CodeX™ HL7 FHIR Accelerator

Steve Bratt, CodeX Program Manager (sbratt@mitre.org)
July 26, 2022
ONC FHIR WG

https://www.hl7.org/codex/
https://confluence.hl7.org/display/COD/CodeX+Home
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• CodeX Intro

• mCODE – CodeX’s 1st HL7 FHIR IG
  • The common language for cancer data collection and sharing

• CodeX Community

• Use Cases

• Appendices:
  • Use Case summaries
  • Membership Information
The CodeX HL7 FHIR Accelerator

A Member-driven community accelerating interoperable data modeling and implementation around the FHIR and mCODE HL7 standards, leading to substantial improvements in health care and research in oncology, cardiovascular medicine and genomics

http://hl7.org/CodeX
CodeX works closely our siblings ...

What is a FHIR Accelerator?
“... creation and adoption of high quality FHIR Implementation Guides .. to move toward the realization of global health data interoperability”
https://www.hl7.org/about/fhir-accelerator/
Data are collected and shared via FHIR Implementation Guides, like the mCODE standard and CodeX supplemental IGs

Ensuring every patient’s journey improves all future care
1. Welcome!
...a motivated Community of key stakeholders necessary for success

2. Prioritize
...Use Cases around community commitment and potential to improve patient care and research

3. Build
...core, standard FHIR IGs (ex: mCODE) and supplemental IGs

4. Implement
...standards into real products, systems and new workflows

5. Execute
...Pilots in the field with patients, providers and other future users to demonstrate impact and feasibility, and enable rapid adoption and scaling
People’s lives are depending on what we do and what this data tells us.

minimal Common Oncology Data Elements

Every patient’s journey improves all future care

DR. MONICA BERTAGNOLLI
Chief of Surgical Oncology, Dana-Farber Cancer Institute/Brigham and Women’s Hospital
Professor of Surgery, Harvard Medical School
President, Alliance for Clinical Trials in Oncology
A FHIR-based core set of common data elements for cancer that is standardized, computable, clinically applicable and available in every electronic health record for patients with a cancer diagnosis.

A **standard health record** for oncology.

The **minimal set of data elements** applicable to all cancers, and collected for:

- Standardized information exchange
- Use-case driven and targeted use

Oncology data element domains: **patient, disease, treatment, outcomes, genomics, lab/vital**

VP @JoeBiden discusses #mCODE - our collaboration w/ @ASCO to create a new data standard to improve cancer research & treatment - at today’s @BidenCancer update on progress against cancer bit.ly/2HGnPZ3
#MITREhealth Learn more: health.mitre.org/mcode/

https://www.youtube.com/watch?v=AKklpOuSCE&feature=youtu.be
Cancer patients are willing to share their data in hopes of finding solutions, not just for themselves but for patients in the future.

Smarter Data for the Fight Against Cancer

http://www.hl7.org/CodeX
**CodeX™ Community of Practice**

https://confluence.hl7.org/display/COD/mCODE+Community+of+Practice

A growing group of health systems and other key stakeholders, learning together in a monthly public forum focused on real-world applications of mCODE and new areas of interest around information technology applications across oncology, cardiovascular, and genomics.

Latest developments on mCODE, CodeX, and cancer data exchange

Ask questions and learn from the experience of other community participants

Develop and share best practices for clinical workflows, data modeling, and exchange

![Community Composition](chart)
## CodeX Members
*(July 2022)*

**CodeX Founders**

### Premier

- AMERICAN ASSOCIATION of PHYSICISTS in MEDICINE
- ASTRO
- HL7 International
- Pfizer
- ALLIANCE for CLINICALS & ONCOLOGY

### Principal

- CANCER ACTION Network
- American Cancer Society

### Benefactor

- CIBMTR
- ASCO
- TEMPUS
- Trialjectory

### Government Agency

- CDC
- U.S. FOOD & DRUG ADMINISTRATION
- University of Nebraska Medical Center
- MCSF

### Sponsored Member

- AMGEN
- ONS
- COMP
- OCPM
- NRG Oncology
- SIIM

### Developer/Implementer

- Oncora
- Patientlink
- PRINCIPIA
- Quantum Leap Healthcare Collaborative
- Varian
- Wemedoo
CodeX Governance Structure

