EHR Modernization

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CC

High Value Asset (HVA) Description

- The Clinical Research Information System (CRIS) is a hospital information system that serves the NIH Clinical Center (CC) as well as other NIH Institutes and Centers (ICs). The mission of the CC is to provide hope through pioneering clinical research to improve human health. CRIS supports approximately 1,600 active research studies of which approximately 1,000 are actively recruiting and/or following participants. The data within CRIS includes protocol information, personally identifiable information (PII) and health information to provide protocol-based clinical research. The CRIS user community of 4,600 includes credentialed and non-credentialed users: IC Physicians, IC Research Nurses, Clinical Center Nursing, Patient Care Services, IC Clinical Staff, CC Clinical Department Staff, Occupational Medical Services Staff, CC and IC Administrative Staff and IT support users.

Sunrise Clinical Manager & CRIS

- **The commercial name of the platform is Sunrise Clinical Manager.**

- **NIH CC moniker: Clinical Research Information System (CRIS).**

- **Installed in 2004 as the best available EHR solution for the clinical research environment.**

- **The Sunrise product line has been controlled by three separate parent companies.**
  - Eclipsys (2004-2010),
  - Allscripts (2010-2022), and
  - Altera (2022 to the present).

NIH Clinical Center HIMSS Analytics

- **The EMRAM model measures the adoption and utilization of EMR functions, Stage 7 being the highest level.**

- **Electronic Medical Record Adoption (EMRAM)**
  - Assessed at Stage 6; 2015
  - Certified at Stage 7; 2015
  - Recertified at Stage 7; November 2021

- **HIMSS Outpatient Electronic Medical Record Adoption Model (O-EMRAM)**
  - Assessed at Stage 6; 2017
  - Certified at Stage 7; 2018
  - Recertified at Stage 7; November 2021

Bottom Line Up Front

- **The current EHR, CRIS, used in the NIH Clinical Center is reaching the end of its useful life.**
  - Complexity
 - Fragility
  - User acceptance

2003 Proposed System "Flower Diagram"

Originated by Elaine Ayres and Dr. Stephen Rosenfeld, 2001.

[Garnett, C. Aged pioneer to retire-gradually: new clinical research information system planned to replace MIS. October 16, 2001, NIH Record, Vol. LIII, No. 21](#)

"The first 5 years will definitely be the most intense," he concluded. "That initial period is the critical time. You start with what is basically a shell, and you have to describe your hospital in the language of their new system. That is the really rough part. It's necessary, though. With MIS, we've developed work-arounds for 26 years. I'd like CRIS to evolve for the next 26 years." R
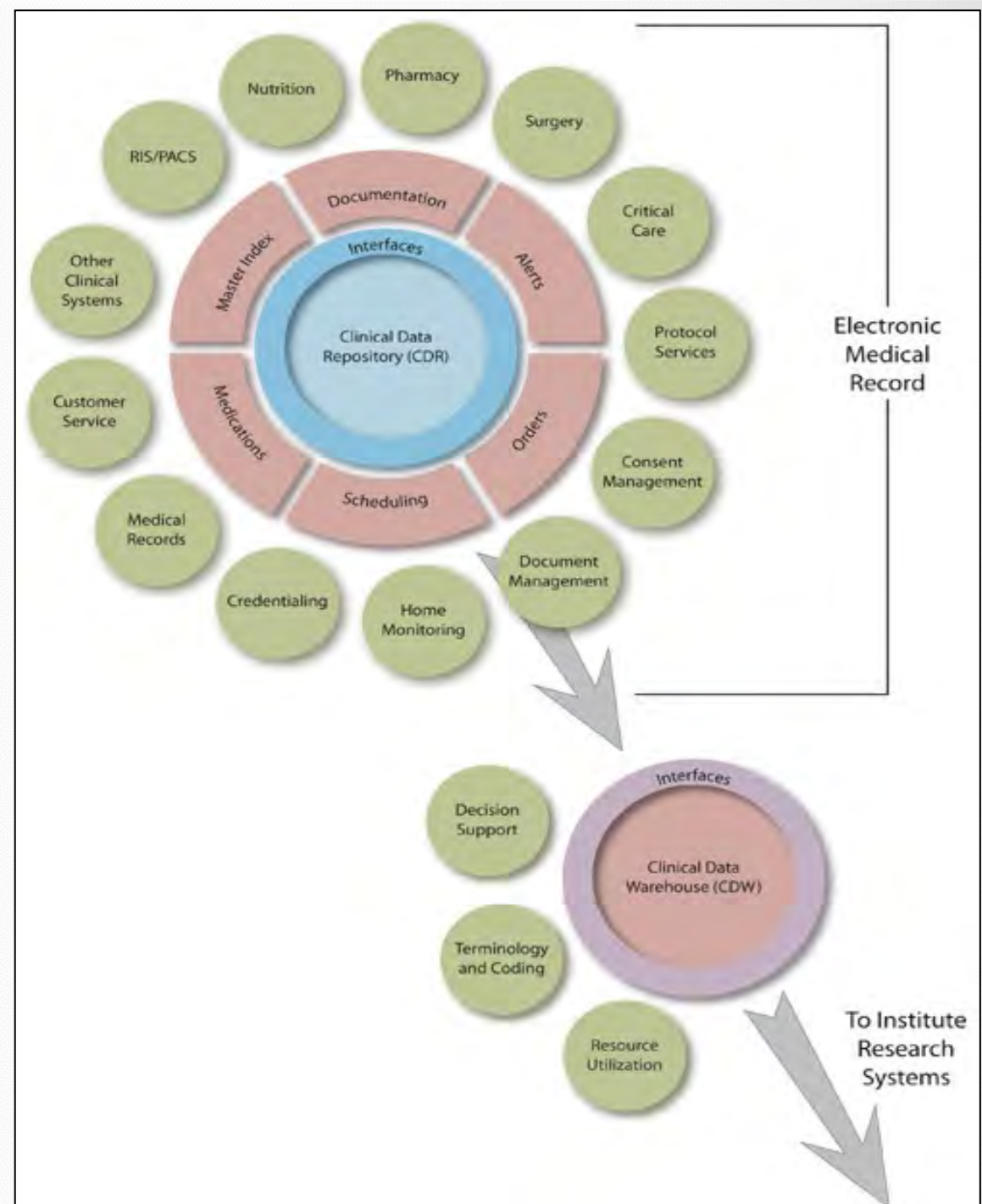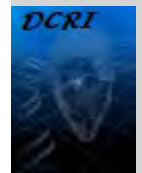
CRIS 2004

