The Learning Healthcare System: Create, Implement and Maintain

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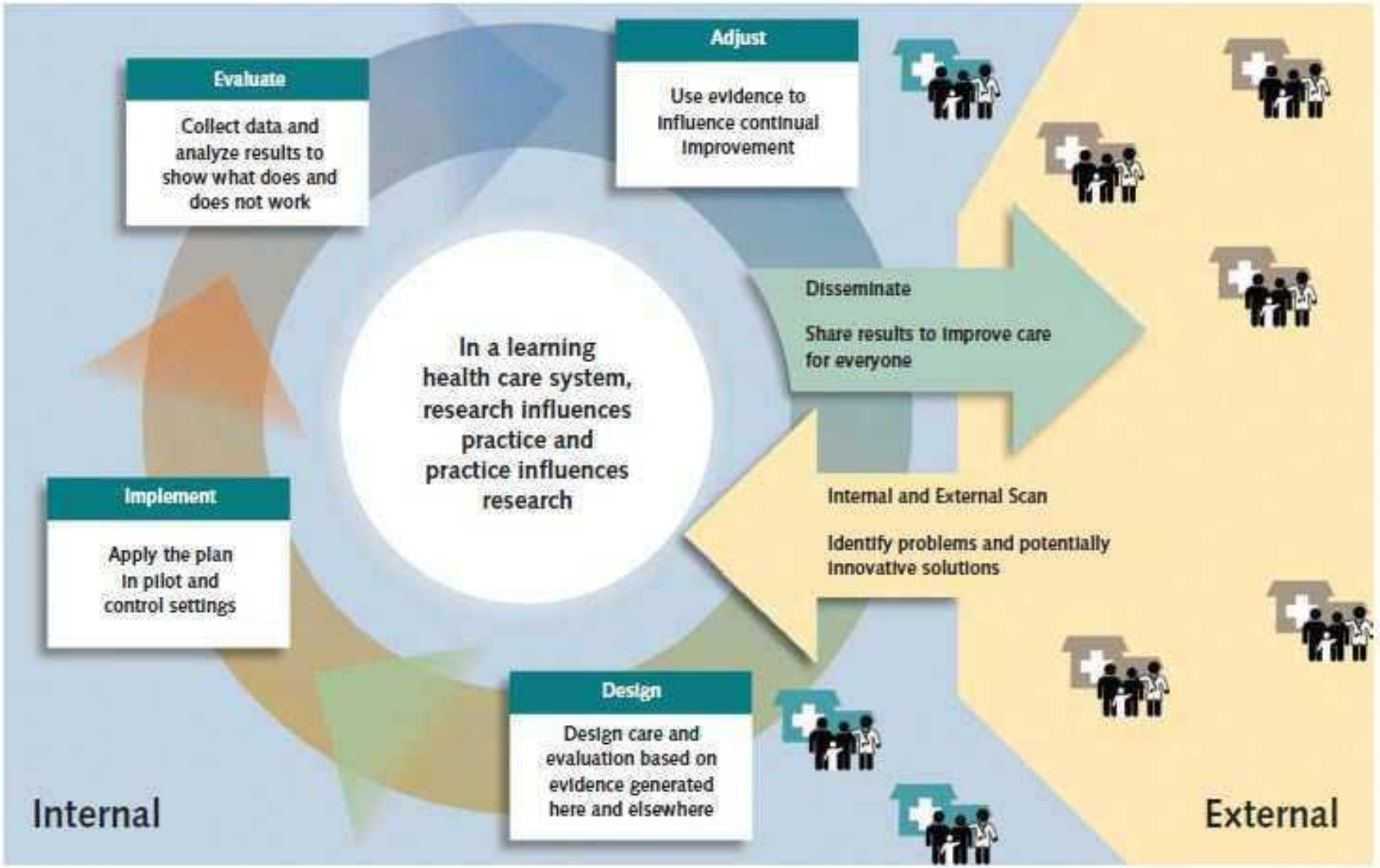
LEARNING OBJECTIVES

What is a learning healthcare system?

- The IOM's vision:
  - Research happens closer to clinical practice than in traditional university settings.
  - Scientists, clinicians, and administrators work together.
  - Studies occur in everyday practice settings.
  - Electronic medical records are linked and mined for research.
  - Recognition that clinical and health system data exist for the public good.
- Evidence informs practice and practice informs evidence.

Figure. **The 6 phases of the rapid-learning health care system, from scanning to dissemination.**



INTERNAL/EXTERNAL SCAN

- Perform an internal scan to determine what issues or problems need to be corrected
- Also perform an internal scan to determine what data is being captured and how much of that data can be used for analysis
- Do both an internal and an external scan to look for intrinsic data solutions as well as external capabilities that can provide support for an LHS
- Your approach is similar to that of any PI/QI project

DESIGN

- As with a PI/QI project, the next step is to design your approach to solving the problems/address the issues discovered in the SCAN phase
- Remember the rules of an LHS - design the solution so that you get ongoing and valid feedback from the point-of-care so the system can continue to improve
- Design how the data will be captured, which includes making sure the UX makes it easy to capture valid and accurate data
- Design the database and analytics tools to perform any calculations and support any analysis needed
- Design the feedback loop so the LHS provides ongoing, improving information to the end users so they can provide ever better care

IMPLEMENT

- Once you have designed your system, pilot it in a small, real-life setting (a simulation lab is also acceptable as long as there are well-designed use cases and real end users)
- Once the pilot is complete and validated, implement the solution in either a progressive or "Big Bang" format
- Monitor end users closely to ensure there are no immediate system glitches; make immediate repairs as needed
- When fully implemented and operational for 30 days, move into maintenance phase
- Make updates to the system as needed (for hard stop problems), but on a regularly scheduled interval for routine improvements

EVALUATE/ADJUST

- As with any PI/QI project, design your evaluation criteria and intervals before you implement
- Collect ongoing data, both electronically and by end user interviews, about all aspects of the implemented solution: UX, data and knowledge returned, usability of the resulting CDS
- Using both end user and development/implementation team feedback, make ongoing adjustments to the system to improve functionality and accuracy/validity

MAINTENANCE

- Once you have completed a full cycle of Design-Implement-Evaluate-Adjust, it is time to move to maintenance phase
- Maintenance does not mean place on auto-pilot
- Maintenance means continue the D-I-E-A cycle on a regular, pre-determined interval and continue to make incremental adjustments based on feedback/objective measures
- Depending on the topic for the LHS component, it is also important to involve SME's on a regular basis to ensure the validity of the rules engine for the LHS/CDS
- In addition, updates to OS, the EHR itself or to the data analytics engine underlying the LHS/CDS make for ongoing maintenance requirements/updates

DATA INFRASTRUCTURE FOR AN LHS

WHY IS THIS IMPORTANT?

