Making EHR Data More Available for Research and Public Health (MedMorph)

PCORnet and the Research Content Implementation Guide (IG)

May 6, 2021

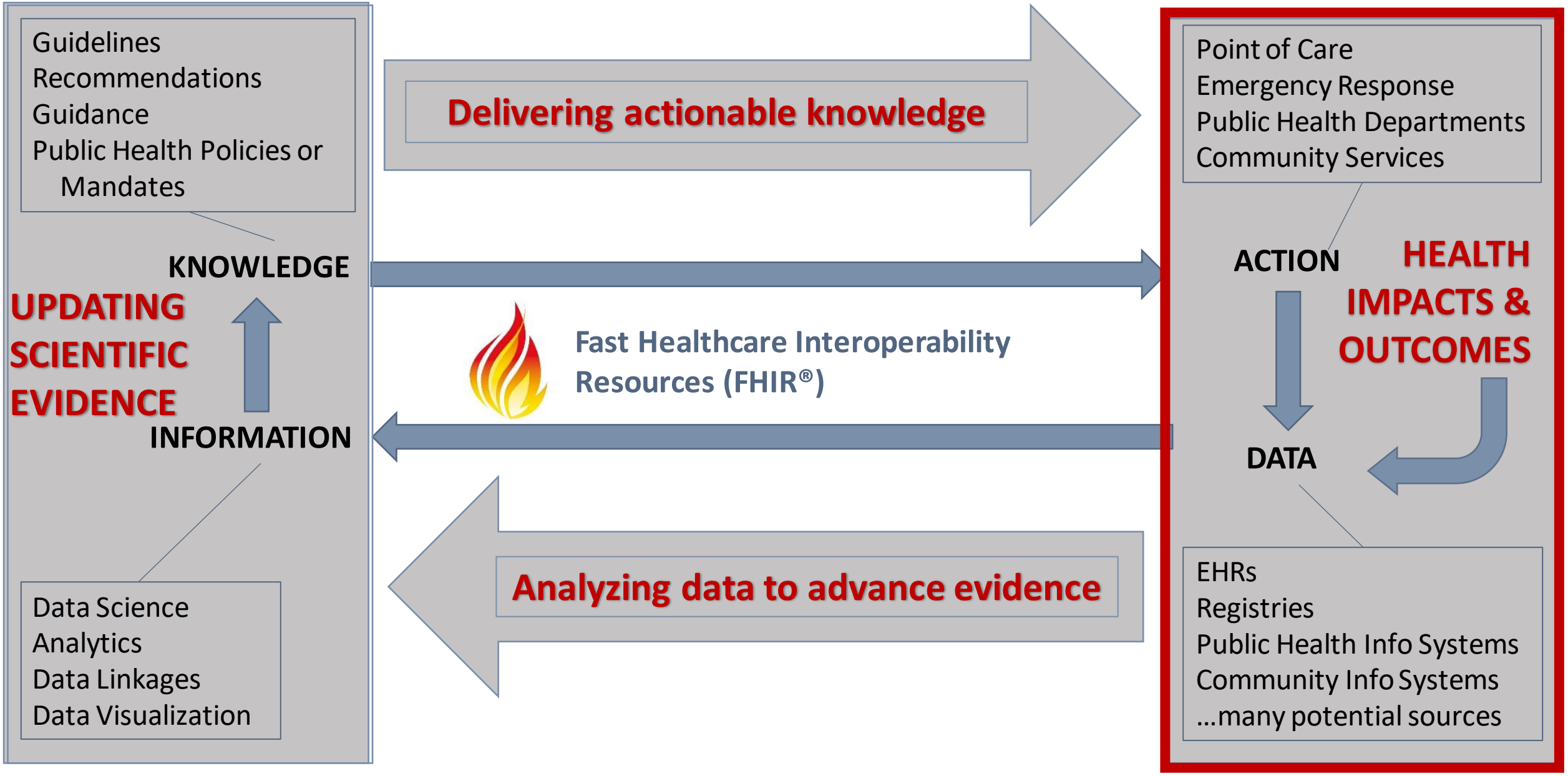
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Meeting Agenda