- **CRIS is the Electronic Health Record (EHR) used to support patient care, research, and administrative activities at the NIH Clinical Center**
  - Eclipsys Sunrise Clinical Manager (SCM) 3.X
    - Nursing Documentation, eMAR, Vitals
    - Physician Documentation
    - Clinical Results and Reports
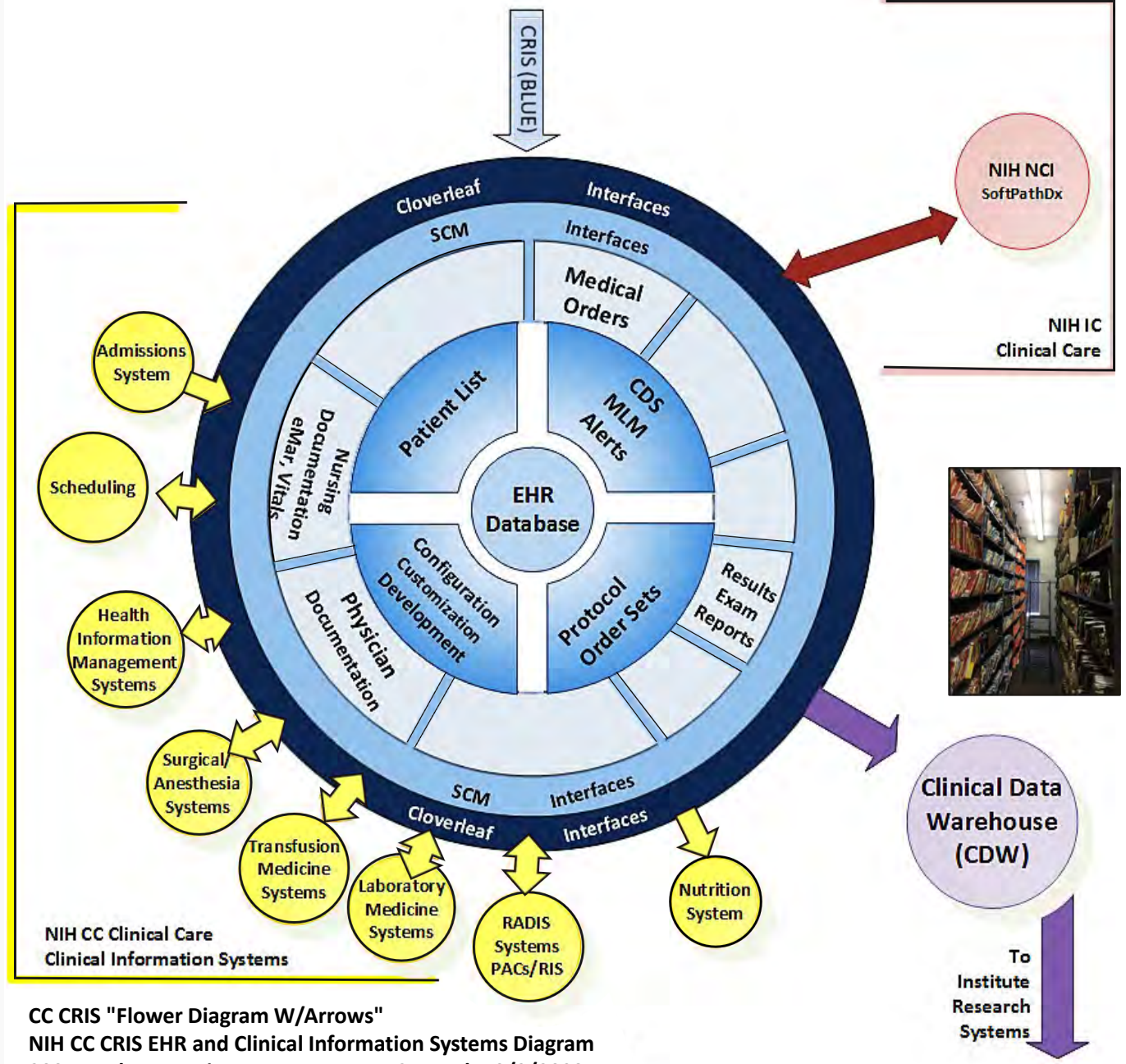
CC CRIS "Flower Diagram W/Arrows"
NIH CC CRIS EHR and Clinical Information Systems Diagram
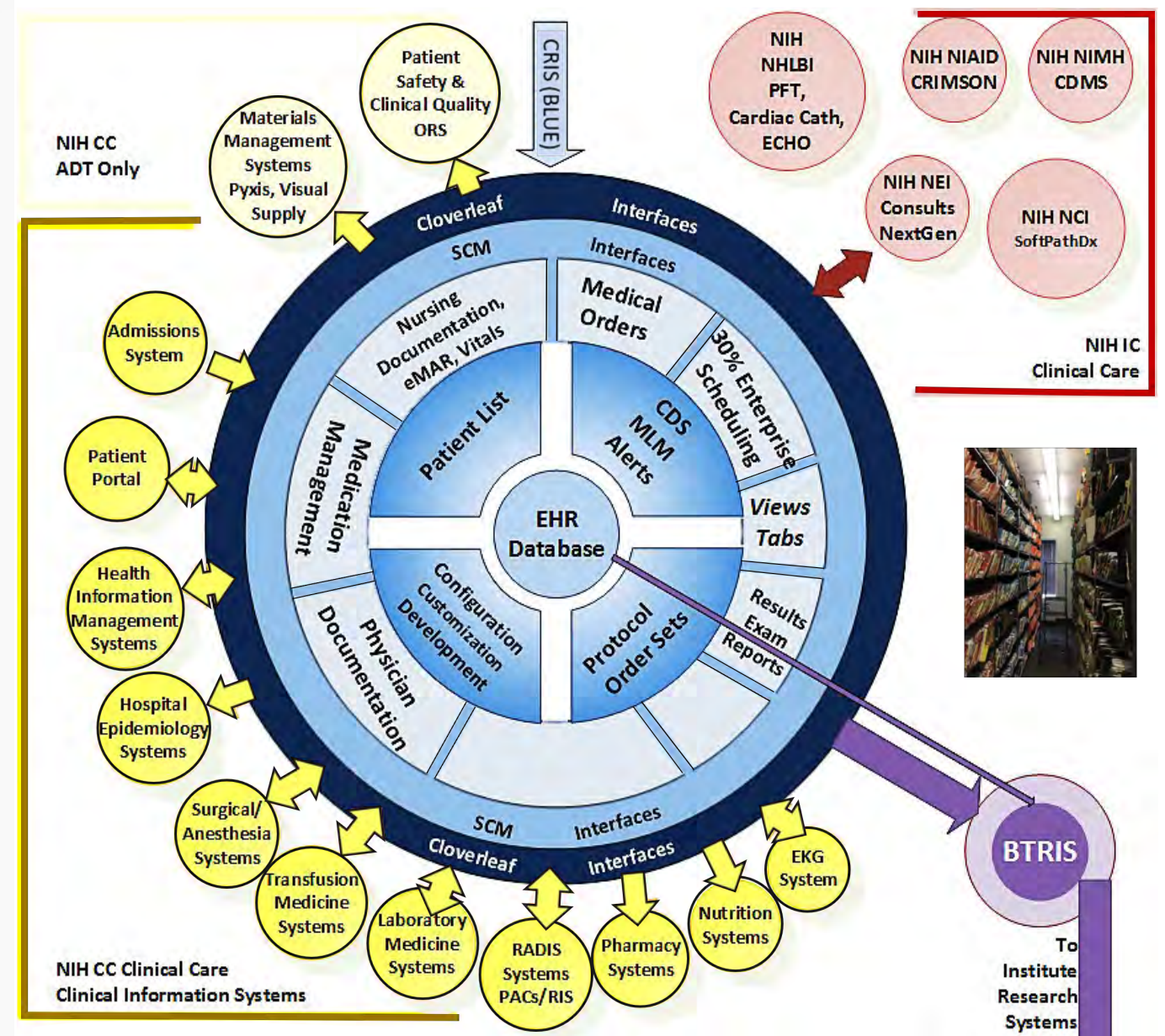2004 Implementation   Date Created: 10/2/2023