- SINCE EHR INTEROPERABILITY AND DATA INTEROPERABILITY FROM THOSE EHR'S ARE BOTH YEARS AWAY, CREATING A DATA INFRASTRUCTURE IS CRITICAL TO THE VARIOUS ASPECTS OF THE LEARNING HEALTHCARE SYSTEM
- NUMEROUS DATA SHARING SYSTEMS/COLLABORATIVES HAVE BEEN CREATED TO ALLOW FOR DATA SHARING AND DATA GOVERNANCE
- THESE SYSTEMS/COLLABORATIVES SHARE A COMMON THEME THAT ALLOWS THEM TO POOL DATA FROM DISPARATE EHR'S AND CREATE A UNIFIED LHS FOR CDS, COMPARATIVE EFFECTIVENESS RESEARCH, POPULATION-BASED RESEARCH, QI/PI AND OTHER FUNCTIONS OF AN LHS

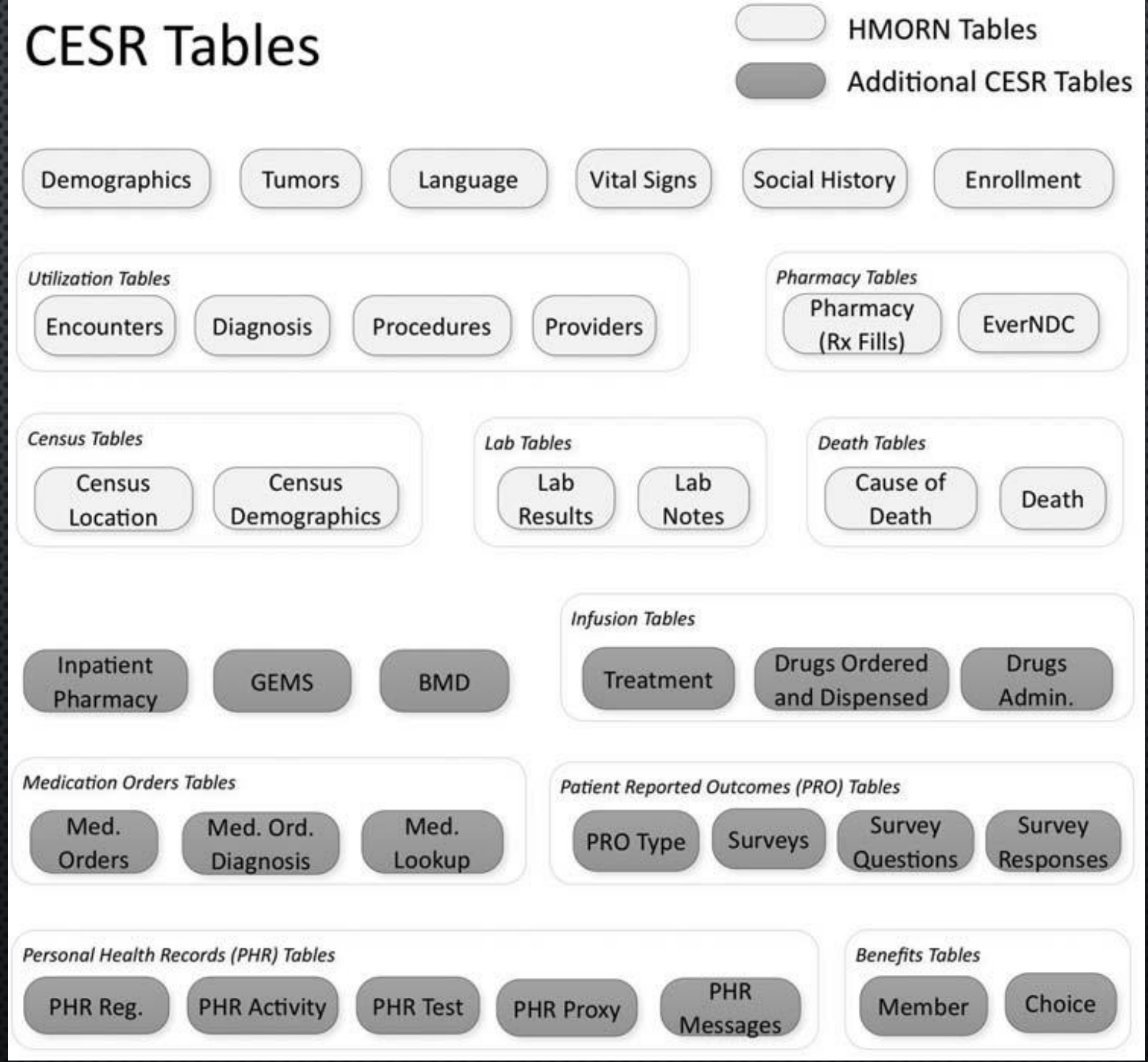
WHAT IS INVOLVED?

- Differences in configurations, workflows and codes (as well as differences in various applications/EHR's) creates significant barriers to data sharing between partners
- Even among systems using the same EHR or ancillary applications, different configurations create barriers with dissimilarities in data variable names, formats and meanings
- The best practice approach to addressing these issues is the use of a common data model (CDM)
- The CDM provides definitions for how each shared data element must be structured and which codes must be assigned to data values

WHAT IS ALREADY AVAILABLE?