Topic	Presenter	Time
MedMorph Background	Maria Michaels (CDC)	10 mins
Value for PCORnet	Maria Michaels (CDC)	5 mins
Research Requirements Collected	Becky Angeles	20 mins
Research Requirements Needed	Becky Angeles/Dragon Bashyam	20 mins
Next Steps	Maria Michaels (CDC)	5 mins

MedMorph Background

The Data Lifecycle & Impacts to the Public's Health



Making EHR Data More Available for Research and Public Health (MedMorph)

- Funded by the **Patient-Centered Outcomes Research Trust Fund (PCORTF)** via the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Planning and Evaluation (ASPE)

  Total project timeline: 3 years

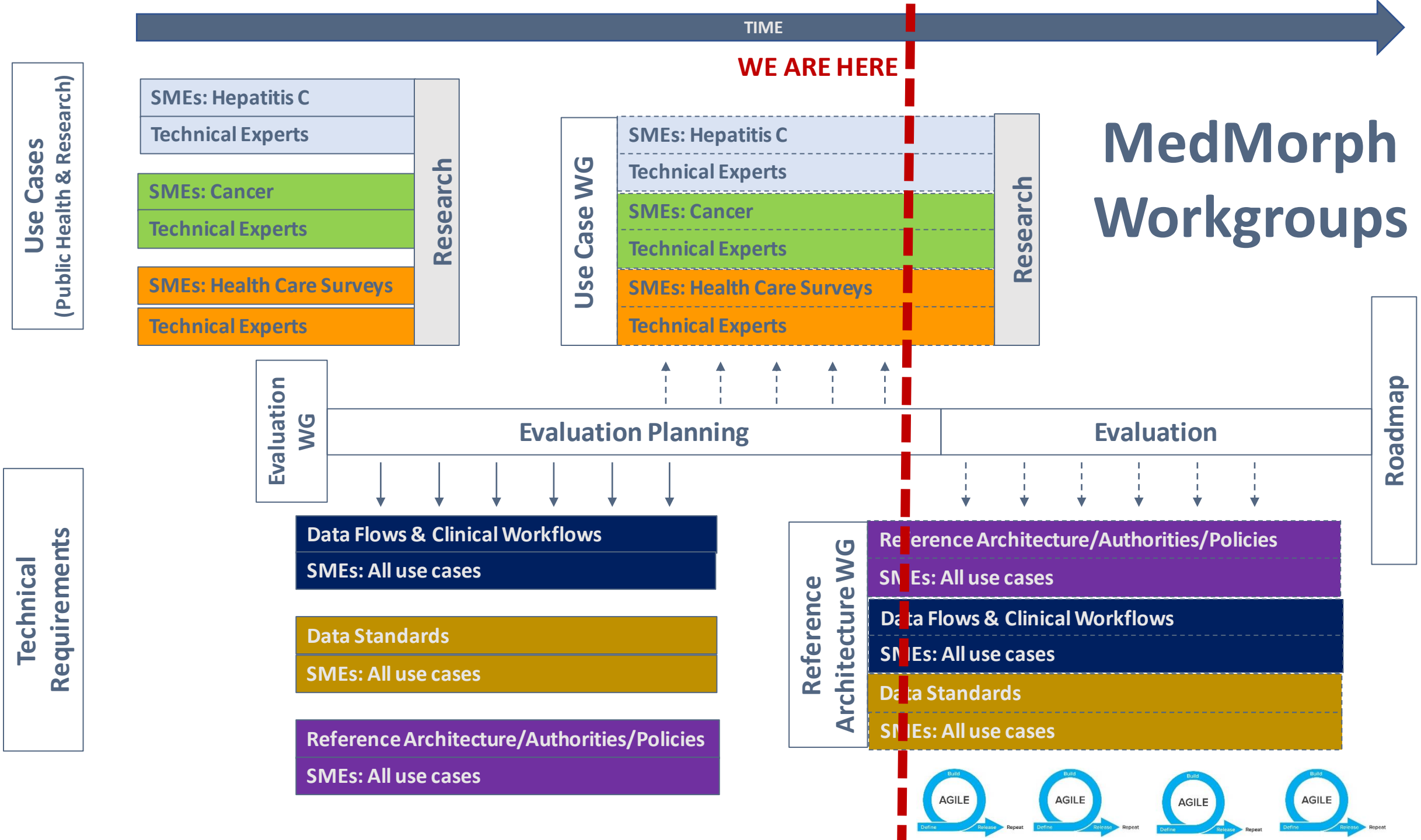
- **PROBLEM:** Patient-centered outcomes researchers and public health professionals need better ways to get data from different electronic health record (EHR) systems without posing additional burden on health care providers
- **GOAL:** Create a reliable, scalable, generalizable, configurable, interoperable method to get EHR data for multiple public health and research use cases
- **OBJECTIVE:** Develop a reference architecture and demonstrate a reference implementation (including implementation guides (IGs)