**Program Management**
Cross-Program Support Options: Governance Support, Use Case Meeting Support, Architecture, Informatics, Membership Engagement, Communications, Education, Implementation

**Steering Committee**
(elected by Operating Committee)

**Operating Committee**
(1 representative from Paying, Government and Sponsored Members)

**Use Case 1**

**Use Case 2**

**Use Case 3**

**Use Case n+**

**Community of Practice**

**External Expert Groups**

**WG's & other Accelerators**

**HL7 International**
CodeX Use-Cases
Discovery -> Planning -> Execution

https://confluence.hl7.org/display/COD/CodeX+Use+Cases

**Oncology**
- mCODE++ Extraction
- EHR Endpoints for Cancer Clinical Trials
  (including, future extensions of the ICAREdata study)
- Integrated Trial Matching for Cancer Patients and Providers
- Cancer Registry Reporting
- Radiation Therapy Treatment Data for Cancer
- Prior Authorization in Oncology
- Risk Evaluation and Mitigation Strategies (REMS)

**Cardiovascular**
- CardX - Hypertension Management

**Genomics**
- GenomeX - FHIR Genomics Data Exchange
- GenomeX - Enabling Access to Complex Genomic Information through FHIR Genomics Operations

-------- Stages --------
- Discovery
- Planning
- Execution
Potential New CodeX Oncology Use-Cases Under Discussion

- Structuring inclusion and exclusion trial matching criteria
- Regulatory grade RWE
- Oncology nurse case manager
- Clinical quality measurement

- Internationalization of mCODE (could be tied to one or more Use Cases)

- Oncology Clinical Pathways (hibernating – awaiting community interest)
Building an Engaged Network of Health System Solutions

Brigham and Women’s Hospital
City of Hope
Dana Farber Cancer Institute
Duke University
Heartland Cancer Research
Massachusetts General Hospital
McGill University
MD Anderson Cancer Center
Metro-Minnesota Community Oncology
Missouri Baptist
Northwell Health
Rush University Medical Center
Saint Joseph Mercy Health System
The Ohio State University

The University of Chicago Medicine
ThedaCare
Trinity Health
UNC Lineberger Comprehensive Cancer Center
University of California San Francisco
University of Kansas Medical Center
University of Michigan
University of Pennsylvania
University of Texas Southwestern
Veterans Health Administration
Virginia Commonwealth University
Wake Forest University
Washington University in St. Louis

Oncoclinicas
Taiwan Cancer Registry
Netherlands Cancer Registry
UC Los Angeles
Mayo Clinic

Scaling through Industry Implementations

CancerInsights
Cerner
Clinical Pipe
Elekta
Elsevier
Epic
Flatiron
IQVIA
Jitterbit
MassiveBio
Mettle Solutions
Microsoft
NeuralFrame
Nuance
PatientLink
Pfizer
RaySearch
Roche
Semedy
Syntropy
Trial Scope
TrialJectory
Varian
Wemedoo

IC = ICAREdata, TM = Trial Matching, RR = Registry Reporting, RT = Radiation Therapy Treatment Data

Engaged & Previously Expressed Interest – Engaged in multiple conversations and/or in the process of being Active
Active – Committed or actively participating in planning, design, development, piloting
Tools being leveraged by the CodeX Community

This is a list of GitHub repositories that contain FSH code. Only repositories that use FSH are included. Please see the README for more details on how this works. Last refreshed about 4/30/2023.

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FSH School

FSH School is a free resource provided by the MITRE Corporation for learning and applying FHIR Shorthand. FSH School includes FSH Online (a coding playground for FHIR Shorthand complete with example of FSH), FSH Finder (a list of public FSH projects found on GitHub, refreshed daily), as well as documentation and tutorials for naming SUSHI and goFSH (the compiler and decoder for FSH).

https://fshschool.org/about/

https://fshschool.org/fsh-finder/

https://fshschool.org/about/

Inferno

Inferno Framework is a rigorous and extensible testing development framework for HL7 FHIR® and beyond.