- One model is the HMO Research Network Virtual Data Warehouse (HMORN VDW).
- Another model is the 3M Health Data Dictionary (HDD)
- MU2 required certain terminologies (but not specific versions of those terminologies) for EHR certification
  - In order for a CDM to truly be "Common", the parties involved have to agree on which exact versions of the required terminologies will be used (i.e., data and terminology governance)

CESR Tables


HMORN Tables
Additional CESR Tables
Demographics
Tumors
Language
Vital Signs
Social History
Enrollment
Utilization Tables
Encounters
Diagnosis
Procedures
Providers
Pharmacy Tables
Pharmacy (Rx Fills)
EverNDC
Census Tables
Census Location
Census Demographics
Lab Tables
Lab Results
Lab Notes
Death Tables
Cause of Death
Death
Inpatient Pharmacy
GEMS
BMD
Infusion Tables
Treatment
Drugs Ordered and Dispensed
Drugs Admin.
Medication Orders Tables
Med. Orders
Med. Ord. Diagnosis
Med. Lookup
Patient Reported Outcomes (PRO) Tables
PRO Type
Surveys
Survey Questions
Survey Responses
Personal Health Records (PHR) Tables
PHR Reg.
PHR Activity
PHR Test
PHR Proxy
PHR Messages
Benefits Tables
Member
Choice

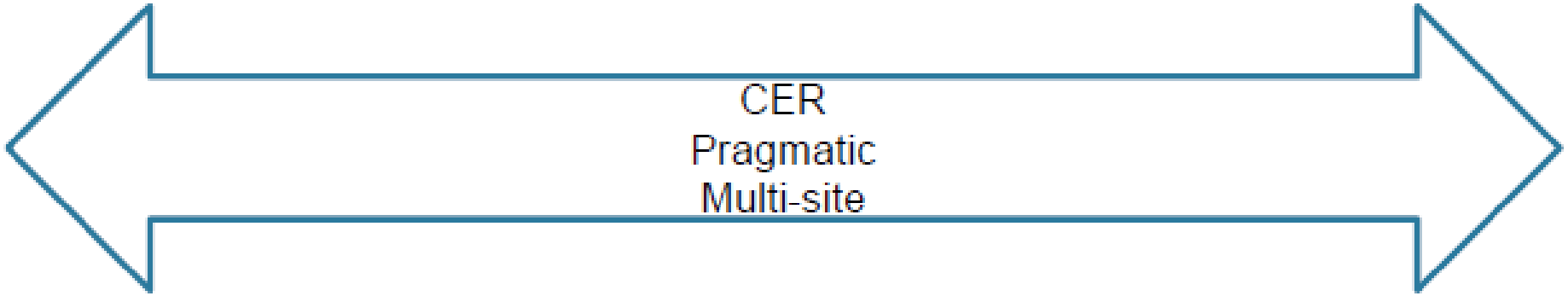
SOME EXAMPLE USE CASES

OSCHNER CLINIC AND REACHNET

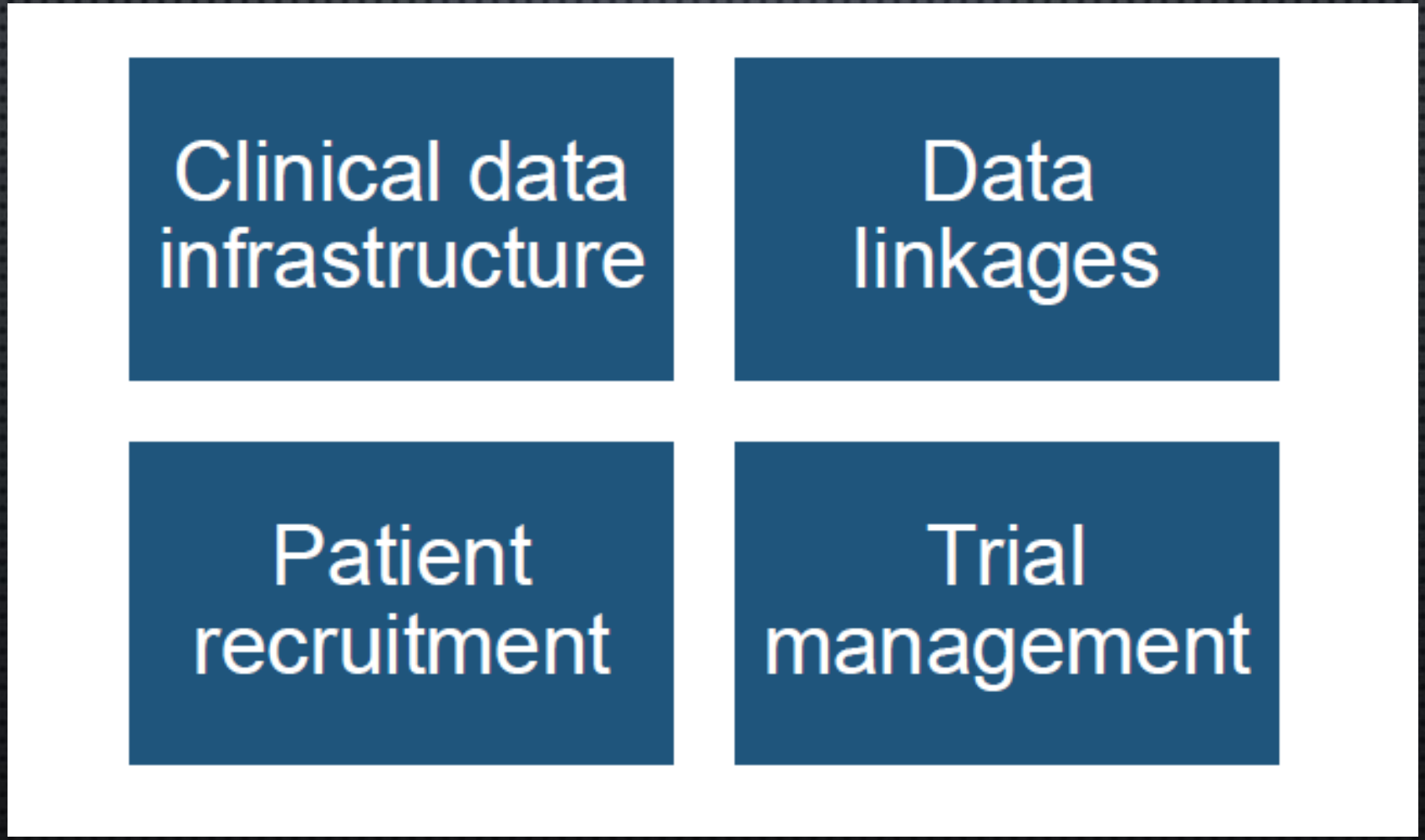
IMPROVING PATIENT ENROLLMENT IN CARDIOVASCULAR RESEARCH

Two dosing trials for coronary heart disease patients

PCORI ADAPTABLE	NIH INVESTED
• Aspirin maintenance dosage comparison	• Flu vaccine—high vs. standard dose
• $10,000,000	• $20,000,000
• 20,000 patients	• 10,000 patients



ENHANCED EFFICIENCIES



REACHnet

REACHnet is a network of health systems containing clinical records for more than 3 million patients in Louisiana and Texas, facilitating patient-centered comparative effectiveness research (CER).

