



The Office of the National Coordinator for  
Health Information Technology

# Making an Impact on Interoperability: High Impact Pilots (HIP) and Standards Exploration Awards (SEA) Cooperative Agreement Program

Mera Choi, Director, Standards Initiatives Division, ONC  
Caroline Coy, Senior Program Analyst, ONC

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# HIP/SEA Program Objectives

- Focus on addressing interoperability through implementation of Technology Solutions
- Support increased use of health information technology solutions
- Incentivize use of standards from the Interoperability Standards Advisory (ISA) and newly emerging standards
- Lessons learned, and evidence generated, by these Cooperative Agreements will help advance industry understanding of health IT's potential



# High Impact Pilots (HIP)

Awardee	Priority Category/ Subcategory	Impact Dimensions	Standards
The Health Collaborative	(3) Care Coordination	<ol style="list-style-type: none"> <li>1) Safety</li> <li>2) Privacy and Security</li> <li>3) Interoperable Exchange</li> </ol>	ADT, CCD, IHE
Lantana Consulting Group	(3) Care Coordination	<ol style="list-style-type: none"> <li>1) Clinical Quality</li> <li>2) Practice Efficiency</li> <li>3) Interoperable Exchange</li> </ol>	ePhCP
RxREVU Inc.	(1) Comprehensive Medication Management (i) Price Transparency at the Point of Care	<ol style="list-style-type: none"> <li>1) Clinical Quality</li> <li>2) Cost Efficiency</li> <li>3) Interoperable Exchange</li> </ol>	FHIR
University of Utah	(3) Care Coordination (ii) Close-Loop (surgical) Referrals	<ol style="list-style-type: none"> <li>1) Clinical Quality</li> <li>2) Cost Efficiency</li> <li>3) Practice Efficiency</li> </ol>	SMART on FHIR



# Standards Exploration Awards (SEA)

Awardee	Priority Category/ Subcategory	Impact Dimensions	Standards
Arkansas Office of Health Information Technology	(3) Care Coordination	1) Interoperable Exchange	CCD
Cincinnati Children's Hospital Medical Center	(4) Self-Identified	1) Cost Efficiency	RFD and FHIR
Sysbiochem	(4) Self-Identified - Genomics	1) Clinical Quality 2) Interoperable Exchange	FHIR

# Presenters

- Deven Atnoor, Chief Technology Officer, Sysbiochem
- Rick Geimer, Chief Innovation Officer, Lantana Consulting Group
- Keith Marsolo, Associate Professor, Division of Biomedical Informatics, Cincinnati Children's Hospital Medical Center

SEA-ONC Award

**FHIR®-based Predictive Analytics:  
A Breast Cancer Pilot**

Sysbiochem, LLC

Date: Dec 1, 2017

# Agenda

- Project Overview
  - Objectives and Goals
  - Planned tasks and Deliverables
- Product Presentation
  - Rationale
  - Status and Achievements
  - Lessons Learnt
  - Post Grant Activities
- Q&A

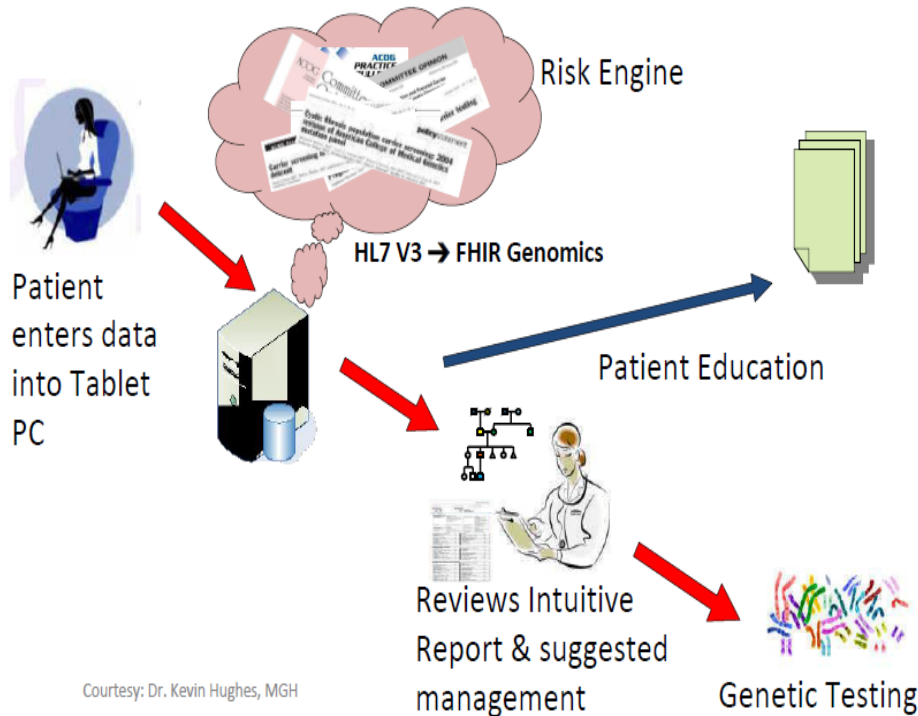
# Value Proposition

The combination of detailed family health history, medical history, clinical evaluation, and genomic sequencing, could shed more light on accurate disease risk prediction, diagnosis, with more informed treatment recommendations and better patient outcomes.