This is an instance of Inferno hosted by ONC for purposes of testing for the ONC Health IT Certification Program and to support community-driven health IT standards development projects. You can build your own tests using Inferno Framework and host your own local instance of Inferno by following the instructions in "Inferno Framework Development" below.

https://inference.healthit.gov/

Lantern

Lantern is an open source development supported by the MITRE Corporation for creating, testing, and supporting Health Level Seven International (HL7) FHIR®-based patient data and associated health records in a variety of formats. Read our FAQ for more information.

https://lantern.healthit.gov/
Example CodeX Use Case
EHR Endpoints for Cancer Clinical Trials
EHR Endpoints for Cancer Clinical Trials

**CHALLENGE**
- Structured patient outcomes are not available in the EHR to support real world evidence, limiting participation and impact of clinical trials

**OPPORTUNITY**
- Enable investigators to leverage clinical treatment data captured in the EHR to expand participation in clinical research
- Build the foundation to transform clinical trials and cancer research by enabling unprecedented inferences across populations

**DESIRED IMPACT**
- Clinical treatment data captured in the EHR to derive trial endpoints
- Generate research quality data for standard of care patients in the routine care setting
- Expand participation in clinical trials
- Enable generalizability studies to compare clinical trials cohorts for expanded insights
ICAREdata® Multi-Phase Approach

**Goal**
Support the collection electronic health record (EHR) data, based on mCODE, to broaden participation in clinical oncology research.

**Phase 1**
Validation of the Methodology
- Disease Status
  - 5 sites, 2 trials
- 96% Concordance with 95% probability when disease absent

**Phase 2**
Clinical Events and National Scale
- 25+ sites
- 11+ trials

**Phase 2+**
Alignment with Sponsor Objectives
- Funding to support operations and adverse events
- Additional interest to expand
Questions?
codex@hl7.org
sbratt@hl7.org
Appendix
CodeX Use Case Summaries
Use Case Development and Transition Guidelines

https://confluence.hl7.org/display/COD/Use+Case+Development+Guidelines

Members, Potential Members, Thought Leaders

Proposed, Pre-Discovery Use Cases

Use Case Backlog
Proposed Use Cases:

- # 1
- # 2
- # 3
- #N

Discovery

Planning

Selection

Execution

Members and orgs with written commitment to join work together on Use Case Discovery and Planning

Concept and Impact

Team
Members. Commitments.

Plan
Phases. Implementation. Adoption.

Multi-Phased Approach

Steering Committee
Assess preparation for Execution and any resource requests, based on plan and discussions

Led by Members, with regular public meetings

Build/improve FHIR IGs, Implementation in systems, Pilots, Adoption, Scale

Members,
Potential Members,
Thought Leaders

Proposed,
Pre-Discovery
Use Cases

Assess preparation for Execution and any resource requests, based on plan and discussions
mCODE++ Extraction
EHR Endpoints for Cancer Clinical Trials

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Phase 2: Clinical Events and National Scale
- 25+ sites
- 11+ trials

Phase 2+: Alignment with Sponsor Objectives
- Funding to support operations and adverse events
- Additional interest to expand

Objectives:
- Funding to support operations and adverse events
- Additional interest to expand
EHR Endpoints for Cancer Clinical Trials
(As of Jun 2022)

Collaborators
• ICAREdata Health Systems: Dana-Farber, Mass General Hospital, Brigham & Women’s, UChicago, University of Pennsylvania, Metro MN, Ohio State, ThedaCare, UNC, WashU and others

Project Updates
• Currently 10 active clinical trials partnering with ICAREdata with 5 with embedded ICAREdata language and consent and another 5 active trials participating through a companion study protocol.
• Epic native solution for ICAREdata collection is available via Nov 2020 and May 2020 releases
• 8 ICAREdata clinical site partners have built the Epic native tools for ICAREdata collection
• 7 ICAREdata clinical site partners have begun data collection
• 2 ICAREdata clinical site partners have completed the extraction implementation
• 2 ICAREdata clinical site partners have submitted data to ICAREdata infrastructure
• Alliance received grants from FDA and NCI to expand ICAREdata exploration
• ICAREdata Adverse Event pilot completed a draft IG and clinical workflow documentation.
• mCODE extraction framework updated to include AEs and AE site implementation tracker developed for sites.
Integrated Trial Matching for Cancer Patients and Providers

Problem
• Patients are not made aware of clinical trial opportunities outside of their treating institution

