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

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The Office of the National Coordinator for Health Information Technology

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)

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

CRNs - Typical Domains

1

CRN REGISTRIES

(registry section of CRN)

2

CRN CLAIMS

(administrative claims data linked to registry)

3

CRN EHR

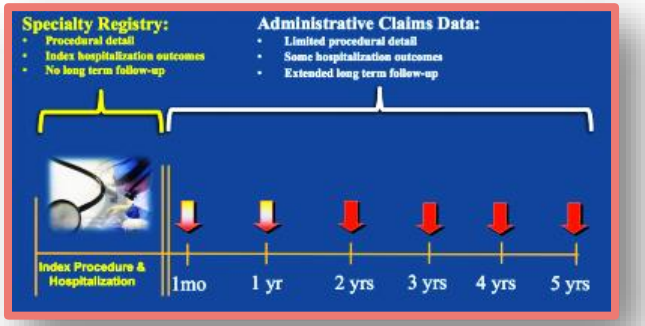
(electronic health records data to augment the data)

4

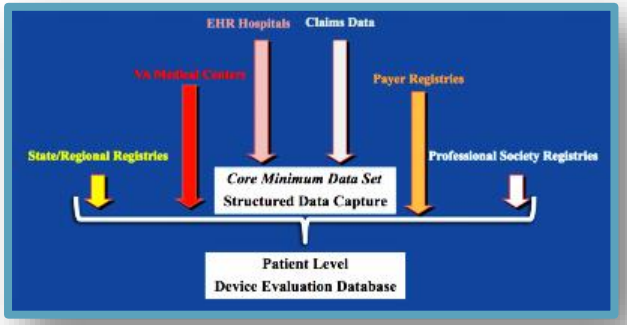
CRN PATIENT

(patient generated data)