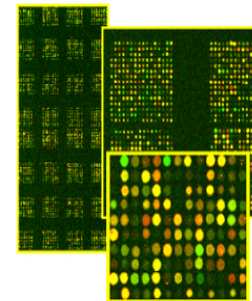
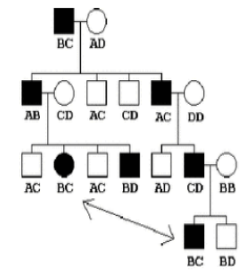


# Value of Family History in Clinical Care

## Current Data Flow (at best)



Courtesy: Dr. Kevin Hughes, MGH



Family history remains the best and least expensive genetic 'test' currently available for clinical use.

A major effort will entail developing tools to collect this information –

1. In a standardized format,
2. Store it in the patient's electronic health record,
3. Apply risk assessment, and
4. Develop messages to clinicians that may alter patient care based on the information obtained.

# Project Objectives and Goals

- Build a minimal viable product for FamilyMemberHistory (FHx) FHIR harmonization and return of validated analytics w/ message intact.
  - To provide merged risk assessment mappings with FHIR message – standardized and unified by working with the appropriate workgroups
  - Merging genetic test data to FHx message
  - Build a module that will merge FHIR messages from various sources to create the standard FHx message
  - Create a web-service for getting risk propensities for the patient.

# Project Deliverables

- Standards for CDS analytics (FHIR/HL7)
  - Interoperable Message: Provide cancer risk assessment mappings for integration into any third party system
- Standards Harmonization: Validate Family Member History tools to support the round-trip payload for CDS. (including genomic test observations)
  - Provide beta demonstration tool for vendors and hospitals to integrate analytics for use by providers

# Goals

- Build a common/Harmonized FHIR based FamilyMemberHistory profile
- Build a round-trip application
  - Submit FHIR based message to HughesRiskApp
    - By translating the message that application understands
  - Return risk profile
    - By translating the message into FHIR based message
  - Consume the message for display to clinician

# FamilyMemberHistory

## Minimum Data Elements - HughRiskApps

<b>Demographic</b>	Age
	Gender
	Alive or dead
	HL7 Fx Structure – relationship
	Identical Twins
	Race / ethnicity
<b>Disease / Condition Hx</b>	
	Age of onset
	Ovarian Cancer
	Breast Cancer
	Oophorectomy
	Mastectomy
<b>Genetic Observation</b>	
	Code
	Category
	Interpretation

# FHIR resources profiles and extensions

## Resource

- \* FamilyMemberHistory
- \* Observation

## Profile and extensions

- \* [FamilyMemberHistory-Genetic](#) profile
- \* [family-member-history-genetics-parent](#) extension
- \* [family-member-history-genetics-observation](#) extension

# Achievements

- Harmonized FHIR based FamilyMemberHistory with RiskAssessment
- Built a web-service to consume the FHIR message
  - Return FHIR response including RiskAssessment
- Successfully transmitted message from IMH
- Building a harness to submit large datasets from IMH

# Impact Measures

## \* Interoperable Exchange

- \* Process the data through interoperable FHIR enabled pipeline, and return the results back
- \* Track the number of FHIR messages being translated via the application interface

Interoperable exchange			Q1 Actual	Q2 Actual	Q2 Actual	Q4 Actual
Baseline	Original	Updated				
Q1 Target	0	0	0			
Q2 Target	1000	10		10		
Q3 Target	2000	1000			3000	
Q4 Target	0	1990				30
Total		3000	0	10	3010	3040



# Family Member History Summary Status

- \* Extension added to FMH – Genetic parent
  - \* <http://hl7.org/fhir/StructureDefinition/family-member-history-genetics-parent>
- \* Extension Genetic Observation
  - \* <http://hl7.org/fhir/StructureDefinition/family-member-history-genetics-observation>
- \* Mapping between Risk V3 and Risk Assessment FHIR
  - \* <https://www.hl7.org/fhir/riskassessment.html>
- \* US realm based profile – Family Member History
  - \* Containing race and ethnicity
    - \* <https://www.hl7.org/fhir/extension-us-core-race.html>
    - \* <https://www.hl7.org/fhir/extension-us-core-ethnicity.html>

# Lessons Learnt

- \* Resource Availability
- \* Infrastructure Constraints

# Post grant activities

- \* Universal Adapter
- \* Wider Web service availability
- \* SMART app

Thank you.