Resources and Services

- Pragmatic Trial App Suite
- Prep-to-Research Querying & Common Data Model
- Collection of Patient-Generated Data
- Stakeholder Engagement
- Streamlined IRB and Contracting
- Health in Our Hands (HiOH) Patient Network
- REACHnet Coordinating Center

Data Infrastructure

1. PCORnet Common Data Model
   - Standardized clinical data prepared for retrospective/ prospective research and prep-to-research queries
2. Global patient identifier (GPID)
   - Allows for deduplication and matching of patient records
3. Data linkages
   - Ability to link data from other sources with clinical data (i.e., claims, patient-generated data)

PCORnet CDM Domains, v3.0

CONDITION v2.0

A condition represents a patient's diagnosed and self-reported health conditions and diseases. The patient's medical history and current state may both be represented.

DEATH v3.0

Reported mortality information for patients.

DEATH_CAUSE v3.0

The individual causes associated with a reported death.

DEMOGRAPHIC v1.0

Demographics record the direct attributes of individual patients.

DIAGNOSIS v1.0

Diagnosis codes indicate the results of diagnostic processes and medical coding within healthcare delivery.

DISPENSING v2.0

Outpatient pharmacy dispensing, such as prescriptions filled through a neighborhood pharmacy with a claim paid by an insurer. Outpatient dispensing is not commonly captured within healthcare systems.

ENROLLMENT v1.0

Enrollment is a concept that defines a period of time during which all medically-attended events are expected to be observed. This concept is often insurance-based, but other methods of defining enrollment are possible.

ENCOUNTER v1.0

Encounters are interactions between patients and providers within the context of healthcare delivery.

HARVEST v3.0

Attributes associated with the specific PCORnet datamart implementation

LAB_RESULT_CM v2.0

Laboratory result Common Measures (CM) use specific types of quantitative and qualitative measurements from blood and other body specimens. These standardized measures are defined in the same way across all PCORnet networks.

PCORNET_TRIAL v3.0

Patients who are enrolled in PCORnet clinical trials.

PRESCRIBING v3.0

Provider orders for medication dispensing and/or administration.

PRO_CM v2.0

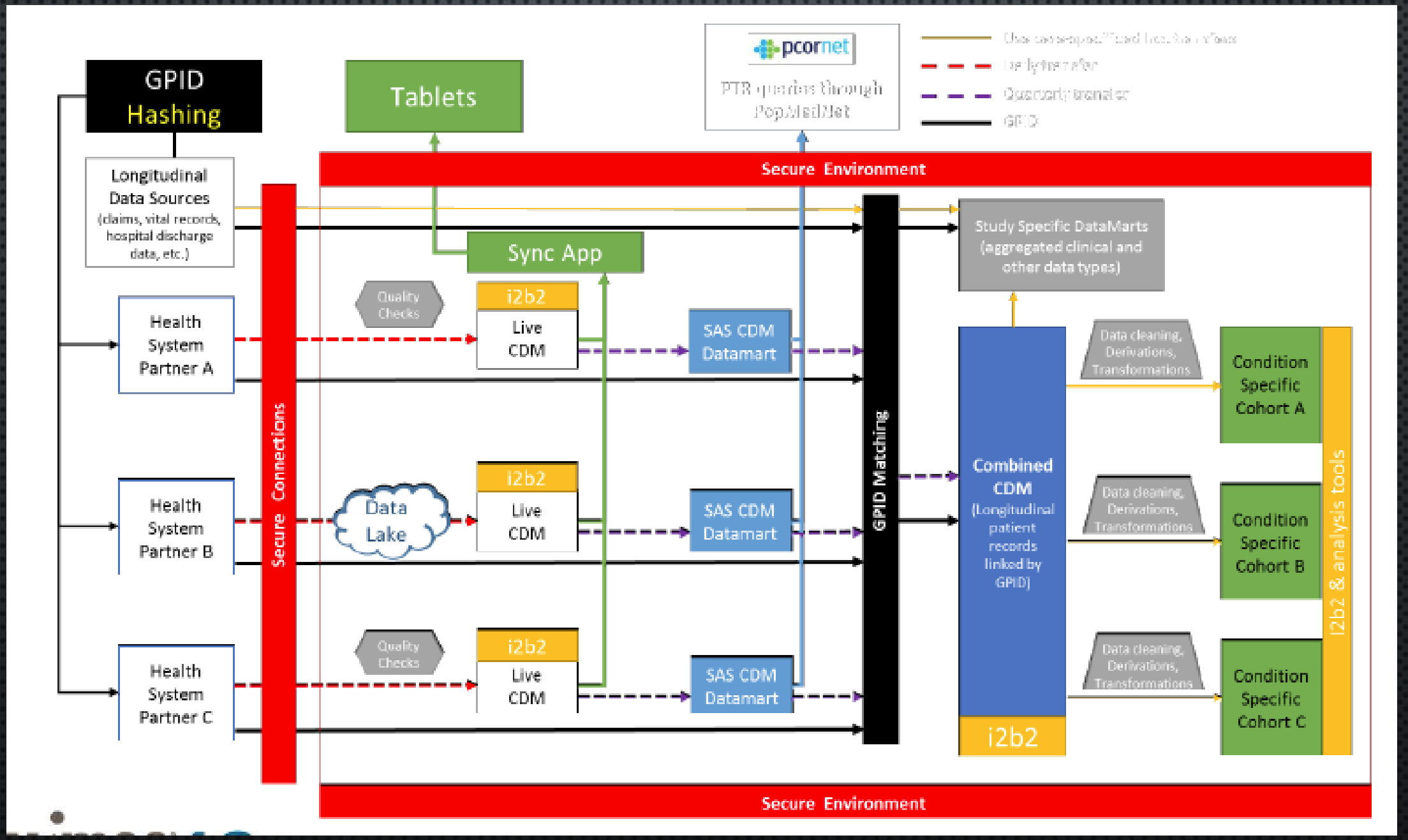
Patient-Reported Outcome (PRO) Common Measures (CM) are standardized measures that are defined in the same way across all PCORnet networks. Each measure is recorded at the individual item level: an individual question/statement, paired with its standardized response options.