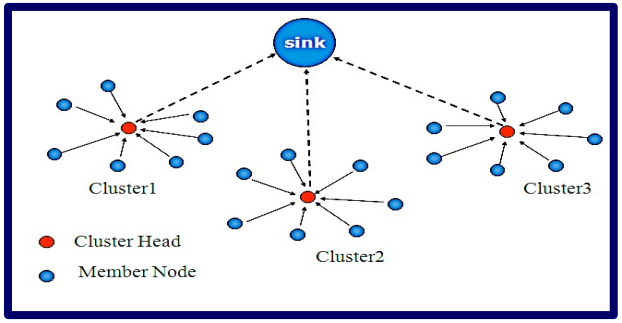
CRNs Data Sharing Solutions



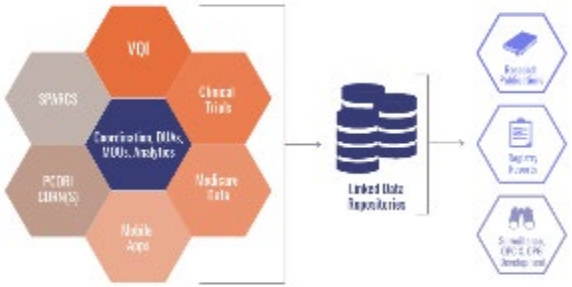
A. Linked complementary data sources



B. Multiple source structured data extraction

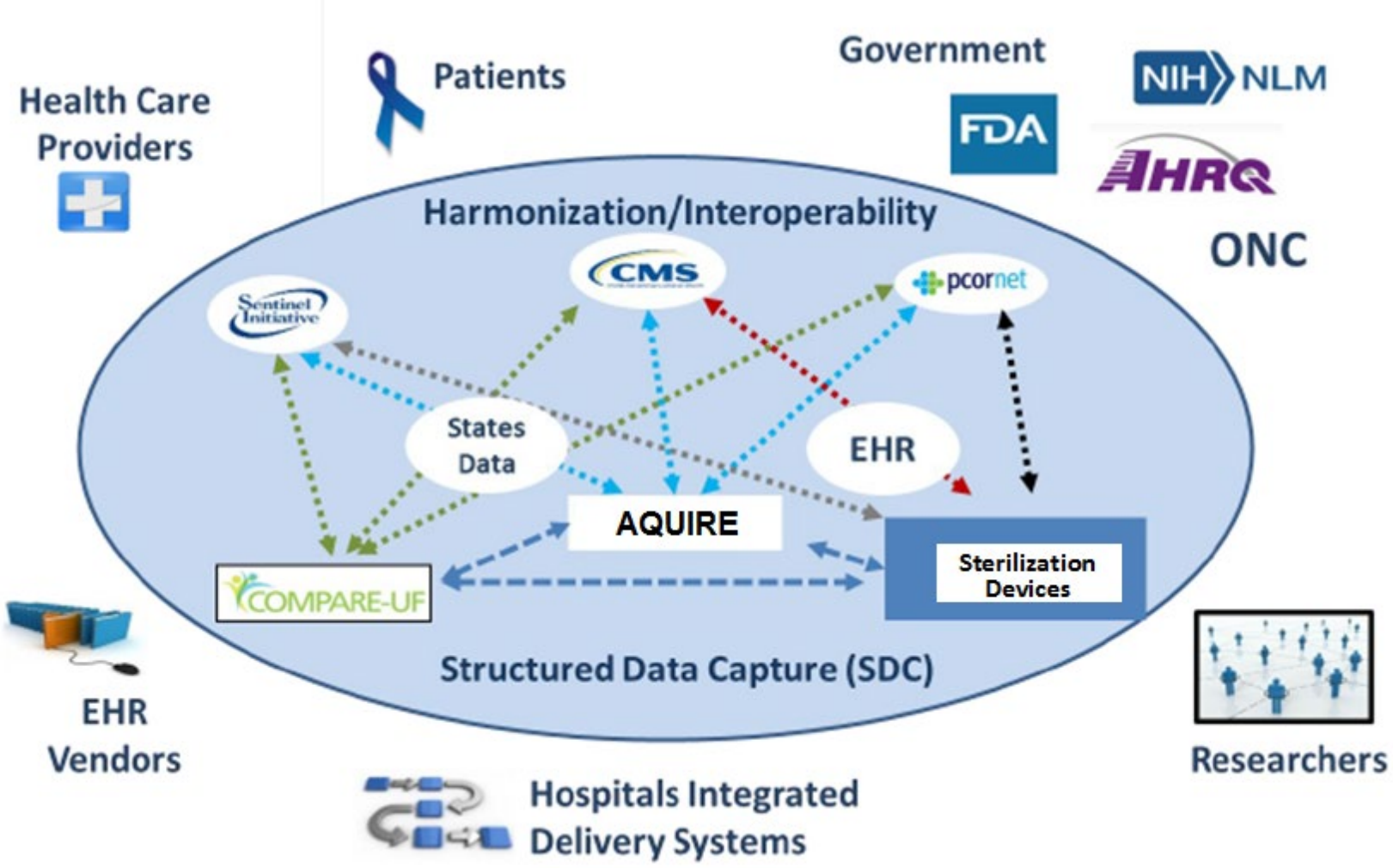


C. Distributed data networks



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

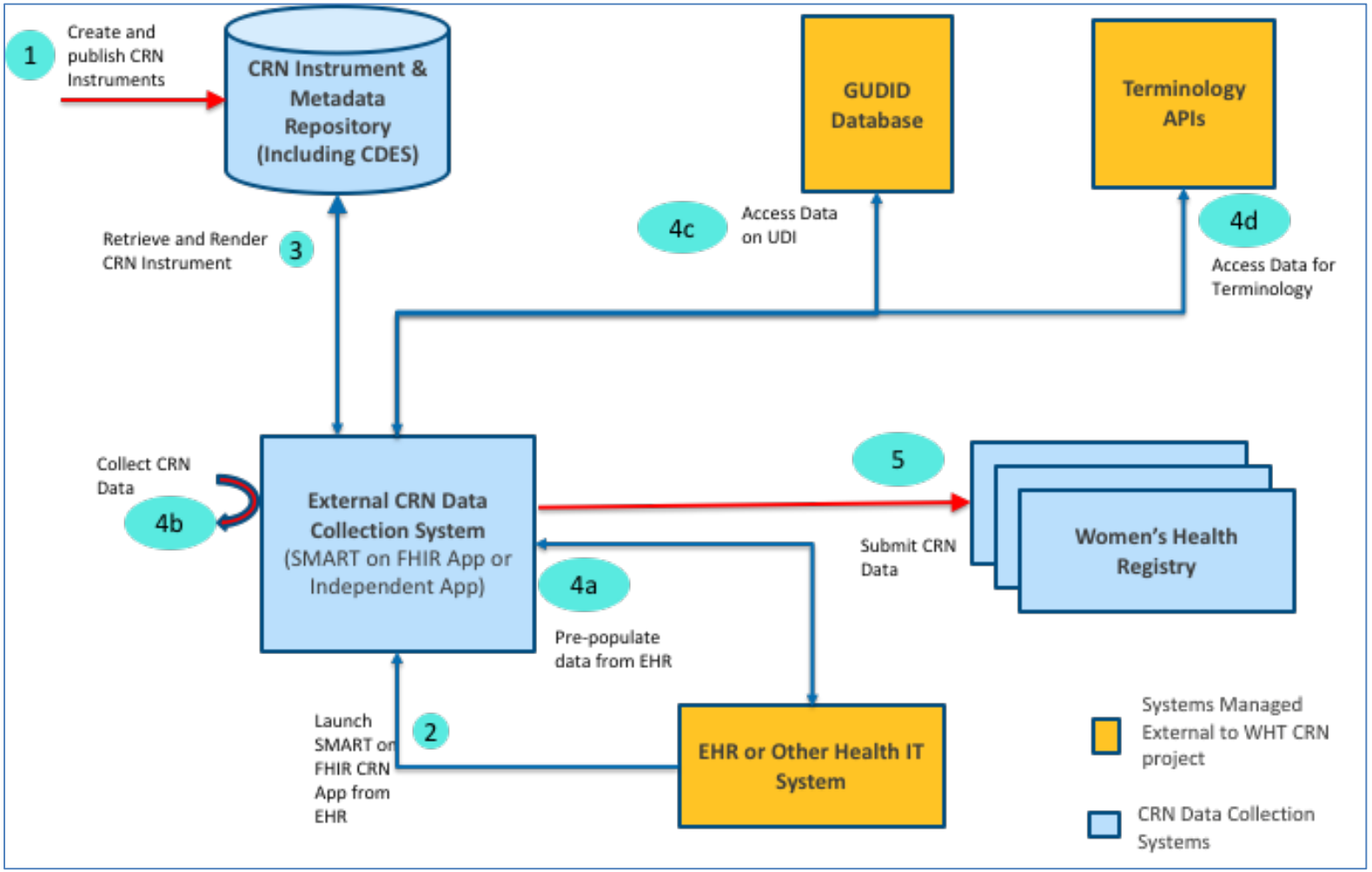
Efficient

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