**Questions?**

# ONC-HIP: PHARMACIST CARE PLAN (PHCP)

## ONC Annual Meeting

Rick Geimer  
Lantana Consulting Group

## ONC High Impact Pilot Grant

- Awarded to Lantana Consulting Group
- Collaborators:
  - Community Care of North Carolina (CCNC)
  - PioneerRx
  - QS/1

## 1. Improve practice efficiency by

- Eliminating duplication of effort by pharmacists
- Supporting pharmacists to focus on patients at high risk for negative outcomes and developing care plans incorporating CMRs for those patients

## 2. Improve clinical quality by

- Enhancing free-text narratives with structured data
- Sharing structured data from patient interactions between providers, pharmacist and payers

## 3. Support interoperable exchange by enabling CCNC to

- Receive PhCPs from pharmacy management systems
- Validate against the specification

# Phases of the Project

**Phase 1:** Project Launch, Standards Development, and Training

**Phase 2:** Initial Implementation, Refinement, and Testing

**Phase 3:** Full Implementation and Data Collection

**Phase 4:** Data Analysis and Reporting



### Three key tools placed into the public domain:

- CDA (Clinical Document Architecture) and FHIR® (Fast Health Interoperable Resources) implementation guides (IGs) for PhCPs
- A library of bi-directional transformations converting PhCP FHIR to and from PhCP CDA
- PhCP FHIR and PhCP CDA training for implementers delivered in person and materials delivered to ONC

# Dual CDA/FHIR IGs

- First dual CDA/FHIR IG development project
- Included CDA and FHIR examples
- Demonstrated a viable pathway for CDA/FHIR integration and transition planning

CDAR2\_IG\_CCDA\_MTM\_CAREPLAN\_R1\_01\_2017SEP\_Introductory\_Material



**HL7 CDA® R2 Implementation Guide: Pharmacist Care Plan Document, Release 1 - US Realm**  
**Volume 1 — Introductory Material**  
September 2017

The screenshot shows the FHIR Current Build web application interface. The top navigation bar includes Home, Documentation, Modules, Resources, Profiles, Extensions, and Operations. The main content area is titled "Pharmacist Services and Summaries (FHIR)" and contains a notice: "This is a pre-release of a future version of the Pharmacist Care Plan FHIR IG (expected to be STU 1). There is no current official version. For a full list of available versions, see the Directory of published versions." Below the notice are tabs for Overview, Resources (selected), Value Sets, Code Systems, and Extensions. A table lists profiles defined in the guide:

Profile Name	Description
Pharmacist Care Plan Document (FHIR)	
PhCP Intervention List	
PhCP Intervention Request Group	
PhCP Encounter	
PhCP Medication Dispense	
PhCP Care Coordination	
PhCP Education Procedure	
PhCP Referral ProcedureRequest	
PhCP Coverage	

At the bottom of the page, there is a footer with copyright information: "© HL7.org 2011+. FHIR STU3 Candidate (v3.1.0-12258) generated on Mon, Jul 31, 2017 10:17+1000. QA Page Links: Search | Version History | Table of Contents | PUBLIC DOMAIN | Propose a change"

# CDA <—> FHIR Transforms

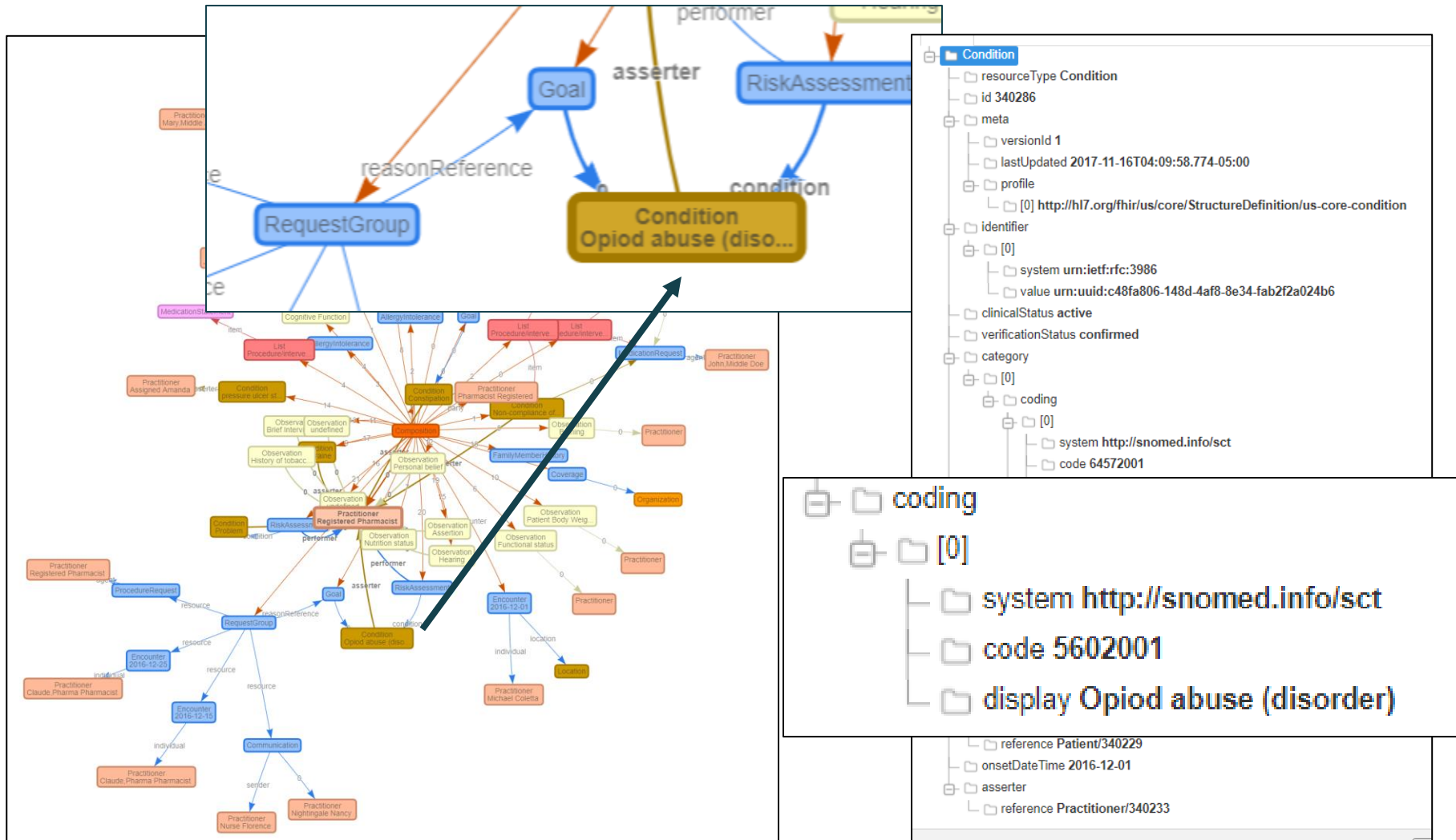
- Open Source
- Targets the PhCP document type, but extendable to others
- Bi-Directional
  - **FHIR to CDA:** Comply with existing C-CDA standards while moving early to FHIR
  - **CDA to FHIR:** Load FHIR systems and servers with C-CDA data