https://www.cdc.gov/csels/phio/making-ehr-data-more-available.html

Technical Expert Panel (TEP): Participating Stakeholder Groups

- Federal Partners
- Health IT developers
- Clinicians/ Healthcare Organizations
- Medical Societies
- Public Health Organizations
- Evaluation experts
- Laboratory Professional Groups
- Standards experts
- Clinical decision support developers
- Clinical quality measure developers
- Researchers
- Policy or technical support for implementation

***NOTE:** Over 100 individuals from these partner groups have participated in the MedMorph TEP and at least one of its workgroups.*


TIME
WE ARE HERE
MedMorph Workgroups
Use Cases (Public Health & Research)
SMEs: Hepatitis C
Technical Experts
SMEs: Cancer
Technical Experts
SMEs: Health Care Surveys
Technical Experts
Research
Use Case WG
SMEs: Hepatitis C
Technical Experts
SMEs: Cancer
Technical Experts
SMEs: Health Care Surveys
Technical Experts
Research
Roadmap
Evaluation WG
Evaluation Planning
Evaluation
Technical Requirements
Data Flows & Clinical Workflows
SMEs: All use cases
Data Standards
SMEs: All use cases
Reference Architecture/Authorities/Policies
SMEs: All use cases
Reference Architecture WG
Reference Architecture/Authorities/Policies
SMEs: All use cases
Data Flows & Clinical Workflows
SMEs: All use cases
Data Standards
SMEs: All use cases
AGILE
AGILE
AGILE
AGILE

Technical Expert Panel:

End Users, Data Recipients, Stakeholders – Including representatives of additional use cases

Foundation of standards supported by health IT certification (CCDS/USCDI, APIs, FHIR)

Fully Modeled Use Cases

Hepatitis C, Cancer, Healthcare Surveys

Implementation Guides

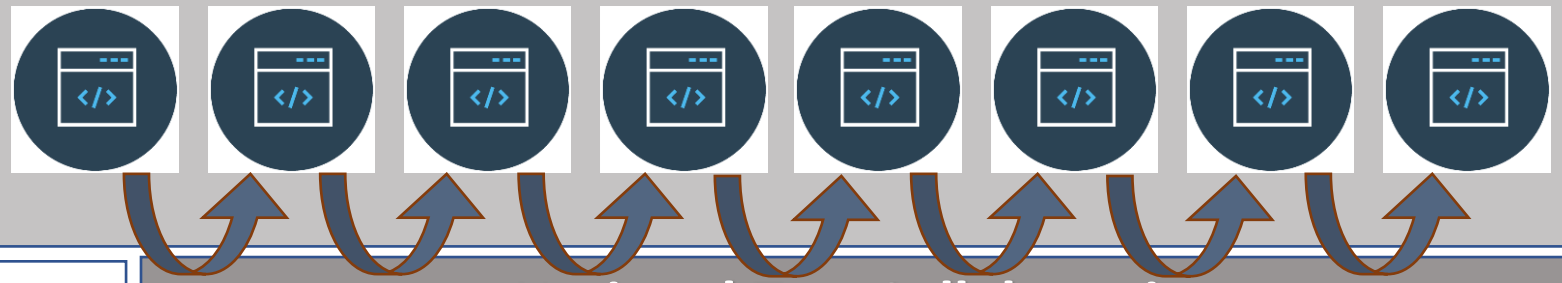
For general use and for each use case

Technological Strategies

To develop scalable and extensible architecture

CCDS: Core Clinical Data Set
USCDI: US Core Data for Interoperability
APIs: Application Programming Interfaces
FHIR: Fast Healthcare Interoperability Resources