Targeted

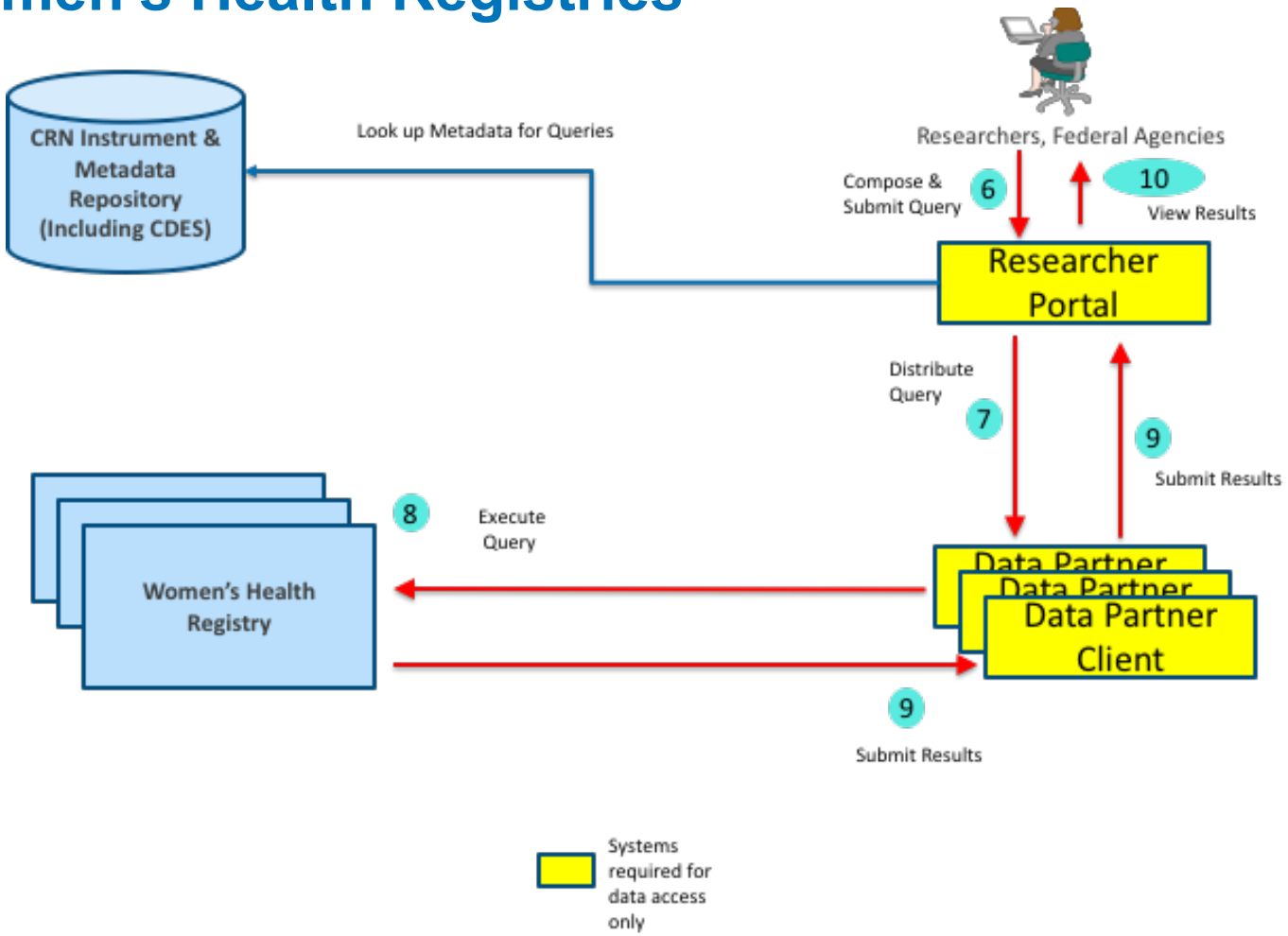
Address performance of devices and therapies for treatment of uterine fibroids, pelvic floor disorders and female sterilization

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 Urodynamics, 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
2	Ability to retrieve the instrument, render the instrument and collect the necessary data.