# CDA to FHIR Transformation

```
<observation cl
  <!-- [C-CDA R
  <templateId r
  <id root="1a6
  <code code="5
    codeSystemN
  <translatio
    displayNa
  </code>
  <statusCode c
  <effectiveTim
    <low value=
  </effectiveTi
  <value xsi:ty
    codeSystemN
  </observation>
```

```
<Condition>
  <meta>
    <profile value="http://hl7.org/fhir/us/core/StructureDefinition/us-core-condition"/>
    <!--CDA templateId: urn:hl7ii:2.16.840.1.113883.10.20.22.4.4:2015-08-01-->
  </meta>
  <identifier>
    <system value="urn:ietf:rfc:3986"/>
    <value value="urn:uuid:1a673d3c-0a8a-4c79-974e-83aa84df1b2a"/>
  </identifier>
  <clinicalStatus value="active"/>
  <verificationStatus value="confirmed"/>
  <category>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="55607006"/>
      <display value="Problem"/>
    </coding>
    <coding> [4 lines]
  </category>
  <code>
    <coding>
      <system value="http://snomed.info/sct"/>
      <code value="14760008"/>
      <display value="Constipation"/>
    </coding>
  </code>
  <subject>
    <reference value="urn:uuid:92ace695-0312-4b1d-803e-98d41bcaa5b0"/>
  </subject>
  <onsetDateTime value="2016-08-19"/>
```

# ClinFHIR Resource Graph



# Pharmacy Management Vendor Training

## Training plan:

- 3 days for CDA/FHIR training
- 1 week virtual Connectathon

**Initial target:** 2 vendors

**Final trained:** 22 vendors

## Implementation of the standard, improved:

- **Practice efficiency** (objective #1)
  - Reducing redundant manual data entry
  - Increasing time for patient engagement with pharmacist
- **Clinical quality** (objective #2)
  - Increasing structured data capture, supporting automated clinical quality measurement
  - Speeding data sharing (pharmacies → CCNC), supporting reporting
- **Interoperability** (objective #3)
  - Delivering standard-based structured and coded reports
  - Validation, conversion (CDA to FHIR) done by CCNC

### Clinical Quality—structured data capture, supporting automated clinical quality measurement

- Assessed PhCP data for calculating three pharmacy-based measures:
  - Percent of Antihypertensive Drug Users Adherent to Antihypertensive Therapy
  - Percent of Antihyperlipidemic Therapy Users Adherent to Antihyperlipidemic Therapy
  - Percent of Patients Adherent to Multiple Chronic Medications
- Found that PhCP specifications and submitted files contained all data elements required to calculate these measures



### **Interest in the standard grew substantially during the pilot.**

- At start of pilot, only 2 pharmacy management vendors involved
- By the end of pilot, trained 20 more organizations

**The standard will be reviewed by a larger audience as both specifications move through the HL7 ballot process, opening an opportunity for nationwide adoption.**

# Questions?

# Cincinnati Children's Hospital Medical Center Standards Exploration Award Project Summary

## ONC Annual Meeting

Keith Marsolo, PhD

Associate Professor

Division of Biomedical Informatics

Cincinnati Children's Hospital Medical Center

December 1, 2017

# Cincinnati Children's Hospital Medical Center (CCHMC) – FY16 numbers

- 629 inpatient beds
- 1.3M patient encounters
- 15K+ employees
- \$200M in research grants & contracts (3<sup>rd</sup> in pediatrics)
- Informatics / Information Technology support
  - Operations – Department of Information Services (IS)
  - Research – Division of Biomedical Informatics (BMI)