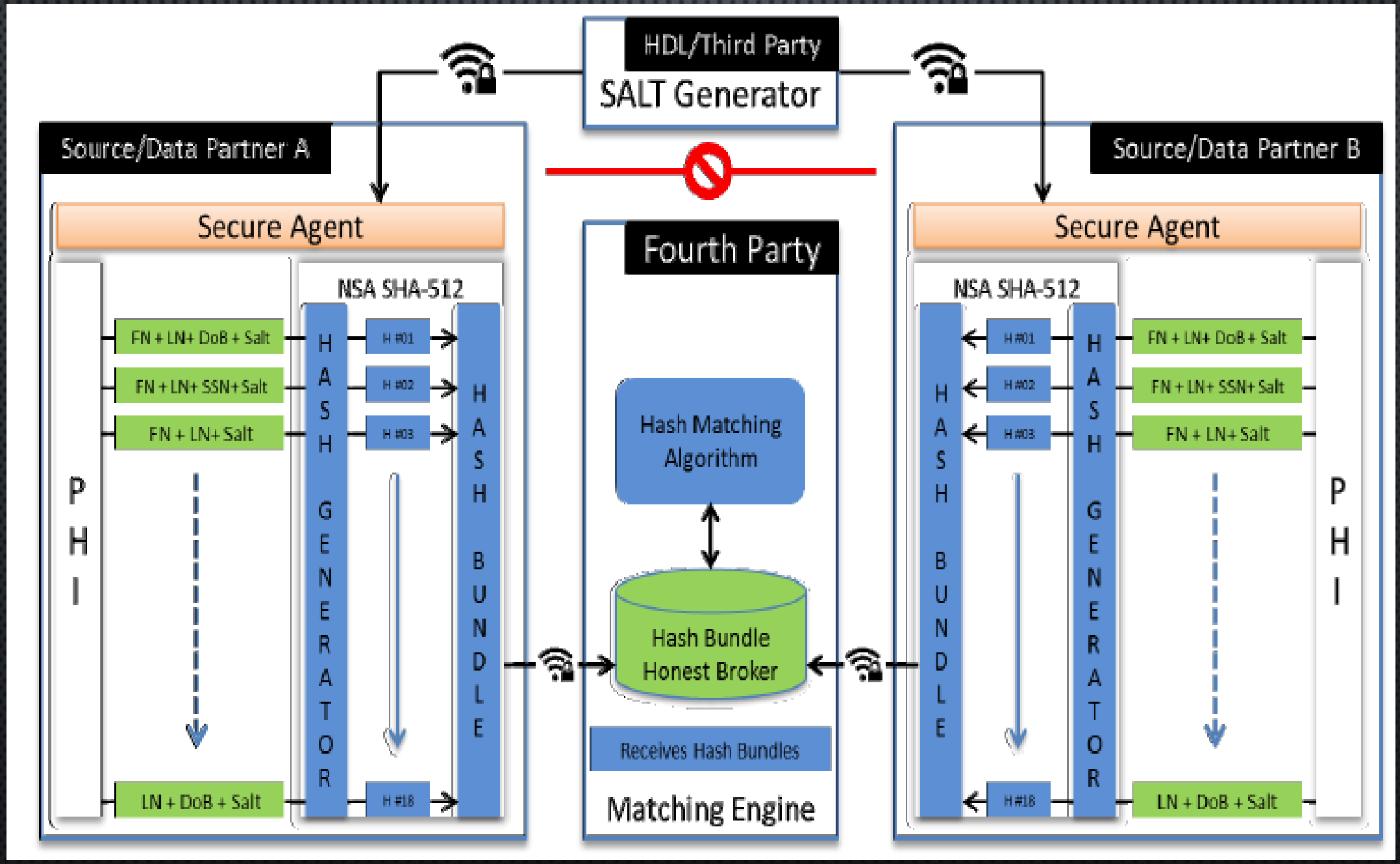
PROCEDURES v1.0

Procedure codes indicate the discreet medical interventions and diagnostic testing, such as surgical procedures, administered within healthcare delivery.

VITAL v1.0

Vital signs (such as height, weight, and blood pressure) directly measure an individual's current state of attributes.


GPID Hashing
Tablets
pcornet
PTR queries through PopMedNet
Secure Environment
Longitudinal Data Sources (claims, vital records, hospital discharge data, etc.)
Sync App
Study Specific DataMarts (aggregated clinical and other data types)
Health System Partner A
Quality Checks
i2b2
Live CDM
SAS CDM Datamart
Secure Connections
GPID Matching
Data Lake
Health System Partner B
Combined CDM (Longitudinal patient records linked by GPID)
Data cleaning, Derivations, Transformations
Condition Specific Cohort A
Condition Specific Cohort B
Condition Specific Cohort C
i2b2 & analysis tools
Health System Partner C
Secure Environment