Created Case Report Forms (CRFs) of previously-established POP data elements

Created FHIR Server

Created SMART on FHIR app and completed client implementation

Women's Health Technologies CRN Sprint 2

#	Capability
3	Ability to retrieve, render and auto-populate the CRN instrument and collect additional data.
4	Ability to retrieve, render and auto-populate the CRN instrument and collect data and transform data into FHIR Resources

SMART on FHIR app

- Modified and deployed the app for the HIVE ecosystem
- New questionnaires were added to the ecosystem based on data elements

Provisioned the HIVE servers for deployment

- HIVE servers were prepared and equipped for deployment with HAPI FHIR server

Creation of Auto-population Instrument

- Creation of an API to auto-populate from FHIR API
- Translate data to FHIR resources
  - 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.
6	Ability to retrieve, render and auto-populate the CRN instrument and collect data and transform data into FHIR Resources

Added the SUI module

Revamped some of the questionnaire interface based on feedback

Modified the app structure based on clinician feedback

Performed more testing with GUDID

Unified the questionnaire layout across SUI and POP

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

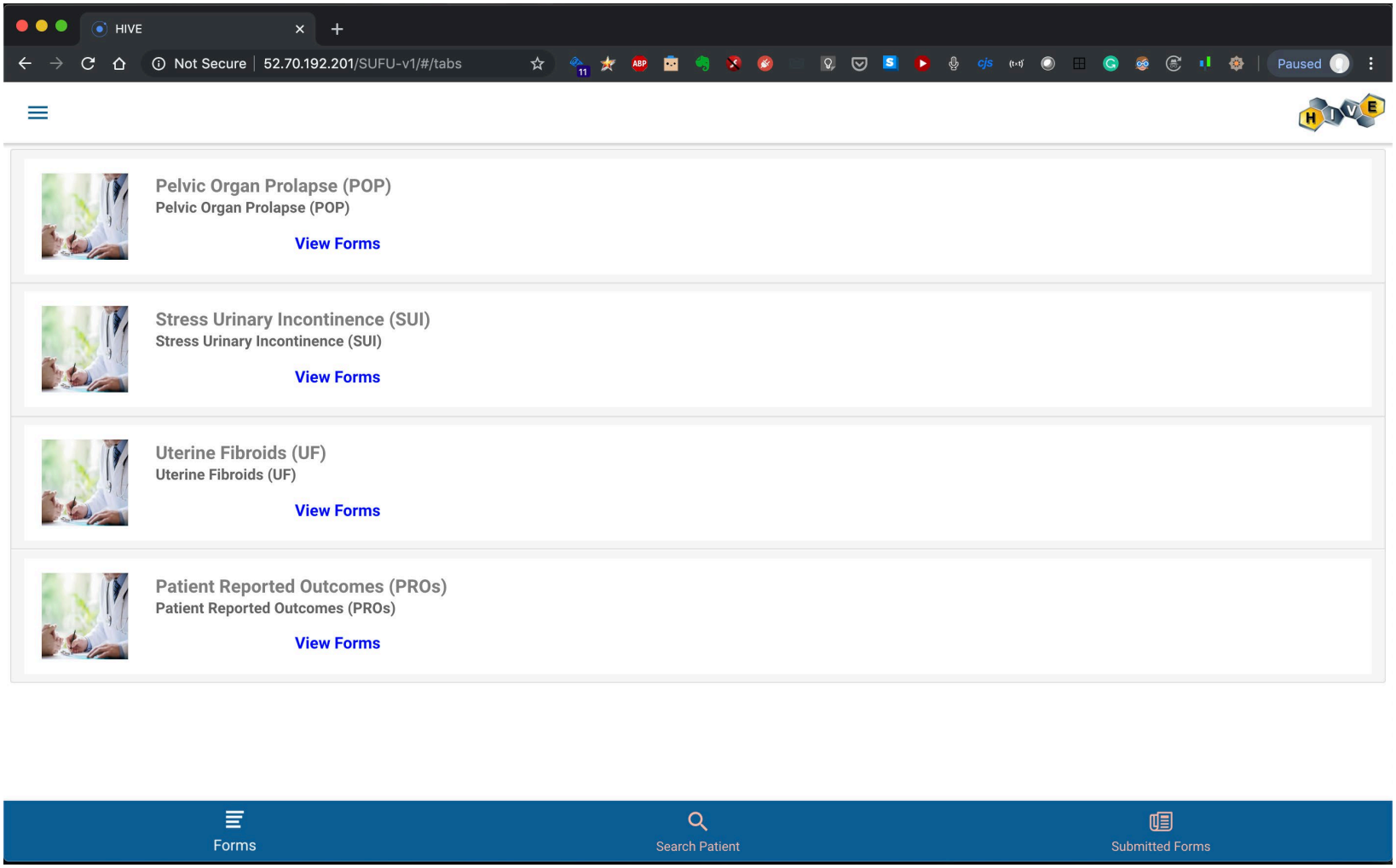
- FHIR resources developed on previous efforts can be effectively utilized for registries
    - SDC IG (Questionnaire, QuestionnaireResposne, Populatable Questionnaire, Extractable Questionnaire)
    - PRO IG (Adaptive Questionnaire, Adaptive QuestionnaireResponse)
- The same FHIR infrastructure can 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