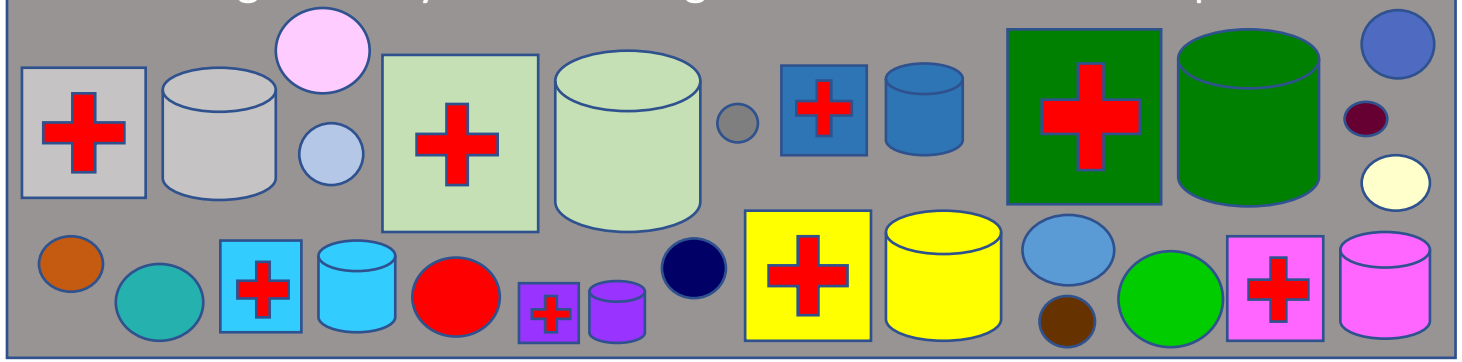
Agile Development: Iterative Design-Build-Test Cycles (test case: Hepatitis C)



- Software
- Clinical organization
- EHR platform
- Other testing partners (e.g., public health departments, registries, health IT developers, etc.)