Solution
• Create integrated, automated, site-agnostic clinical trial matching by developing open data standards and APIs that enable interoperable, scalable, and accessible clinical trial matching services

Desired Impact
• Patients and providers can easily identify potentially lifesaving therapies much faster with tools that leverage structured data from the EHR
• Researchers can find more patients for their clinical trial
Multi-Phased Approach

**Phase 0**
- Standards Development – demonstration of this capability
- Demonstration and Documentation – [https://confluence.hl7.org/display/CO D/Phase+0](https://confluence.hl7.org/display/CO D/Phase+0)

**Phase 1**
- Retrospective Study – validation of optimized patient data elements
- Results – [https://confluence.hl7.org/display/CO D/Phase+1](https://confluence.hl7.org/display/CO D/Phase+1)
- Presentation Summary - [https://confluence.hl7.org/display/CO D/Trial+Matching+Meetings](https://confluence.hl7.org/display/CO D/Trial+Matching+Meetings)

**Phase 2**
- Prospective Study – integration with health site EHR and PDM application

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TrialScope
UT Southwestern
Inteliquent

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Cancer Action Network
MITRE
Cancer Insights
MassiveBio
PatientLink

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AMGEN
TrialScope
Intelliquest
UT Southwestern
Integrated Trial Matching for Cancer Patients and Providers (Update as of July 2022) (Slide 1 of 2)

Collaborators
- TrialScope
- Inteliquent
- UT Southwestern Medical Center

Project Updates
- **Phase 0** (completed August 2020): demonstrate the ability of a trial matching service to become “mCODE-enabled” and present trial matches back to the patient/provider.

- **Phase 1** (completed September 2021): validate optimized patient data elements can effectively filter clinical trials for patients.
  - Recruited patients to join the Cancer Insights application to test out this capability.
  - Tested patient data from UTSW and Massive Bio.
  - Presented findings during September CoP and October Public Call.

- The HL7 Biomedical Research and Regulation Group sponsors this project; PSS approved by the TSC; Hosted a track at the May HL7 FHIR Connectathon.
**Integrated Trial Matching for Cancer Patients and Providers** (Update as of July 2022) (Slide 2 of 2)

**Collaborators**

- Cancer Action Network
- MITRE
- TrialScope
- Inteliquent
- Amgen
- UT Southwestern Medical Center

**Project Updates**

- **Phase 2** (planning underway): demonstrate value of this project by completing a prospective pilot where the capability is integrated at a health site and in a PDM application. Research aims:
  - Overall clinical trial enrollment
  - Demographic diversity of trial enrollment
  - Impact of navigation and support
  - Analysis of usability
- ACS CAN received a $1M grant by Amgen to support a multi-site pilot
Cancer Registry Reporting

Problem
- Clinical data is stored in disparate systems in multiple data formats
- Variability in data collection processes imposes a high burden on data reporters and negatively impacts understanding of patient care
- Heterogeneity of data collection makes it difficult to aggregate and share data for use in clinical research and standards of care

Solution
- A low-burden, standardized reporting of cancer data from cancer centers to registries that are aggregating data for different reasons

Desired Impact
- As a patient begins and continues cancer care, outcomes are tracked, and effectiveness of care is determined in real time and reported in a low burden and interoperable manner
- Reduce reporting burden and enhance insights into clinical practice
Cancer Registry Reporting
(Update as of December 2021)

Collaborators

Pilot Activity
Proof of concept
California focused proof of concept with UCSF, CA Cancer Registry, CIBMTR. Using CDC’s MedMorph IG and reference architecture to send synthetic data to a state and private registry.

Extended Elements and Testing
Further utilize mCODE Operationalize CIBMTR data exchange at UCSF Explore rapid case ascertainment Develop primary/secondary case reporting approach with registry reporting software org. Metric measurement

Transition From Test to Production
Review lessons learned from phase 1 Measure outcomes Build implementation processes Increase the number of health systems Increase the number of registries
Cancer Registry Reporting – Phase 0
(Targeting July 2022 for Completion)

Create a proof-of-concept that demonstrates the ability of a FHIR enabled solution to submit a core subset of mCODE cancer patient data to both a private and state cancer registry, proving the underlying technical architecture and registry agnostic nature of the solution.