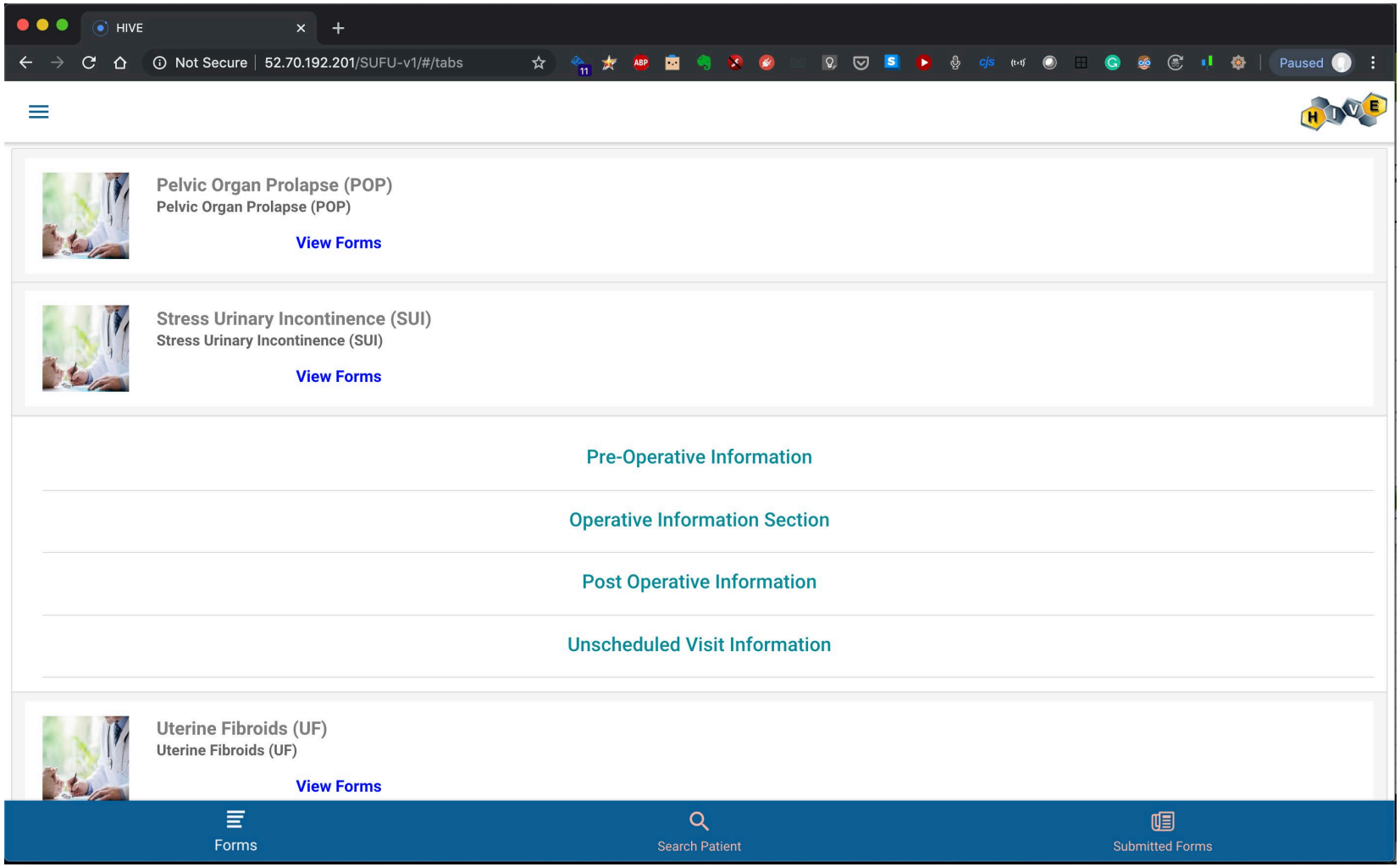
- Properly specifying skip logic
  - Worked with the technical team to simplify the skip logic used by removing multiple nesting levels making the questionnaire(s) easier to use
- Organizing production implementation and workflows
  - Data collection and workflow vary from organization to organization
  - 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