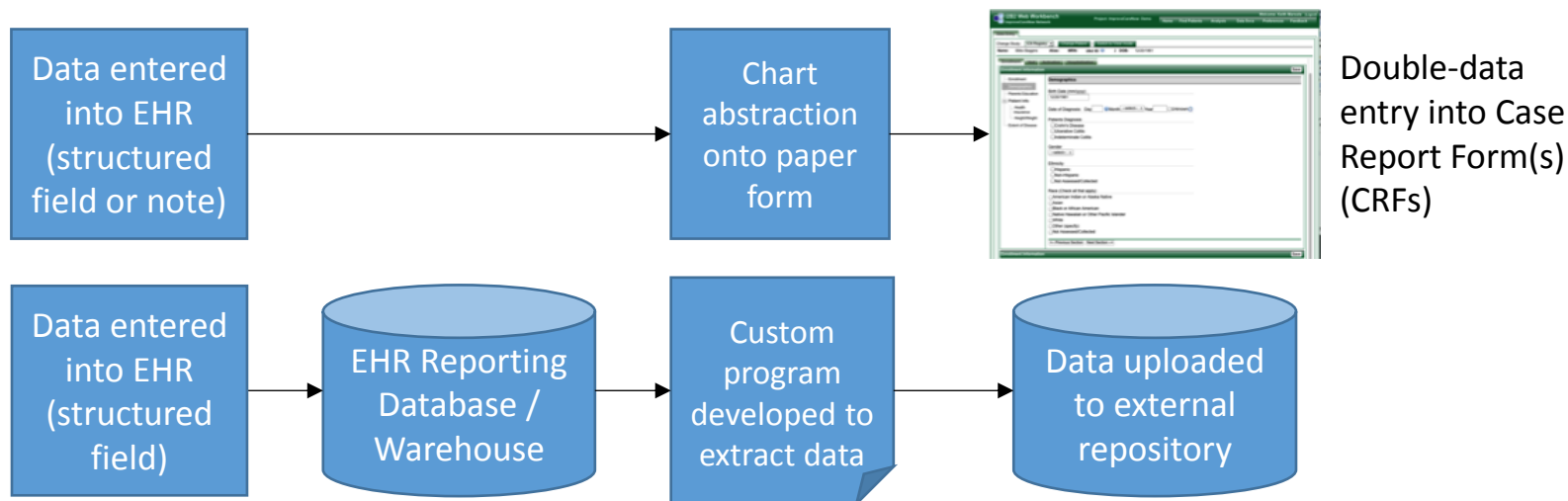


# CCHMC Biomedical Informatics Data Services

- Service areas
  - Research data warehouse & Honest Broker service
  - Support for distributed research networks
  - *Infrastructure & standards to support learning health systems*
  - *Integration with the electronic health record (EHR) to support quality improvement (QI) & research*
- Structure
  - ~25 staff, mix of application & database developers, project management
  - Led by staff director & faculty advisor (Marsolo)
- Project is a collaboration between BMI & Information Services

# Motivation

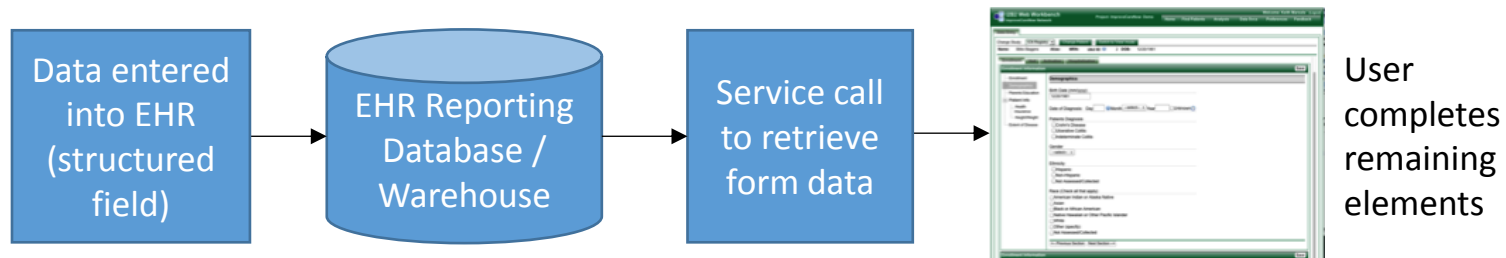
- Learning health system
  - Data captured in EHR supports clinical care, QI & research
  - Supports learning cycle – knowledge to practice & practice to knowledge
- Reusing data from the EHR – typical workflows:



- Challenge with option #2 – process to develop/deploy standardized data collection forms within the EHR at scale is cumbersome

# Other alternatives

- *Capture data in EHR -> pre-populate eCRF -> coordinator completes remaining fields*



- Potential benefits
  - Save time on chart abstraction
  - No need for EHR-specific form (eventually)
- Potential drawbacks
  - Resources need to configure & maintain new interfaces are unknown