CRIS 2014

- **CRIS is the Electronic Health Record (EHR) used to support patient care, research, and administrative activities at the NIH Clinical Center**
  - Allscripts SCM 14.X
    - Since 2004
      - Sunrise Medication Manager
      - Sunrise Enterprise Scheduling Initiated
      - Sunrise Patient Portal
      - Barcode with E-MAR (KBMA)

CC CRIS "Flower Diagram W/Arrows"
NIH CC CRIS EHR and Clinical Information Systems Diagram
2014 State   Date Created: 10/2/2023

CRIS 2023

- **CRIS is the Electronic Health Record (EHR) used to support patient care, research, and administrative activities at the NIH Clinical Center**
  - Altera Digital Health SCM 20.X
    - Since 2014
      - CRIS Mobile
      - Secure Health Messaging
      - Follow My Health
      - All Paper Digital
  - Altera Digital Health SCM 22.1
    - February 2024

CC CRIS "Flower Diagram W/Arrows"
NIH CC CRIS EHR and Clinical Information Systems Diagram
2023 Current State   Date Created: 10/2/2023

CRIS Complexity

- **Altera Digital Health Sunrise Clinical Manager Application is the EHR**
- **Components remain from Veradigm/Allscripts (Patient Registration, Portal)**
- **15+ Clinical Information Systems (LIS, RIS, Nutrition, SIS)**
- **280+ Interfaces**
- **3 Data Centers**
  - 100+ Virtualization Servers (41 production, 62 development)
  - 80+ CITRIX Servers

Complexity Leads to Fragility

- **Goal is 99.99% Uptime which is 52.56 minutes down.**
- **2,160 is 99.58% Uptime**
- **Scheduled Planned CRIS Downtime**

Standing Downtime	#Staff	Frequency	Duration (Hours)	Yearly Downtime
CRIS Private Release	20	Twice a Year	5	10
CRIS Cumulative Upgrade	20	Twice a Year	6	12
CRIS Password Change	20	Twice a Year	4	8
Microsoft Updates	4	Monthly	.5	6
			Total Minutes	2,160

- **Actual CRIS Availability from 2018 to 2023**

|	2018	2019	2020	2021	2022	2023 September 30
CRIS (CRIS, Network, & Interface)	**99.48%**	**98.48%**	**99.32%**	**99.49%**	**98.77%**	**98.52%**
Threshold	**99.99%**	**99.99%**	**99.99%**	**99.99%**	**99.99%**	**99.99%**

Top 6 Issues of 60 Identified

- Lack of seamless integration across Laboratory, Radiology, Medication, Transfusion Medicine, and Perioperative Clinical Information Systems.
- Lack of encounter-based visit model poses limitations for management of ambulatory visits, integration to clinical systems, and synchronization to a protocol pathway.
- Patient engagement modules (FollowMyHealth patient portal, Mobile Patient Experience, etc.) are not intuitive/easy to use for patients and clinicians.
- Documentation and flowsheets not built using standard documentation terminology, scales (e.g., pain), advanced tools to populate documentation, and navigation tools making it difficult to make clinical decisions.
- Workflows are not built into or utilized in CRIS, leaving clinicians to develop their own workflows for patient care. Need improved automation for managing Nursing and Physician tasks, add workflow capabilities and improved patient handoff tasks (e.g., discharge planning workflows, "to do" lists associated with each encounter).
- Inability to sustain custom development based on limitations of current system.

