**Project Goals**

Build a Strategically Coordinated Registry Network (CRN) to improve evaluation of women's health technologies across multiple care settings.

- **Time / Cost-intensive**
- **Challenging to address questions involving multiple therapies**
- **Stand-alone design: Challenges with interoperability due to registry-specific data collection / normalization**

- Establish a CRN capable of addressing clinical questions on devices, therapies, and their combinations for the treatment of uterine fibroids, pelvic floor disorders and female sterilization.
- Create a harmonized, interoperable platform that will link existing registries to each other and to other major data networks for longitudinal follow-up and assessment of patient care across therapeutic areas.
- Develop tools to efficiently extract clinical data from electronic health records (EHR) into the CRN using HL7 FHIR profiles and Structured Data Capture (SDC), and ballot developed standards for further use by the clinical community.
- Test the ability of the CRN to address 2-3 priority questions identified by stakeholders.

**Governance and Organization**

- **Core Team** consisting of representatives from FDA/CDRH, National Library of Medicine, Office of National Coordinator, The American College of Obstetricians and Gynecologists, The American Urogynecologic Society, and Cornell University.
- Clinical area teams (sterilization, uterine-fibroids, and pelvic floor disorder) focused on identification of relevant clinical data elements.
- Core Clinical Data Element and Informatics Workgroups focused on harmonization of CRN data elements, development of harmonized and standardized data ontology, FHIR development, and data interoperability.

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**Project Partnership**

**Women’s Health Technologies CRN**

Core: FDA | ONC | NLM | AHRQ | MDEpiNet

**Cross-Functional Activities**

Clinical Working Group | Informatics Working Group | UDI Working Group

**Registries**

COMPARE-UF | PFDR & AQUIRE | Collaborative Registry for Sterilization Therapies

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**Workstreams**

- **Data element evaluation**
  - Two-tier infrastructure model for some or all clinical areas:
    - Quality Improvement Tier to address safety and quality improvement questions across the CRN
    - Research Tier to address detailed research questions within CRN partners
  - Evaluation of EHR vendor datasets, identification of candidate fields for harmonization, development of common data elements, development of HL7 FHIR profile for data capture and exchange, and integration of Unique Device Identification (UDI) and device information from GUDID into CRN.
  - Validate the use case and create implementation guides for the clinical community. Ballot and disseminate developed standards and tools to partners and other stakeholders.

Robust CRN for women’s health technologies which could be scaled and extended to add new technologies.

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**Timeline**

The poster was prepared by Division of Epidemiology on behalf of WHT CRN team.