California focus for initial pilot activity

- Leveraging CDC MedMorph Technical Architecture for data flow
  - CDC developers and MITRE have collaborated on this architecture
  - Central Cancer Registry Reporting Content IG
- UCSF built the test FHIR server, implemented the Backend Service App
- Synthetic mCODE data elements (demographic, Condition, Observation) are being sent via FHIR
- Bundle delivered to CIBMTR FHIR enabled endpoint
- Bundle delivered to California Cancer Registry FHIR enabled endpoint
Cancer Registry Reporting – Phase 1
(Update as of July 2022)

CDC Collaboration
• Continue participation with the MedMorph team on architecture enhancements
• On-going work with the CDC team to identify and mitigate gaps in mCODE specs and registry reporting requirements

UCSF Production and Expanded Data to CIBMTR Initiative
• Support the data validation process for Observations and Conditions with real data
• Metrics evaluation
• CIBMTR Next Transmission Test (expanded data such as Procedures and Medications)

UCSF and the Greater Bay Area Registry Supplemental Data Requests
• Specific data needed for research
  • Prostate Cancer: TAP (Talking About Prostate cancer)
  • Lung Cancer: FANS (Female Asian Never Smokers) study

Oncora Medical Collaboration
• Exploring opportunities to utilize components of the pilot with a health system and Certified Tumor Registrar (CTR) vendor abstraction software
Radiation Therapy Treatment Data for Cancer

**Problem**
- Treatment details – critical for care coordination – are not readily available in systems other than radiation oncology EHR modules: data is generally manually entered into summary documents, creating clinical burden and potential patient safety issues

**Solution**
- To develop, test and deploy open data standards that enable interoperable, multi-purpose exchange of radiation treatment summary data for care coordination and data reuse.

**Desired Impact**
- Enable sharing of critical radiation therapy treatment data for care coordination or data reuse (research, quality measurement, payer-required reporting)
Cancer Registry Reporting – Phase 1 Exploration

CCR Next Generation Cancer Reporting – asking the question:

- Can we meet basic surveillance measures under the CDC national program of cancer registry guidelines using a primary case reporting approach?

1\textsuperscript{st} Stage (Primary Report):
Collects a cancer diagnosis minimum data set, sufficient to describe population incidence and prevalence

2\textsuperscript{nd} Stage (Secondary Report):
Subsequent case updates and treatment data

3\textsuperscript{rd} Stage (Supplemental Data Requests):
Procures targeted information in response to identified researcher’s needs and supplemental data (Rapid Case Ascertainment)
Radiation Therapy Treatment Data for Cancer
(Update as of May 2022)

Multi-Phased Approach

Phase 0
Standards Development – mCODE radiotherapy
mCODE STU 2: http://hl7.org/fhir/us/mcode/group-treatment.html#radiotherapy

Phase 1
Proof of Concept – End of treatment summary
XRTS Workshop & RTTD IG:
http://build.fhir.org/ig/Hl7/codex-radiation-therapy/branches/master/index.html

Phase 2
Proof of Concept – In-progress treatment summary
XRTS Workshop – May 9-11th, 2022 (Results Pending)

Phase 3
Pilot Study – End-to-end workflow of treatment summary

University of Michigan, Veterans Health Administration, McGill University, University of Pennsylvania, Virginia Commonwealth University, University of California San Francisco, Integrating the Healthcare Enterprise-Radiation Oncology (IHE-RO), RaySearch, Elekta, Washington University in St. Louis

We are here
Project Updates

- **Phase 0** (completed May 2021): updated existing radiation therapy concepts and modeled new extensions for mCODE STU 2
  - To date, 3 new profiles, 4 new extensions, and 4 new value sets have been added
  - Provided feedback and enhancements to mCODE STU 2 specifications

- **Phase 1** (completed December 2021): radiation oncology information system generates an *end of treatment summary* that can be retrieved by another information system
  - Aligned technical efforts with the IHE-RO Exchange of Radiotherapy Summaries (XRTS) Technical Framework documentation
    - XRTS framework includes the mCODE Radiotherapy profiles and value sets defined in mCODE STU 2
    - Varian and RaySearch implemented the XRTS framework