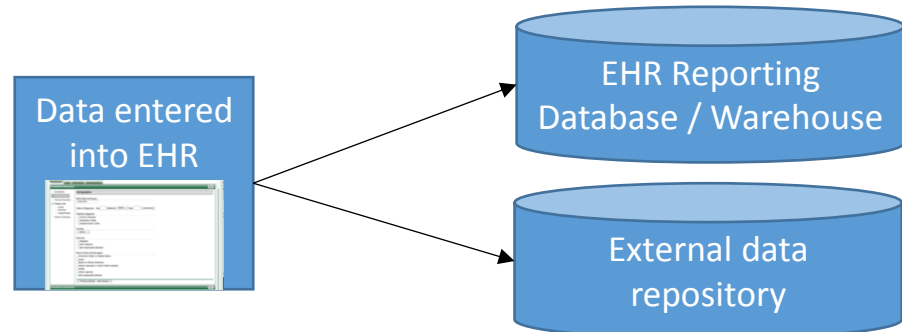
# Proposed project

- Description
  - Collect data on time required to complete eCRFs using double-data entry compared to eCRFs launched from the EHR with pre-populated fields
  - Test using ongoing pragmatic clinical trial, CCHMC as testbed
- Interoperability need(s):
  - Leveraging the EHR and other health information technology (HIT) systems to integrate healthcare and clinical research
  - Pre-population of research CRFs from EHRs
- Priority category – Self-identified
- Impact Dimensions – Cost Efficiency
  - Metric – time to complete form; time spent on chart abstraction



# Relevant standards

- Retrieve Form for Data Capture (RFD)
  - Retrieve Form
  - Display & complete Form
  - Return data to requesting application
- Fast Healthcare Interoperability Resource (FHIR)
  - Application Programming Interface (API)-like approach to healthcare data
  - Web service-based requests for common data elements
- SMART on FHIR
  - Authentication & authorization – OpenID and OAuth2
- Structured Data Capture
  - Successor to RFD
  - May eventually allow external form to write to EHR & to external repository
  - Very early in adoption