Annual CRIS Survey

CRIS Satisfaction has shown decrease over time.
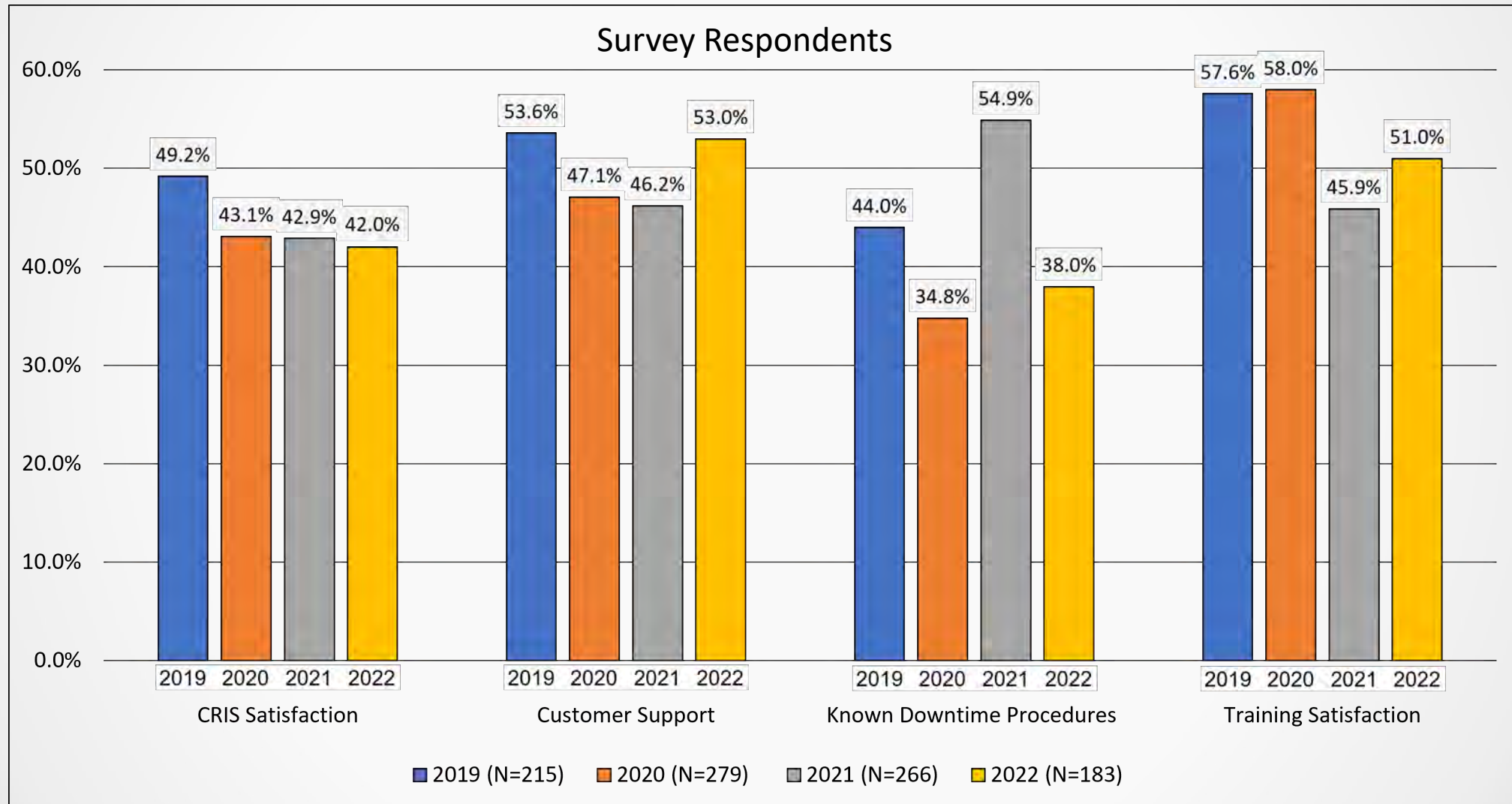
Proposed EHR

- **Monolithic, Integrated**

- **Support Direct Patient-Care**
  - Order entry and orders management
  - Management of medication and other therapeutics;
  - Clinical documentation (eMAR, vitals, problems lists);
  - Results: retrieval, display, queries, re-use, etc.
  - Nursing Workflows
  - Physician Clinical Workflows
  - Surgery/Anesthesia/Interventional Radiology
  - Diagnostic Imaging (Radiology)
  - Lab Medicine
  - Transfusion Medicine
  - Cell Therapy