- **Phase 2** (completed May 2022): radiation oncology information system generates an *in-progress treatment summary* that can be retrieved by another information system
  - Aligning technical efforts with XRTS; tested Phase 2 modeling and implementation at XRTS Workshop in May 2022
  - Varian, RaySearch, Epic, Wemedoo, MITRE participated and tested implementation of the radiotherapy profiles

- **Phase 3** (targeting Fall 2022): prepare pilot study to test end-to-end, real-time workflow of RT information
  - Additionally, ROIS and EHRs to test profile implementation at a third XRTS Workshop in Fall 2022

Collaborators

University of Michigan, Veterans Health Administration, McGill University, University of Pennsylvania, Virginia Commonwealth University, University of California San Francisco, Integrating the Healthcare Enterprise-Radiation Oncology (IHE-RO), RaySearch, Elekta, Washington University in St. Louis
2022 Timeline (Update as of May 2022)

December
- XRTS Workshop
- Discuss results + Establish next steps
- Hold public call
- Begin preparing for public call

January
- Create a RI for the Postman queries – Observer profile demoing

February
- Hold another XRTS Workshop to test in-progress summaries
- Test workflow of RTTD information between systems for pilot

April
- Hold public call

May
- Continue working through HL7 RTTD FHIR IG Ballot Process items

June/July
- Test workflow of RTTD information between systems for pilot

(1) Define/model Planned Course and Planned Phase profiles
(2) Implement in XRTS technical spec and CodeX RT IG

Fall 2022

(1) Define/model Prescription and Plan profiles
(2) Implement in XRTS technical spec and CodeX RT IG
Prior Authorization in Oncology

Problem
• Prior authorization imposes a burden on patients, providers, and payers
• Prior authorization documentation requirements vary by payer plan
• Current manual processes are costly and may delay treatment

Solution
• Reduce clinical burden when requesting oncology treatment regimens by building on Da Vinci CRD/DTR/PAS specifications to supplement prior authorization request with mCODE data elements.

Desired Impact
• Develop automated prior authorization capability in which 80% of approvals do not require manual inspection

Da Vinci Exchange
• Implementing this use case in oncology produces the standardized exchange for use in any specialty or other PA services or procedure.
Prior Authorization in Oncology
(Update as of July 2022)

Collaborators

Project Updates

- Monthly Public calls – the last Tuesday of each month, 3:00-4:00 ET
- Weekly member calls and bi-weekly Technical group calls
  - Radiation Oncology Prostate Cancer focused
- Collaborative approach in pressing toward a synthetic data pilot
  - Utilizing and building on Da Vinci CRD/DTR/PAS specifications to supplement prior authorization request with mCODE data elements
- Current Pilot Phase metrics
  - Case completion time - PA Process
    - Time is takes to perform the work - related to pilot itself
    - Time to perform individual steps - physician and clinic staff
  - Success rate - #/% of cases that reach completion stage
  - Mouse clicks - # Mouse clicks will be dependent on interface
  - Answers able to answer automatically - # of questions vs. # of questions that had to be answered manually
- CodeX membership inquiries should be directed to kim.ball@pocp.com
Prior Authorization in Oncology – Planning Phases
(Updated as of March 2022)

Collaborators

Phase 0
- Proof of concept for breast cancer and colorectal cancer prior authorization
- Demonstration of the Da Vinci CRD/DTR/PAS IGs working in a medical oncology flow
- Test and demonstrate use of adaptive forms in questionnaires to show variations and flexibility of trigger (encounter, order)
- Document scenarios and open-source code for the questionnaires and CQL

Prior Authorization in Oncology Supporting Materials

Phase 1
- Design – Validate workflows, define process and requirements, includes demographic and patient clinical data elements
- Build & test the exchange of prior authorization between provider and payer systems using EHR test patients
- Evaluate lessons learned and rescope iteratively
- Implementation into production environment
- Use of mCODE data elements in PA transactions
- Demonstrate PA transactions in the FHIR-based Da Vinci CRD/DTR/PAS information exchange

Phase 2
- Scale
- Advance and apply lessons learned from Phase 1 (MVP)
- Add additional cancer types
- Expansion consideration into medical oncology and progress into modality sequencing
- Add additional participating organizations (Payer, Provider, Oncology EHR)
Prior Authorization in Oncology

Project Timeline:
Rad Onc Prior Auth Pilot for Prostate Cancer (MVP) (as of June 2022)

Future Use Case Concepts/ Phase 2 Ideas:
- Scale
- Advance and apply lessons learned from Phase 1 (MVP)
- Add additional cancer types
- Expansion consideration into medical oncology and progress into modality sequencing
- Evaluate PA workflow and data that could be collected to understand/influence health equity
- Add additional participating organizations (Payer, Provider, Oncology EHR)
Risk Evaluation and Mitigation Strategy (REMS)

A drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of a medication outweigh its risks.