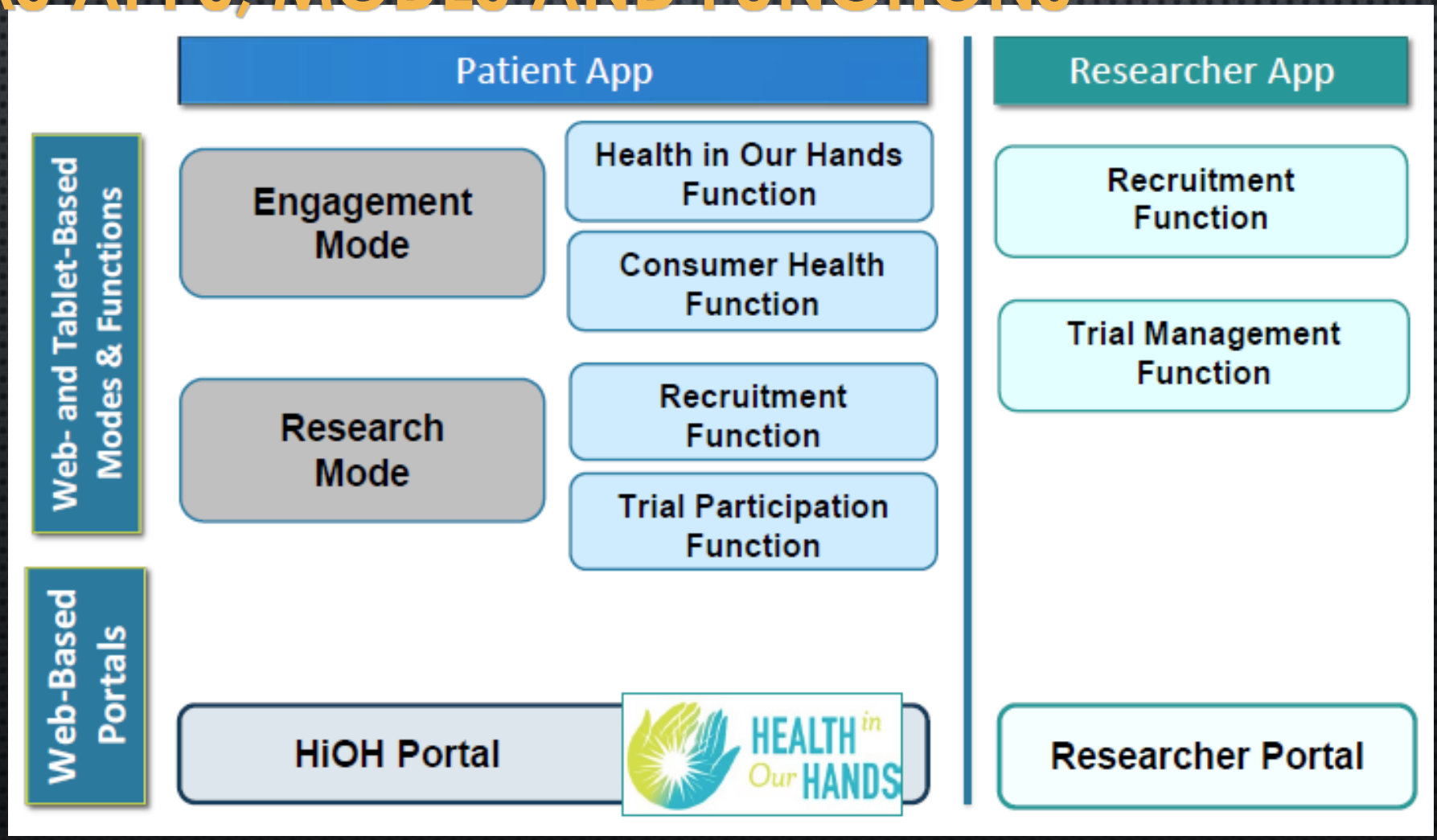

HDL/Third Party
SALT Generator
Source/Data Partner A
Source/Data Partner B
Secure Agent
Secure Agent
Fourth Party
NSA SHA-512
NSA SHA-512
FN + LN+ DoB + Salt
FN + LN+ SSN+Salt
FN + LN+Salt
LN + DoB + Salt
H #01
H #02
H #03
H #18
HASH GENERATOR
HASH BUNDLE
HASH BUNDLE
HASH GENERATOR
PHI
PHI
Hash Matching Algorithm
Hash Bundle Honest Broker
Receives Hash Bundles
Matching Engine

Patient Engagement Infrastructure

1. Pragmatic Trial App Suite (PTAS)
   - Web- and tablet-based platform designed to engage patients (patient app) and facilitate pragmatic trials (researcher app)

2. Health in Our Hands (HiOH)
   - Patient network through which patient enrollees are engaged in research activities through the PTAS inside and outside of clinic settings
   - Enrollees receive health information, research results, and opportunities to participate in specific studies

PTAS APPS, MODES AND FUNCTIONS



HEALTH IN OUR HANDS PATIENT NETWORK

Patients join HiOH on tablet in exam room at clinic visit

Enrolled patients may be contacted by email or text message

Enrolled patients receive:

- Trial recruitment invitations
- Patient-reported outcomes surveys
- Consumer health information
- Research results
- Opportunities to engage in research processes

HiOH Patient Network	• Almost 4,000 consents from 2 health systems over 10 months
WeighSmart	• Text messaging and smart scales for weight loss
ADAPTABLE	• PCORnet national aspirin dosing trial
CHAP	• Chronic Hypertension and Pregnancy trial investigating HTN drug therapy
PPRN Partnerships	• Co-recruitment with Health eHeart, AR-PoWER, and CPPRN
IPC	• Facilitation of inter-pregnancy primary care visits

Consent Rates
30% HiOH Network
40% PRO Survey

Adaptable
The Aspirin Study

Natural Experiments Network	• Natural experiment of impacts of population-targeted health policies to prevent diabetes
YMCA Diabetes Prevention Program	• Recruitment of pre-diabetic patients for YMCA's Diabetes Prevention Program (DPP)
INVESTED	• Comparative effectiveness of high vs. low dose flu vaccine
RELIANCE	• Comparative effectiveness of Roflumilast vs. Azithromycin to prevent COPD exacerbations
Diabetes Medication Decision Tool	• Web-based diabetes medication decision tool for shared-decision making
Precision Medicine Initiative	• Presidential initiative to build a national, large-scale research participation cohort with cancer

Clinic Recruitment

- Ochsner Leadership and Senior Physicians approached for approval of pilot
- Clinical sites identified by measures including physician research interests, clinical care type, site location

EMR Integration

- Tablet launch is initiated through EPIC EMR (hyperlink within MA navigator)
- Data collected via the tablet is sent directly to the REACHnet Data Center
- Select information (e.g. survey responses) is returned to Ochsner EMR in real-time