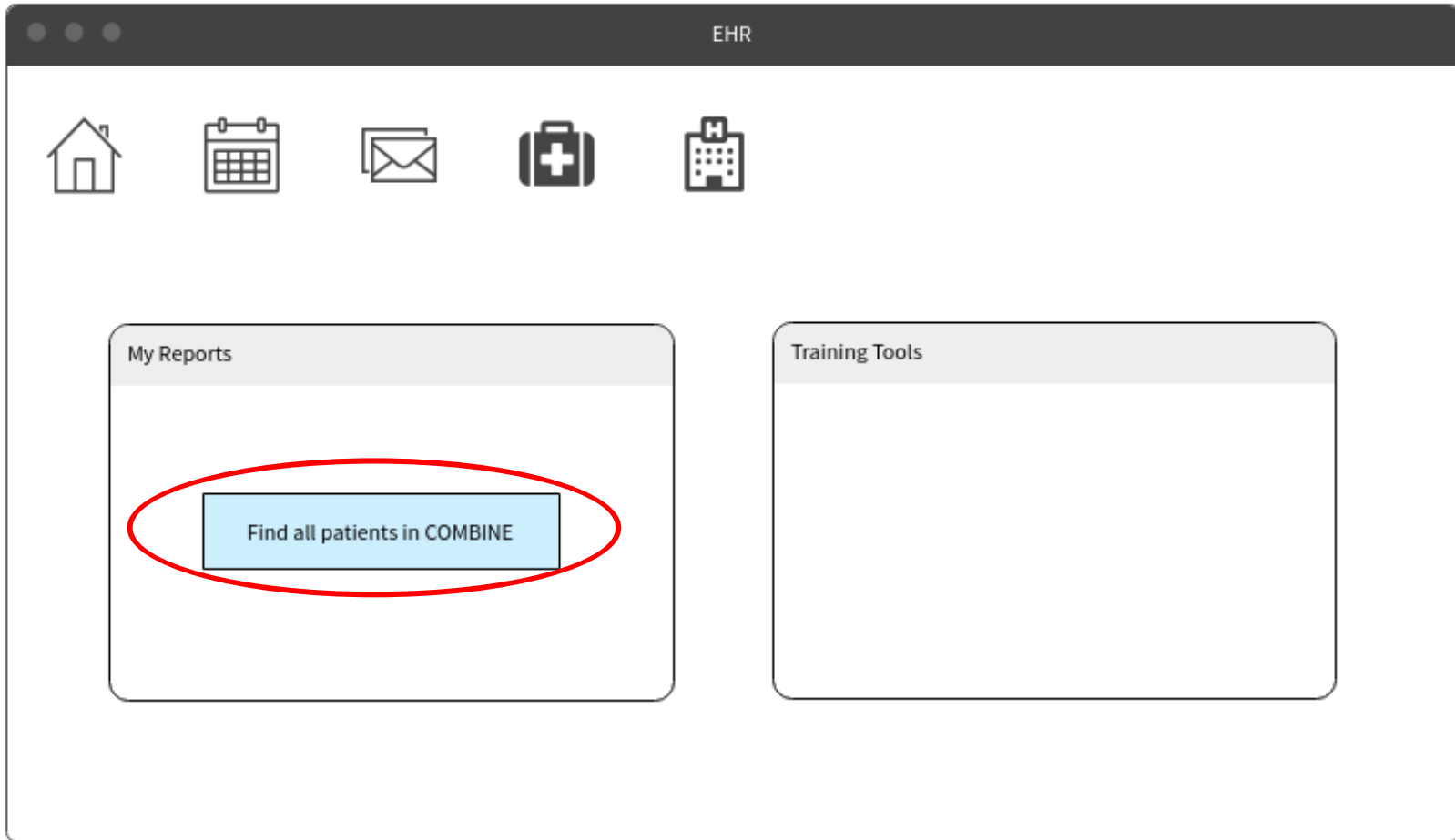
# Trial information

- Clinical Outcomes of Methotrexate Binary treatment with INfliximab or adalimumab in practiceE (COMBINE)
  - Funded by the Patient-Centered Outcomes Research Institute (PCORI)
  - Compare outcomes of patients with Crohn's Disease who receive anti-tumor necrosis factor (anti-TNF) medications with those that receive anti-TNFs and low-dose methotrexate
- Patients recruited from centers in the ImproveCareNow (ICN) Network
  - 106-center quality improvement & research network focused on pediatric Inflammatory Bowel Disease
- Trial data are collected in a module of the ICN registry
  - Screening / randomization + follow-up study visits (every ~10-13 weeks)
  - Currently have 102 patients randomized across 25 sites

# High-level project tasks

- Determine optimal placement in EHR for “button” (hyperlink) to launch registry
- Develop extensions to allow registry to be called from the hyperlink
- Reconfigure the registry to minimize extraneous display content
- Configure web services to allow EHR data to pre-populate the CRF
- Allow research coordinator to log in to the registry using EHR credentials

# Project workflow



\*Mockup. Unable to share full EHR screenshot publicly.

# Project workflow (2)

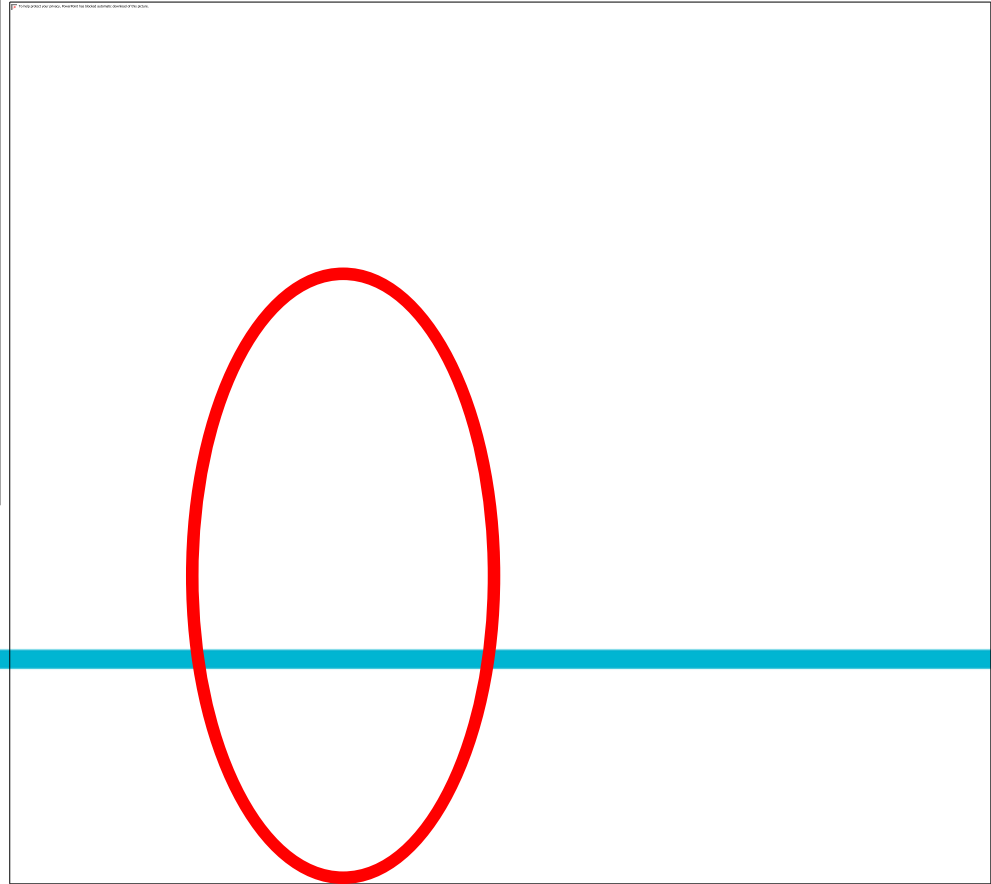
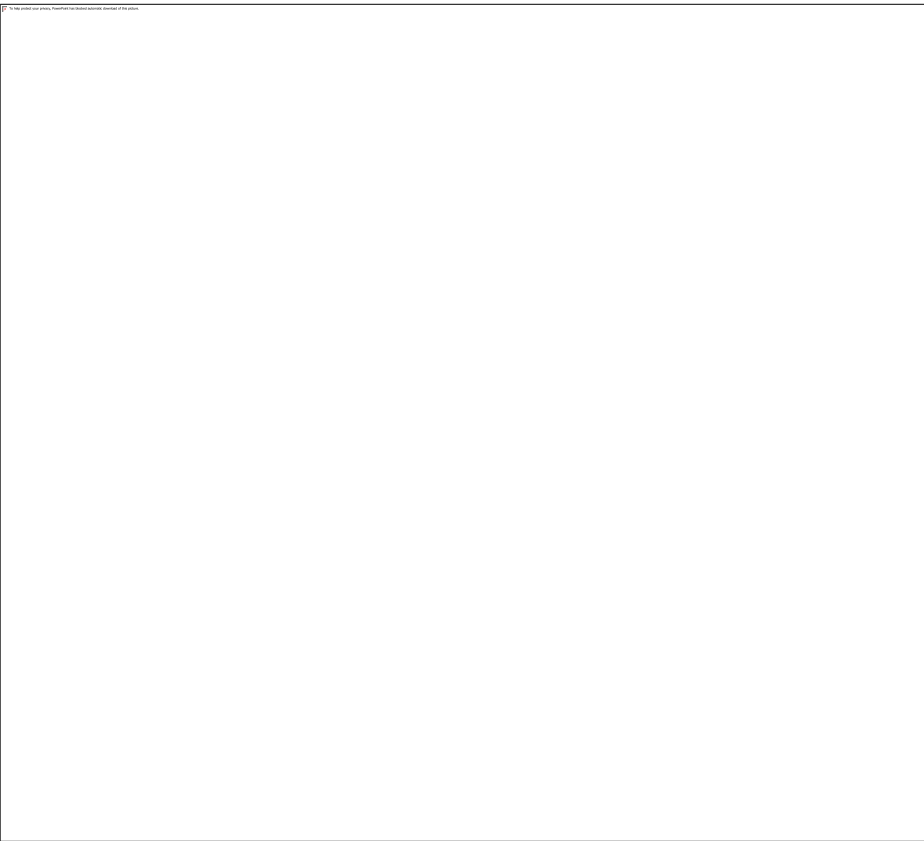
The image shows a mockup of an EHR interface. At the top, there is a header bar with the text 'EHR' and five icons: a house, a calendar, an envelope, a first aid kit, and a hospital building. Below the header is a menu bar with 'File', 'Edit', 'View', and 'Help'. The main content area features a table with six columns: MRN, Patient Name, Age, Sex, Enrollment Status, and Study Identifier. The table contains three rows of patient data. The second row, for 'Patient Test2', is highlighted in blue. Below the table is a section titled 'COMBINE Hyperlink Report' containing a blue hyperlink 'Launch COMBINE Study CRFs' which is circled in red.