Goal of the CodeX REMS Integration Use Case

Create an automated, efficient, and effective REMS ecosystem with a standards-based technical infrastructure for REMS integration into workflow, enabling data sharing and reducing undue burden.
REMS Integration Use Case

**Challenge**

- Multiple stakeholders play an important role in the REMS administration process:
  - Verification of variable completed REMS requirements
  - Dispensing the drug with no unified way to:
    - Coordinate the process
    - Share data among one another
- Gaps in data interoperability make REMS communication and coordination burdensome
- Not in current workflow - the complexity of these leads to

**Solution**

- Leverage data standards and create a data infrastructure to integrate REMS processes into stakeholder workflows
- Facilitate integration, enabling:
  - Prescribers and pharmacists to:
    - Be alerted to a REMS requirement
    - Complete requirements (training, education, clinical actions)
    - Attest and easily confirm in workflow that REMS requirements have been met
  - Patients receive REMS drugs efficiently - without undue burden or delay - via effective, interoperable workflows across all REMS stakeholders
Current REMS Process: Physician, Patient and Pharmacist

Drug Database? or CDS Hook

Can you use existing drug databases as "flag" to trigger CDS hook?

NCPDP SCRIPT Standard And HL7 FHIR IG

Prescriber is notified of REMS

NCPDP SCRIPT (RxFill)?

Patient monitoring, reporting and auditing

HL7 FHIR IG

Prescriber writes Rx for patient and gives patient REMS agreement to sign

Will prescriber "hold" eRx until REMS requirements are met?

HL7 FHIR IG

Pharmacist/Dispenser confirms prescriber REMS requirements

Is there a need for pharmacist to communicate back to provider if they have requirements to meet?

Patient or caregiver counseled at pharmacy per REMS requirements

Is there a need for pharmacist to communicate back to provider if they have requirements to meet?

Pharmacist/Dispenser contacts help desk and/or prescriber to obtain missing information

Patient monitoring, reporting and auditing

Prescription filled/dispensed

Multisource Drugs - 11 of 61 – How do we handle as Provider does not go by NDC

Including questions and comments we’ve heard from Pilot Pass participants!
## Roadmap to REMS Pilot Implementation