Staff Training

- Nurses and MAs are trained in tablet use through lecture-based and hands-on interactive sessions
- Rooming staff are tasked with tablet activation and hand-off to the patient

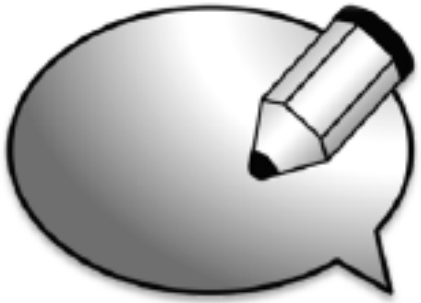
Health in Our Hands (HiOH):

3,315 patients enrolled (March 18-January 17)

4,222 patients completed PRO survey (March 17-January 17)

Characteristics of HiOH enrollees:

- Gender: 62% Female , 38% Male
- Age Range: 19 to 97
- Race: 64% White, 34% African-American, 2% Other



Patient Interest in HiOH:

- "I would like to stay abreast of my healthcare and keep up with current research as it relates to my health."
- "It will offer me information about future research studies related to diabetes."

LESSONS LEARNED

This technology presents a promising method for ***increasing patient engagement*** in research and ***incorporating research*** activities efficiently ***into the clinic***.

Successes:

- Increased rate of patient enrollment
- Positive response from patients and physicians
- Technical integration with EMR

Challenges:

- Workflow integration; flexibility for clinic-specific needs is key
- Continued front-line staff engagement; physician support is key