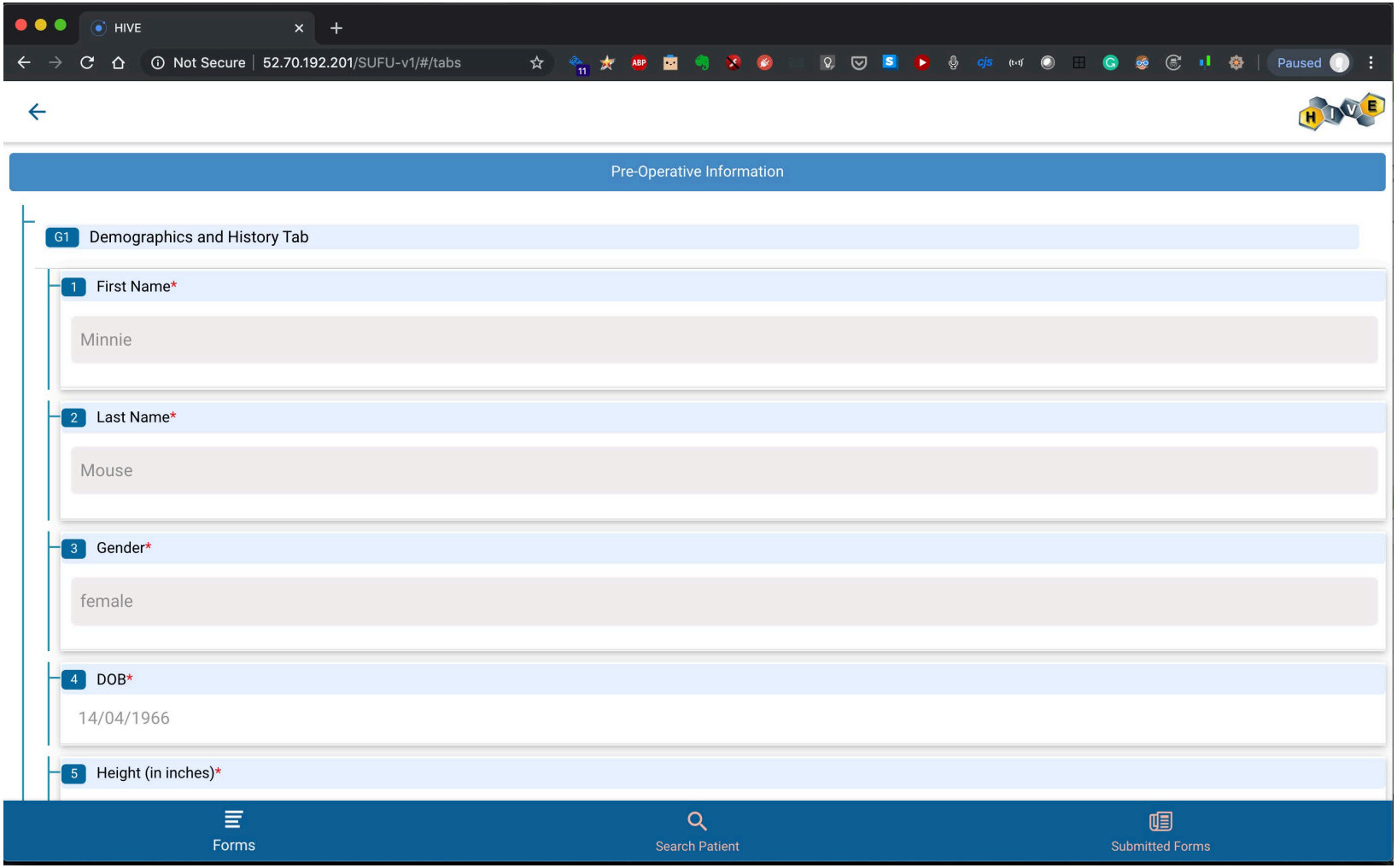
Women's Health Technologies CRN Form Selection



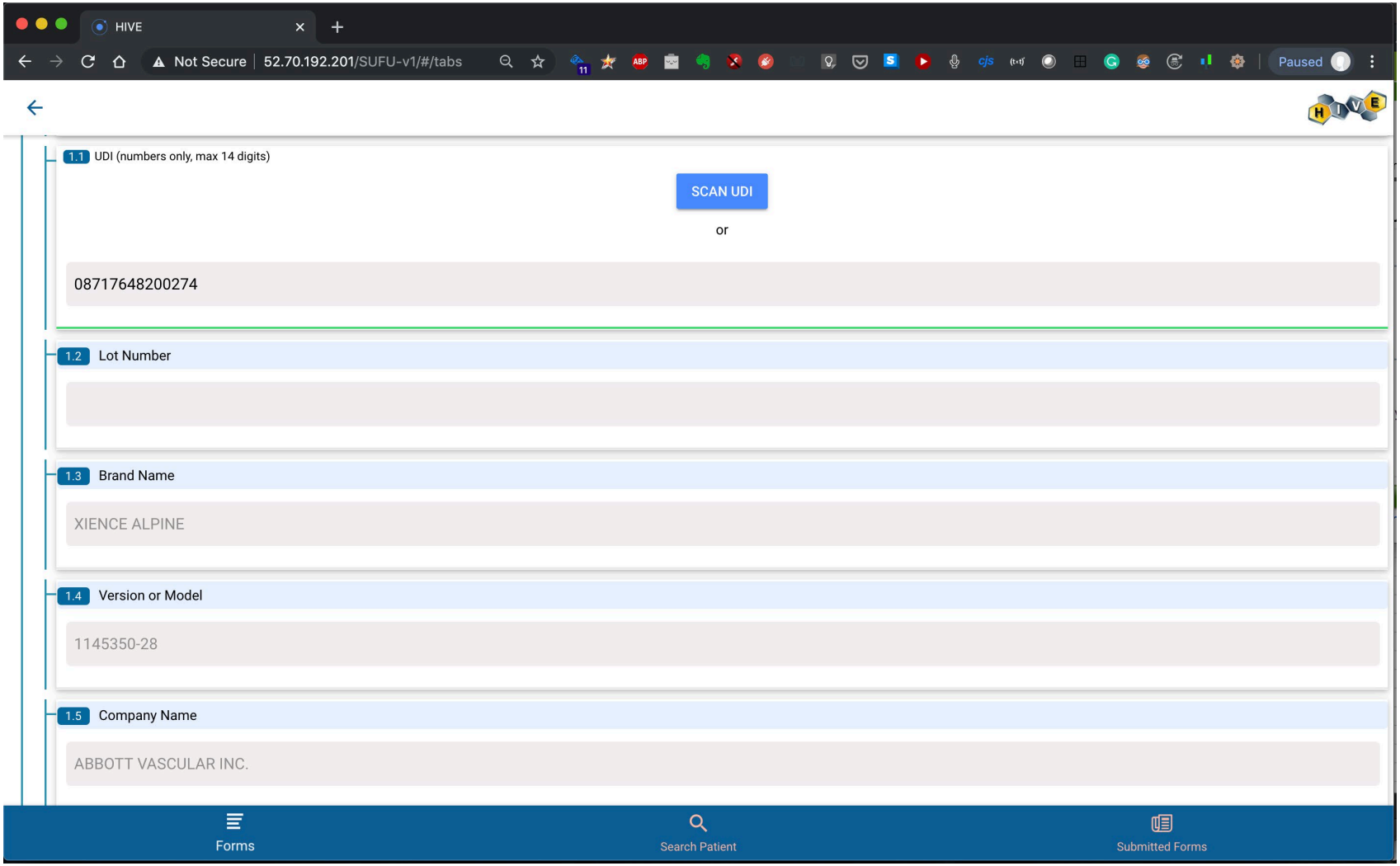
Women's Health Technologies CRN SUI Selection



