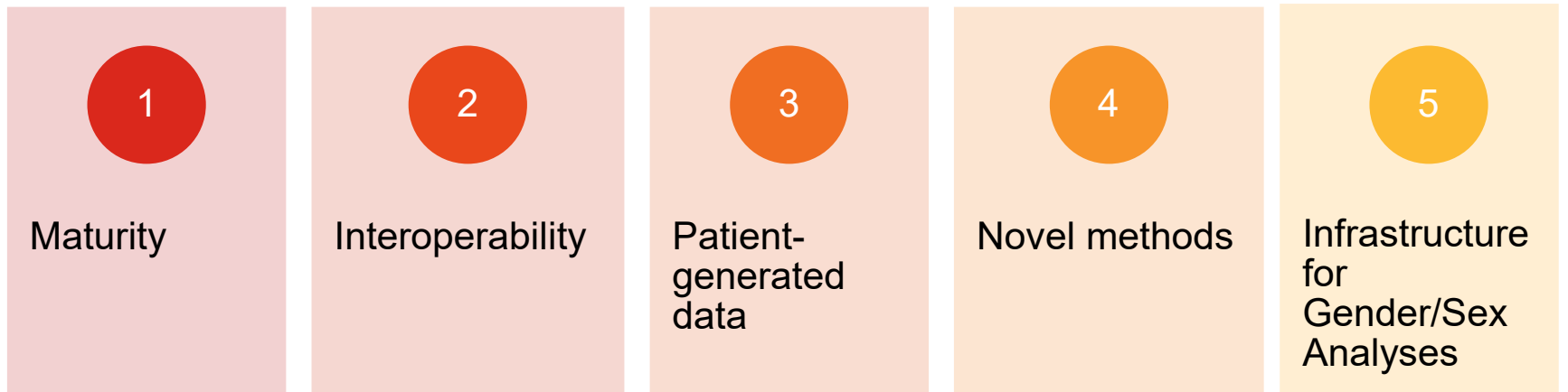
CRN Name	CRN Maturity						Sustainability	TPLC
	Patient Engagement	UDI	Data Quality	Efficiency	Governance			
WHT-CRN	X	X	X	X	X	X	X	
VISION-CRN		X	X	X	X	X	X	
CD-CRN								
Ortho-CRN	X	X	X	X	X			
Abdominal Core	X	X	X		X		X	
DAISI-CRN		X	X		X		X	
VANGUARD-CRN					X	X		
Robotic-CRN			X		X			
SPARED-CRN	X		X	X	X	X	X	
TMJ-CRN	X				X			
NBIR	X	X	X		X		X	
ESRD-CRN	X							

Next steps: Specific Objectives

- Advance CRN COP by implementing the following 7 attributes of CRN maturity : (1) Patient Engagement, (2) Device Identification, (3) Data Quality, (4) Efficiency, (4) Governance, (5) Sustainability and (7) Fitness for Use During Total Product Life Cycle (TPLC).
- Pilot test device-specific FHIR profiles such as using the SMART on FHIR platform and the FHIR Structured Data Capture Initiative (SDC) to demonstrate the capture and exchange of data to inform development of an HL7 FHIR profile
- Develop a module for capturing patient generated information and the methodology to evaluate scientifically valid data regarding patient uncertainty in accepting a variety of benefit/risk tradeoffs
- Develop and apply methods to link heterogeneous data from multiple data sources comprising a CRN (e.g. registry data, claims, patient generated data)
- Establish infrastructure (e.g. linked data sets) and framework for routine assessment gender/sex specific outcome in the six most mature CRNs (e.g. in orthopedics. vascular, cardiac, colorectal, abdominal hernia and neurologic spaces).



Next Steps: Workstreams



Moving Forward

- Expand to other clinical areas to promote standards and interoperability across data sources
- Leverage MDEpiNet/CRN Community of Practice to advance PCOR and help support National Evaluation System for health Technology (NEST)
- Promote other national and international harmonization efforts

WHT CRN Partners

- FDA
 - Danica Marinac-Dabic
 - Mary Jung
 - Laura Gressler
 - Yasameen Azarbaijani
 - Nilsa Loyo-Berrios
 - Sharon Andrews
 - Martha Velezis
 - Behnaz Minaei
 - Terrie Reed
- Weill Cornell Medicine/MDEpiNetcc
 - Art Sedrakyan
 - Jialin Mao
 - Courtney Baird
 - Suvu Aryal
- The American Urogynecologic Society (AUGS)
 - Michelle Zinnert
 - Charles Rardin
- University of California San Francisco (UCSF)
 - Vanessa Jacoby
- COMPARE-UF
 - Evan Myers
- NLM
 - Lisa Lang
 - Richard Ballew,
 - Robin Taylor
- ONC
 - JaWanna Henry
 - Mike Flanigan
 - Gayathri Jayawardena
 - Sweta Ladwa
 - Nagesh (Dragon) Bashyam
 - Abdullah Rafiqi
 - Becky Angeles



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