University of Rochester VNA LHS

Creating a Learning Healthcare System Around VNA's

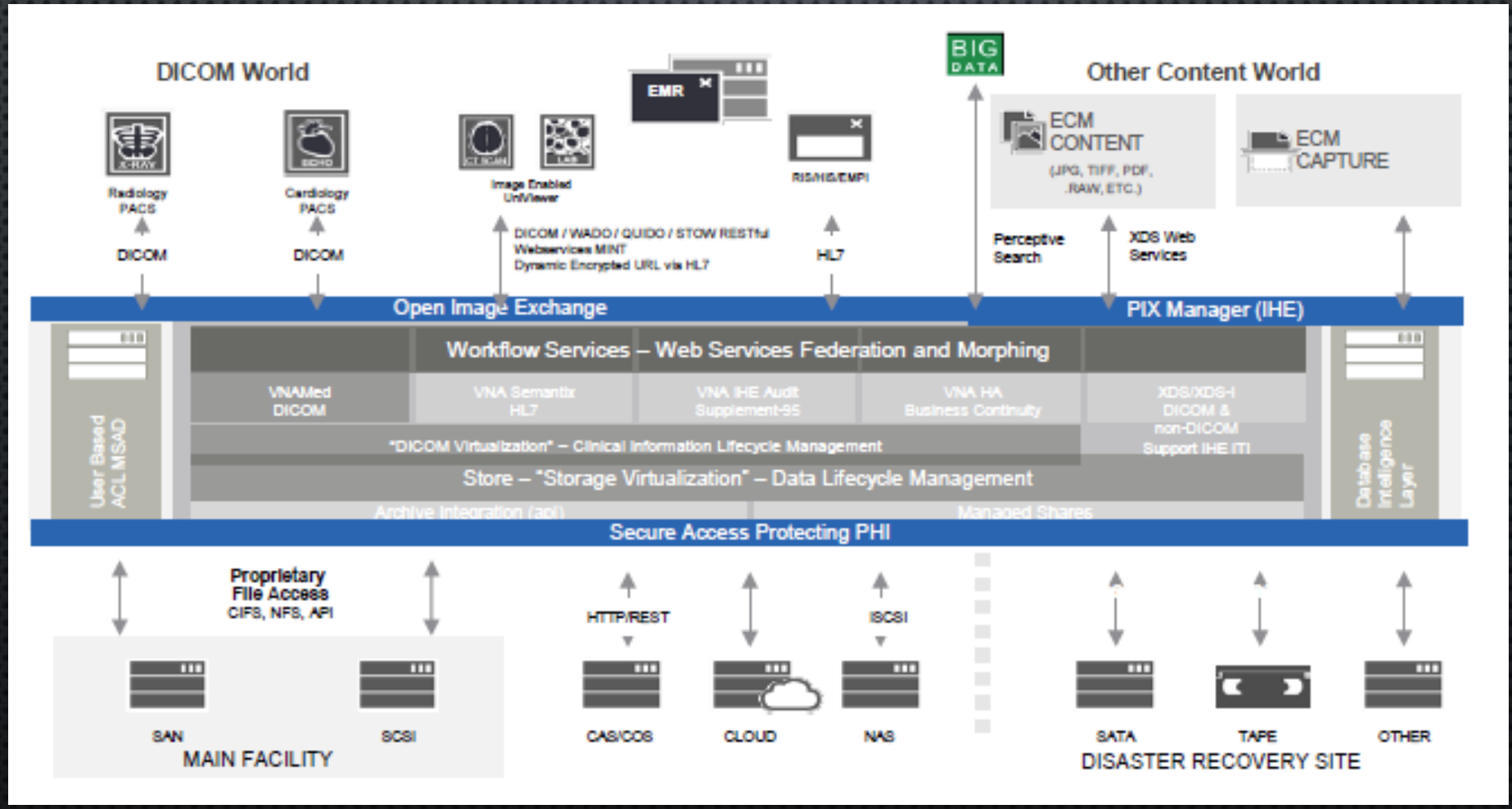
Learning Healthcare System

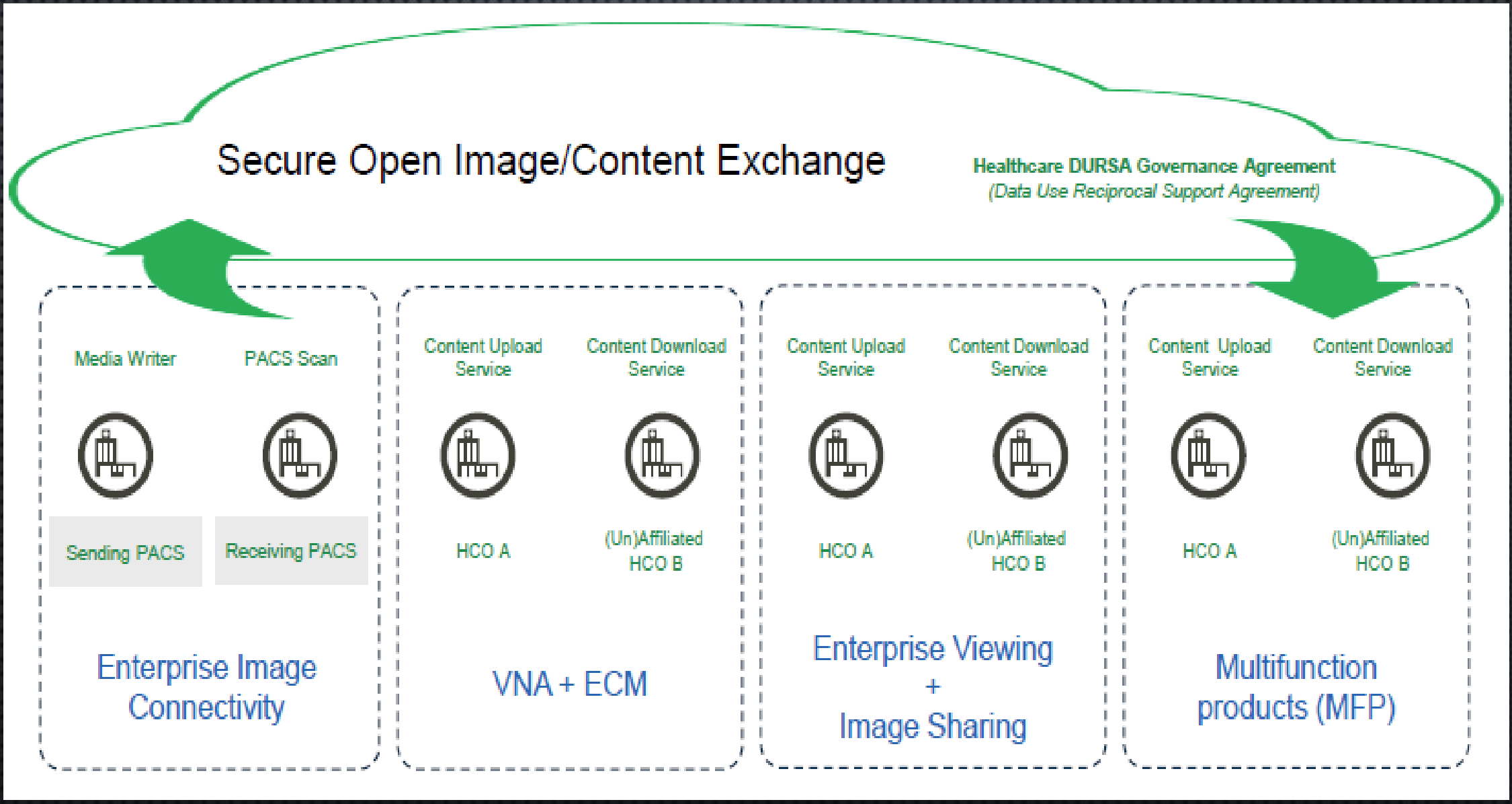
- Build upon the existing HIT system
- One size does not fit all
- Empower individuals
- Leverage the market
- Simplify
- Maintain modularity
- Consider the current environment and support multiple levels of advancement
- Focus on value
- Scalability and universal access

Mature VNAs

- Can install under/over traditional PACS
- Interoperable now and into the future; Canonical data models
- Reduces complexity, eliminating vendor lock and vendor block
- Consolidates storage and improves its management
- Modular scalability; Adopts new technology and virtualization; Additional benefits emerge
- Savings helps offset investments
- Interoperability through certified standards

HEALTHCARE CONTENT MANAGEMENT SYSTEM




Secure Open Image/Content Exchange
Healthcare DURSA Governance Agreement
(Data Use Reciprocal Support Agreement)
Media Writer
PACS Scan
Sending PACS
Receiving PACS
Enterprise Image Connectivity
Content Upload Service
Content Download Service
HCO A
(Un)Affiliated HCO B
VNA + ECM
Content Upload Service
Content Download Service
HCO A
(Un)Affiliated HCO B
Enterprise Viewing + Image Sharing
Content Upload Service
Content Download Service
HCO A
(Un)Affiliated HCO B
Multifunction products (MFP)

Monthly Image Volume

- Provides a metric that is understandable by C-Suite execs
- Useful for monitoring and trending –
  - Used to trend average images per study as compared to patient outcomes. As average image count per study increases, does diagnostic accuracy increase? Does turn around time of diagnostic read improve?

Image Access from EMR

- Provides a metric that is understandable by C-Suite execs
- Useful for understanding clinical workflow (referring provider)
- Useful for capacity planning

Foreign Image Ingestion

- Useful for understanding confirmation of “gatekeeper” functionality
- Useful for understanding trends and resulting implications
  - Such as consult load on radiologist for foreign studies

VNA Image Study “Prefetch”

- Useful for understanding customer\end user experience
- Useful for finding anomalous usage patterns

Create Historic Imaging Order Set

Create historic order load from VNA image study archive meta data

- Imaging studies migrated in to UR Medicine VNA from foreign or internal archive
- Studies are modified for demographic information upon migration to match UR Medicine Epic demographics
- Upon migration a data extract is queried from UR Medicine VNA SQL database which includes study information such as modality type, exam code, exam date.
- This extract is converted to HL7 and fed in to imaging downstream systems so that they can now readily access the imaging studies from VNA. Can also be fed in to EMR as reportable order.
- This is a powerful tool for imaging study migration and consolidation

Study Completed

- Imaging studies tech complete timestamp
  - Grouped by hour of day and day of week
  - Average over 52 weeks
- Useful for understanding imaging study acquisition patterns

ED CT Data

- Similar to prior dataset but specific to trauma center ED CT acquisition
- Useful for understanding implications of planned and unplanned downtimes for ED trauma center
  - Demonstrates\confirms known ED encounter and usage patterns
- Useful to plan staffing for 3D\advanced visualization processing lab


Questions?