- **Administrative functions**
  - Patient registration and profile management
  - Bed and other facility-type management

- **Research Functions**
  - Support clinical research workflows
  - Support clinical research data/terminology
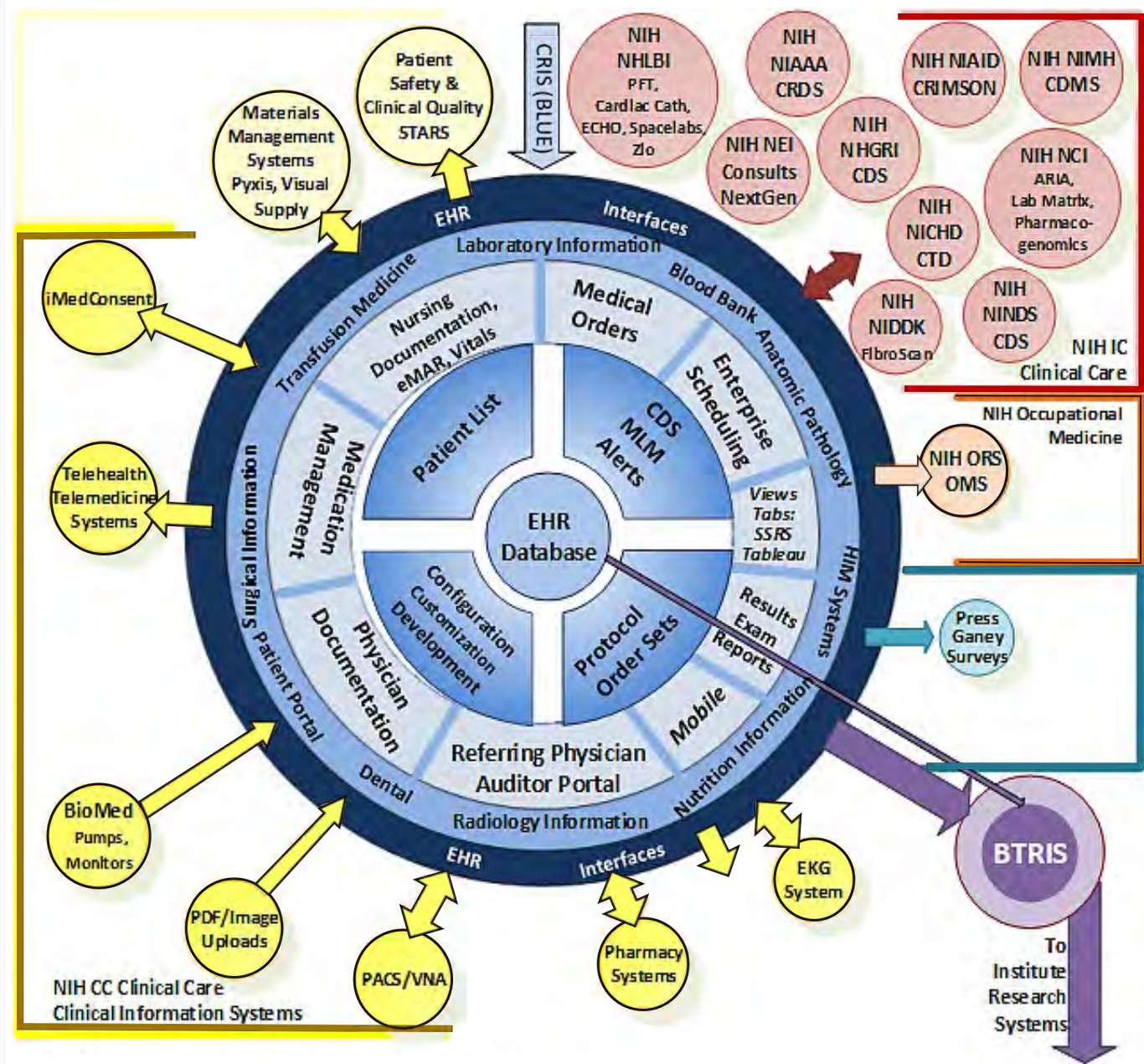
EHR Modernization "Flower Diagram W/Arrows"
Version 1 With Arrows   Date Updated: 03/02/2023

The EHR Modernization Project

- **This is a Complex Organizational Project with IT Components**
- **This will require all of our participation to be successful**
- **This will migrate external Clinical Information Systems into an Integrated EHR**

Top 6 Desired Outcomes

- Streamline patient throughput and clinical workflow to provide the patient story in a very concise manner.