National Test Collaborative

Including a variety of clinical organizations and their EHR platforms

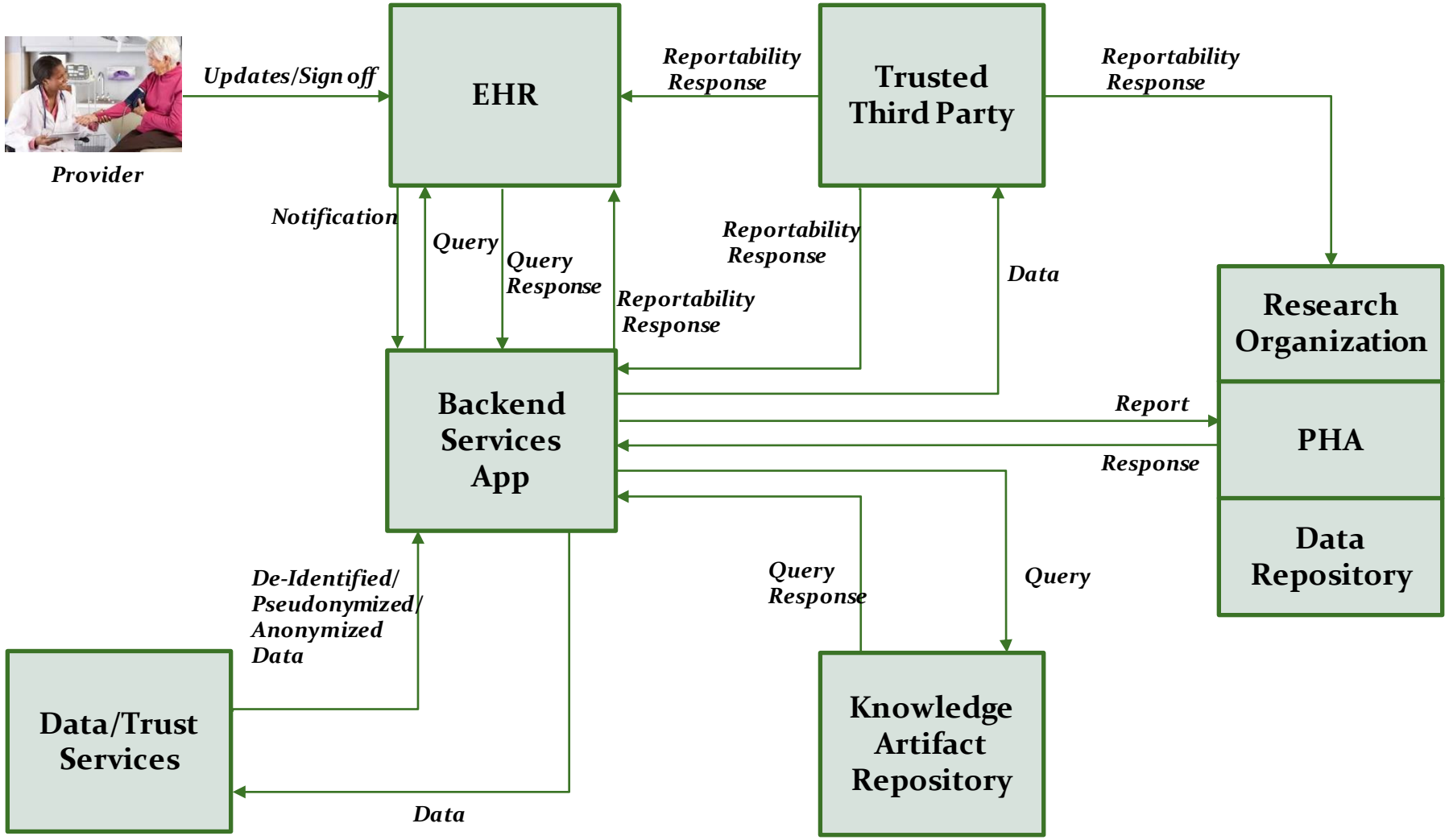


Evaluation Planning

Measure and Evaluate

PRODUCTS: Reference Architecture, Reference Implementation (Open Source Software) & Balloted Implementation Guides, Roadmap for Scalability and Sustainability

MedMorph Abstract Model of Actors and Systems

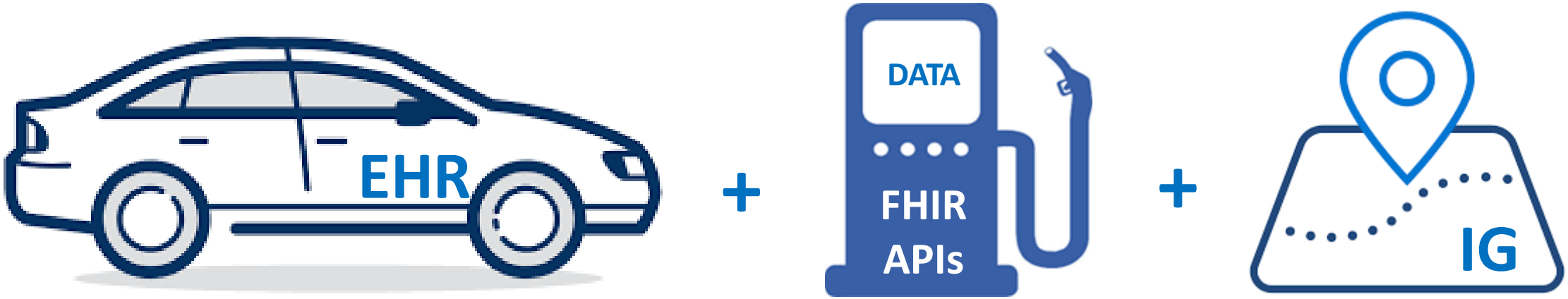


Value for PCORnet

What's in it for PCORnet?