Women's Health Technologies CRN SUI Data Entry Screen



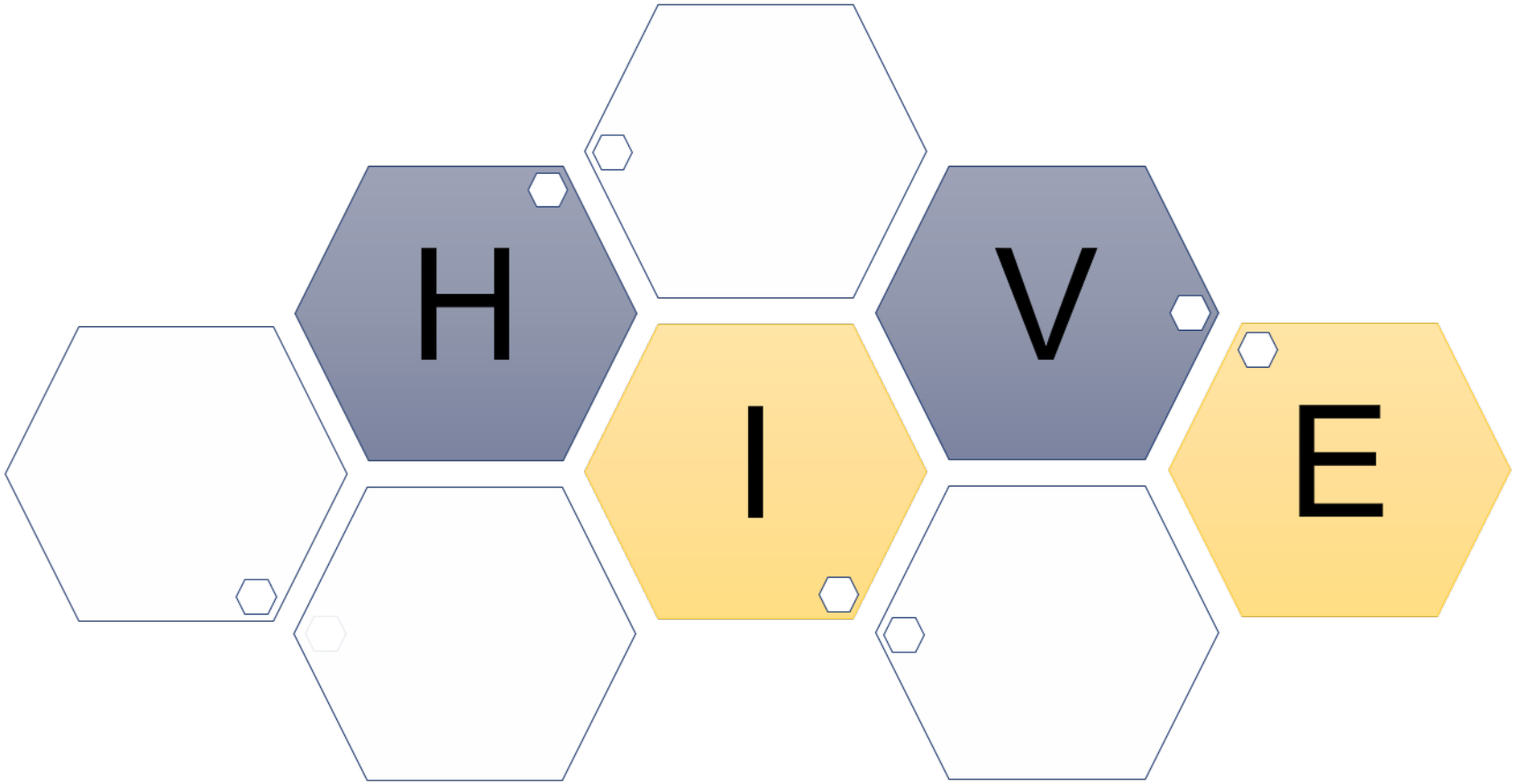
Women's Health Technologies CRN
SUI UDI/GUDID Entry