- Improve patient safety and clinical care delivery quality.

- Improve patient experience and engagement.

- Improve decision making across clinical care roles within the CC.

- Reduce complexity to support systems from security patching, configuration, and customization.

- Improve system availability.
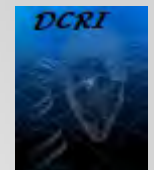
Delaying Procurement: Major Improvements Needed

- **Implement Encounter Based Visits**
  - 2 years, 8 staff, Altera, $5.6 Million
  - Difficult to utilize capabilities of other systems HIM 3M Replacements
  - Adds complexity to ordering especially for long-term outpatients

- **Improve Usability**
  - Continual, 3 staff, Altera, $1.4 Million Annually
  - Difficult to understand the patient story
  - Timeline, Tasks, Workflow, Implement New Features

- **Improve Physician and Nursing Documentation**
  - 3 Years, 8 staff, Altera, $8.4 Million and Annual License Fee
  - Knowledge based charting allows for reduced variation in practice, incorporating evidence based practice information that is real-time and provides many tools for clinicians to provide safe, patient-centered care.

- **Implement E-Prescribe**
  - 3 years, 8 staff, Altera, $8.4 Million and Annual Maintenance Increase

- **Implement Interoperability Mechanisms to/from External Organizations**
  - 3 years, 4 staff, $4.2 Million and Annual Maintenance Increase

- **Precision Medicine, Clinical Decision Support**
  - Continual, 3 staff, Altera, $1.4 Million Annually

EHR Modernization SOW

- MITRE Creation of Performance Work Statement/Statement of Work
- Modernization could include an extensively overhauled CRIS/SCM or could include moving to a different vendor.
- Open bid to all vendors
- All bidders will have to indicate how they would address the requirements.
- Detailed, accurate, well-stated requirements provide a crucial foundation for a successful acquisition and implementation of an EHR.
- An EHR that will
  - Support safe, quality clinical care.
  - Aligns with current and future Good Clinical Practice standards.
  - Reviews the components that are needed.
  - Reviews how the components are to be implemented.
  - Reviews how the system will provision data in a manner most useful to the clinical research enterprises.

Statement of Work Status

- **MITRE Creation of PWS/SOW**
  - Initial contract ended 3/31/2023
  - Restarted 10/1/2023
  - Contract with Two Tasks:
    - o Finalization of PWS/SOW
      - Additional Focus Group Opportunities
      - Vendor Days and Demos
    - o Clinical Workflow Modeling (February 2024)

Focus Groups

- **Engagement directed and conducted by MITRE**
- **Focus Groups**
- **Live, direct "shadowing", observation of staff while they use the EHR**
- **Interviewed 20 CC/IC Leaders, 30 + Focus Groups, and 5 days performing Job Shadows.**

Leadership Interviews	Focus Groups	Focus Groups	End-User Observations
Dr. James Gilman	Administrative	Nursing	1NW, 1NWDH, Peds Clinic
Mr. Pius Aiyelawo	Anatomic Pathology	Nutrition (CBORD)	3NE
Dr. Brian Brooks	Anesthesia and Surgery	PET Nuclear Medicine	3SEDH Ambulatory
Dr. Christopher Koh	BTRIS	Pharmacy	3SEN inpatient Oncology
Dr. Steven Holland	CC Leadership	Privacy and Security	5NW
Dr. Janice Lee	Change Management	Radiology	5SWS/N
Dr. John Gallin	Clinical Documentation	Rehabilitation Medicine	7SE (Behavioral)
Dr. Maryland Pao	Clinician Focus Group	Transfusion Medicine	7SWN
Dr. Henry Masur	CRIS DB and Infrastructure	Social Work	Autoimmunity, Wound Care, & Family Nurse Practitioner
Dr. Michael Solomon	CRIS Orders and Order Sets	Telehealth	ICU (pre-rounds & rounds)
Dr. Richard Childs	CRIS Reporting, Data Analytics	Training	ICU Nurse Shadowing (3SWS)
Dr. William Dahut	CRIS Results Management		ICU Rounds (3SWS)
Dr. Jeremy Davis	Dentistry	Monthly Recurring focus Groups (*open to all will restart in October*)	Laboratory Medicine
Dr. Elliot Levy	Downtime Preparedness		OP9
Dr. Richard Davey	Enterprise Scheduling		PACU, PAC, IR
Dr. Maura Manion	Interoperability		Pharmacy
Dr. Colleen Hadigan	Laboratory Medicine		Radiology
Dr. David Lang	Materials Management		Transfusion Medicine
Dr. Barbara Jordan			