The Research Content IG will help provide…

- Standardization across EHRs, institutions, etc. so that implementation is more consistent & can be more portable between sites or platforms (e.g., if there are transitions between systems or onboarding of more sites)
- Consistent description of how to leverage EHR FHIR implementations for data exchange between EHRs and an endpoint (e.g., data marts)



Research Requirements Collected

Research Requirements Collected

- We have met with Louisiana Public Health Institute (LPHI) a few times and have collected some requirements for Use Stories and a Research Content IG
- Collected Requirements can be found on the Research Use Case Confluence Page
  - https://carradora.atlassian.net/wiki/spaces/MedMorph/pages/858980359/Research+Use+Case+-+DRAFT

User Stories

- User Story 1 – Onboard a New Research Data Partner
  - User story text and diagrams
- User Story 2 – Accessing Additional Data for a Specific Research Question
  - Needs additional work on the user story text and diagrams

Actors

- User Story 1 - Onboard a New Research Data Partner
  - EHR System
  - Backend Service App
  - Data Mart
  - Trust Service Provider
- User Story 2 - Accessing Additional Data for a Specific Research Question
  - Researcher Portal
  - Query Translator and Submitter
  - Backend Service App
  - Data Mart
  - Result Translator and Aggregator

User Story 1 - Onboard a New Research Data Partner

- When a new data partner wants to onboard with a research network, the new data partner executes a regulatory agreement (Master Data Sharing and Use Agreement (DSUA)). The data partner would install the MedMorph Backend Services App (BSA). They would then provision the BSA via the appropriate Knowledge Artifact Repository(ies) (KAR). Once provisioned and trust has been established, the BSA would be operational. The new data partner can now provide research data to the research organization. Due to the trust relationships, any responses can flow back to the new data partner.

Data Elements

- PCORnet Common Data Model (CDM) v6 (needs mapped to FHIR)
- PCORnet Common Data Model (CDM) v5.1
  - Used the CDMH FHIR IG mappings of CDM v4 to FHIR

Content IG Requirements – User Story 1

- Research Data Extraction
  - Requirements for EHR
    - Creation of Group Resource
    - Consent Management
    - Validating Consent Before Disclosing Data
    - EHR APIs and Profiles to be Supported
  - Requirements for Backend Service App (BSA)
  - Requirements for Data Mart
    - APIs and Profiles to be Supported by Data Mart
  - Requirements for a Trust Service Provider
  - Sufficiency of US Core Data Elements

Content IG Requirements – User Story 2

- Research Data Query
  - Requirements for Researcher Portal
  - Requirements for Query Translator and Submitter
  - Requirements for Backend Service App
  - Requirements for Data Mart
  - Requirements for Result Translator and Aggregator

Research Requirements Needed

FHIR IG Proposal for the Research Content IG

- https://confluence.hl7.org/display/FHIR/Research+Data+Exchange

User Story 2 – Accessing Additional Data for a Specific Research Question

- An investigator approaches a research organization with a specific research question that wants to acquire data from the organization, but the organization does not currently have access to the data. The research organization negotiates an agreement and the DUA, IRBs are put in place (preconditions).
- Open questions:
  - How does a query get into the BSA? The criteria would need to be established and approved. This needs discussed in the Reference Architecture calls.
  - How do authorities respond to the query - the server would have to handle authorizations. Would the authority be placed on the data receiver? The organization that is sending the data needs to ensure they are only sending what they are supposed to send. This should be a precondition - authorities on both ends (sender and receiver). Note: look at the RA to see if more info is there on this.
- Workflow table, Activity Diagram, and Sequence Diagram need developed based on user story

Data Elements

- PCORnet Common Data Model (CDM) v6 to FHIR Mapping

Use Case Items

- Goals of the Use Case
- Scope of the Use Case
  - In Scope
  - Out of Scope
- Preconditions
- Postconditions

IG Requirements

- http://hl7.org/fhir/us/medmorph/2021Jan/artifacts.html
  - Actor Capability Statements
  - Value Sets
  - Additional Profiles (besides ResearchParticipantGroup)

Next Steps

Next Steps

- Next Meeting:
    - Focus of Next Meeting:
- Test at a Connectathon in June/July

Contacts

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TEP Co-Chairs

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- Bill Lober: lober@uw.edu

Resources/Useful Links

- Research Use Case *(login with Carradora id/password)*: https://carradora.atlassian.net/wiki/spaces/MedMorph/pages/858980359/Research+Use+Case+-+DRAFT
- MedMorph Research Content IG Proposal *(login with HL7 id/password):* https://confluence.hl7.org/display/FHIR/MedMorph+Research
- MedMorph Reference Architecture FHIR IG: http://hl7.org/fhir/us/medmorph/2021Jan/