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

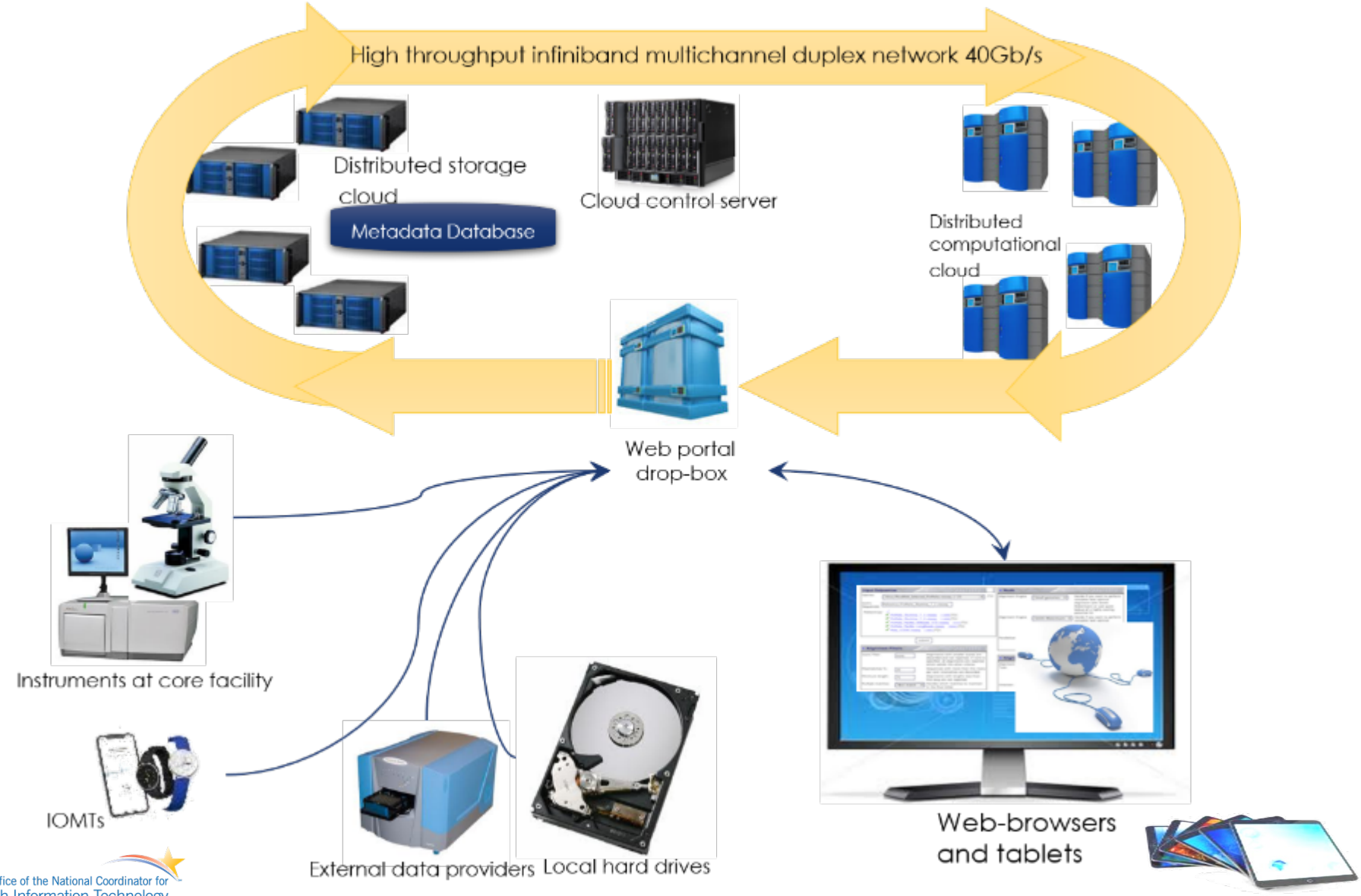
- Technology
  - Secure healthcare and biomedical data archival ecosystem
  - Standardization and harmonization framework
  - High-performance analytics
  - Integrator platform

- 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: USJ_666.13 *

barcodes

Sex: F

constraint to predefined vocabulary

Date Of Birth: 10/10/2000 Age: 18

computable fields

Height: 1.78 meters

built in unit calibrations

Weight: 58 kilograms BMI: 18.3 Underweight

Race: Asian Ethnicity: non Hispanic or Latino Country: United States

dynamic vocabularies per country

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

Screening Visit:

Eligibility and Registration:

Date of Visit: 04/06/2019 *

Date of Consent: 04/06/2019 *

ICF version: s560 Structure of liver

Is patient eligible:

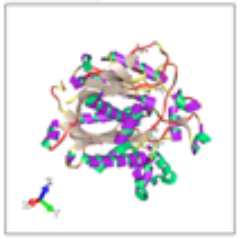
History:

searchable external ontologies: UDI and GUDID

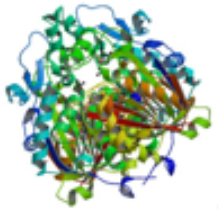
Surgical plan:

dynamic annotation on 3d models

Accession: 5W2S.pdb



Picture: Recombinant Huma...ody single chain :Clipboard_2



ability to integrate pictures and movies taken on mobile devices

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)

- 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

2 CRN CLAIMS

(administrative claims data linked to registry)

- 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

3 CRN EHRs

(electronic health records data to augment the data)

- This effort will leverage recently awarded NESTcc – funded project

4 CRN PATIENT

(patient generated data)

- 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						
	Patient Engagement	UDI	Data Quality	Efficiency	Governance	Sustainability	TPLC
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

1. Maturity
2. Interoperability
3. Patient-generated data
4. Novel methods
5. Infrastructure for Gender/Sex Analyses

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
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  - Art Sedrakyan
  - Jialin Mao
  - Courtney Baird
  - Suvu Aryal
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  - 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
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