Current Requirement Count

- **Over 1,000 individual requirements.**
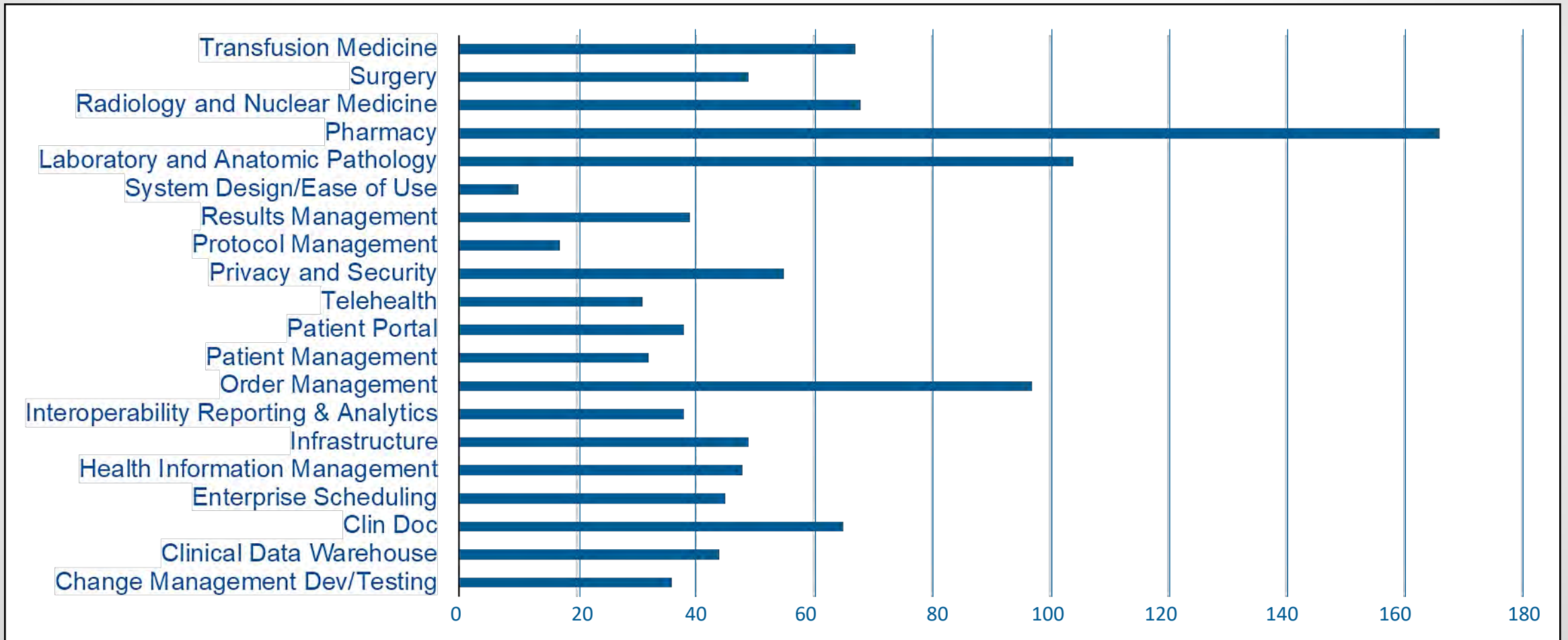
Clinical Workflow Modeling

- **Create inventory of all Clinical Workflows**

- **Identify 50 that Represent**
  - Complexity
  - Clinical Requirements
  - Clinical Research Requirements
  - Variation across CC Departments, ICs and Protocols

- **Document 50 Clinical Workflows**
  - MITRE to Facilitate Project
  - Create a CC/IC Clinical Workflow Interdisciplinary Team
  - Document current and desired future state.

- **After the 50**
  - Clinical Workflow Interdisciplinary Team to document the remaining workflows

EHR Modernization Funding

- **Secure Funding**
  - Reviewing Funding Options with HHS & NIH
  - Complete FITARA/ITAR (Federal IT Acquisition Reform Act)
    - Submitted July 2023
    - NIH Approval September 12, 2023

Next Steps

- MITRE continue work on PWS/SOW
  - Add focus groups/team meetings to finalize requirements
  - Determine way to review all Requirements with Organization
  - Complete Market Research

- MITRE to facilitate Clinical Workflow Modeling

- Secure Funding

- PWS/SOW Submission