MRN	Patient Name	Age	Sex	Enrollment Status	Study Identifier
12345	Patient Test1	7 yrs	Female	Enrolled	CCHMC IRB#2015-8936
12346	Patient Test2	8 yrs	Male	Enrolled	CCHMC IRB#2015-8936
12347	Patient Test3	10 yrs	Female	Enrolled	CCHMC IRB#2015-8936

COMBINE Hyperlink Report

[Launch COMBINE Study CRFs](#)

# Project workflow (3)



# Results

- Deployed technology solution ~1 month ahead of schedule (early June 2017)
- Collected data on study visits pre-deployment (CCHMC & 2 other COMBINE sites) & post-deployment (CCHMC)
  - Slower-than-expected-recruitment limited # of visits
  - Initial findings: decrease in abstraction time (~10 minutes); slight increase in data entry time (~1.5 minutes) – may artifact from low number of visits or potentially for time spent validating pre-populated data

## Pre-deployment

Site	Abstraction	Data entry
CCHMC	20	6
Site X		5
Site Y		28*
Site Y		38*
Site Y	30	4
<b>Average (minutes)</b>	<b>25</b>	<b>5</b>

## Post-deployment

Site	Abstraction	Data entry
CCHMC	10	3.35
CCHMC	15	9
CCHMC	20	6
CCHMC		8
<b>Average (minutes)</b>	<b>15</b>	<b>6.6</b>

\* Numbers reported appear to combine abstraction & data entry into a single value; subsequently removed from analysis

# Key findings / Lessons learned

- Time savings limited by number of CRF elements captured discretely in EHR
  - COMBINE study visit CRF only had a handful of applicable variables (weight, labs)
- Initial sequencing of events posed a challenge (e.g., tried to request access to web service first)
  - Bring all functions together first – make sure everyone understands hand-offs and sequencing
  - Frequent huddle to ensure that progress continues
- Process for deploying & enabling access to FHIR resources is not well-defined
  - Frequent contact with vendor to understand all the steps
  - FHIR standard does not reflect the way data have been captured over time – will need to validate each variable for time range in question
- OpenID not completely supported by EHR vendor
  - Vendor-specific workaround exists, but was not well-documented
  - Suggested as area for vendor improvement in documentation & training



# Acknowledgements

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  - Keith Marsolo
  - Dan Jeffers
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  - Jeremy Nix
  - Ron Bryson
  - Katie Lake
  - Jareen Meinzen-Derr
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  - PCS-1406-18643 (PCORI)
  - CCHMC
- IS resources
  - Jason Napora
  - Kevin Leaton
  - Frank Menke
  - Pushya Ramaswamy
  - Wayne Geers
  - Megan Bachman
  - Nicole Slonaker
  - Steve Metz

For more information, please contact:

Keith Marsolo

[keith.marsolo@cchmc.org](mailto:keith.marsolo@cchmc.org)



Questions?