<table>
<thead>
<tr>
<th>Activities</th>
<th>Design</th>
<th>Momentum</th>
<th>Planning</th>
<th>Pilot Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prototype Design and Iterations</strong></td>
<td>Prototype Design and Iterations</td>
<td>Stakeholder Engagement</td>
<td>Pilot Planning - Contracting</td>
<td>Pilot Implementation</td>
</tr>
<tr>
<td>Research stakeholder roles</td>
<td>Identify key players – outreach</td>
<td>Interested pilot party discussion</td>
<td>Timeline focused implementation</td>
<td></td>
</tr>
<tr>
<td>Understand industry demand/processes</td>
<td>Remove barriers to pilot implementation</td>
<td>Pilot parameters set-synthetic data</td>
<td>Iterations to pilot product</td>
<td></td>
</tr>
<tr>
<td>Proof of concept discussions</td>
<td>Gauge opportunities to pilot</td>
<td>Contractual commitment discussion</td>
<td>Real-world issues and set back discussion</td>
<td></td>
</tr>
<tr>
<td>Understand industry barriers and gaps</td>
<td>Channel public call input/survey</td>
<td>Timeline creation discussions</td>
<td>Pilot phase to execution planning</td>
<td></td>
</tr>
<tr>
<td>Create Prototype</td>
<td>“Why” stakeholder group parameters</td>
<td>Brainstorm partners that may enhance pilot actors</td>
<td>Marketing and real-world education</td>
<td></td>
</tr>
<tr>
<td>Prototype iterations – technology focus</td>
<td>Industry engagement – events</td>
<td>Exploration of opportunities to utilize data</td>
<td>Redundancy and gap review</td>
<td></td>
</tr>
<tr>
<td>Technical validation processes – cyber security focus</td>
<td>Create workflow focused input.</td>
<td>Interoperability and transparency focus.</td>
<td>Launch</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Final Prototype Iteration</th>
<th>Identify Pilot Participants</th>
<th>Pilot Contracting</th>
<th>Product Launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vision and concept organization</td>
<td>Scope and process detail</td>
<td>Contracting and legal detail</td>
<td>Identify/address redundancy and gaps</td>
<td></td>
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<tr>
<td>Public call conversions to membership</td>
<td>Pilot opportunities</td>
<td>Pilot planning and creation into EHR and PIS workflow</td>
<td>Continued member engagement</td>
<td></td>
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<tr>
<td>Member input focused iterations</td>
<td>Pilot parameter whiteboarding</td>
<td>Discover any barriers or gaps to implementation</td>
<td>Product launch discussion</td>
<td></td>
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<tr>
<td>Prototype iterations-final pilot phase</td>
<td>Key actors identified in process</td>
<td>Continued research and iterations</td>
<td>Product launch discussion</td>
<td></td>
</tr>
<tr>
<td>Process and key stakeholders identified with key initiatives and next steps</td>
<td>Workflow focused input/meetings outcomes</td>
<td>Gain any partners or necessary additions to enhance pilot</td>
<td>Continued added support from industry</td>
<td></td>
</tr>
</tbody>
</table>
REMS Integration Use Case Status
(Update as of July 2022)

Collaborators

Project Updates

• Pilot Pass participants (47) meet biweekly to flesh out the REMS ecosystem and workflow and provide input to the prototype team

• FDA’s REMS prototype is designed to demonstrate the value of an integrated REMS solution using Da Vinci FHIR resources and other healthcare data standards

• Outreach activities:
  • Monthly Public Calls scheduled March-July 2022; in scheduling through 2022
  • 1:1 Technical calls with interested parties to explore pilot participation
  • Coordination with broader entities
    • NCPDP REMS Task Group July 2022 call featured REMS prototype demo
    • CodeX CoP in June 2022 featured REMS
  • After August 2022, will confirm pilot participants and members
New Cardiovascular Domain Hosting Multiple Use Cases

Questions
• Can a medical specialty in addition to oncology ...
  • Follow the CodeX / mCODE approach (and faster)?
  • Create a minimal Cardiovascular FHIR IG that is consistent and interoperable with mCODE?
  • Leverage work of oncology use cases (e.g., RWD trials, trials matching, registry reporting)?
  • Improve cardiovascular patient care and research

Plans
• University of Nebraska, leading
• Leveraging previous work on minimal data elements
• Gathering interested members of the community
• Identifying potential first Use Cases
  • Hypertension is of particular interest
New Genomics Domain Hosting Multiple Use Cases

How can we achieve a high level of interoperability in genomic data and use it to improve patient outcomes? By standardizing the data collected and shared across many systems—laboratories, clinicians, researchers, and other stakeholders—enabling a learning health system

Problem
Most genomic tests are sent from the laboratory to health care setting as PDFs, isolating this non-computable information within the EHR and inhibiting its use for clinical care and research.

Solution
Collection of Genomics data via FHIR in a standardized, machine-readable format, allowing the data to be used for many applications. Will work with, leverage and inform the work of the HL7 Clinical Genomics Workgroup and their FHIR Genomics Implementation Guide

Likely Components of GenomeX Use Cases
• Using FHIR Genomics to share genomic data between laboratories, healthcare organizations, and EHR vendors
• Developing and utilizing FHIR Genomics operations. Based on the premise that genomic data is stored in a repository (by a healthcare group, academic institution or vendor), FHIR Genomics operations ‘wrap’ the repository, hiding its complexity, then presenting a clear and uniform interface to developers, regardless of the internal repository’s complexity or data structures
• Create open industry Implementation Guides for use cases of importance to patients, providers, vendors, or the industry as a whole
• Implement select components of FHIR Genomics into commercial systems or Reference Implementations
• Pilots demonstrating feasibility and value of early adoption and scale of FHIR Genomics
Building a Genomics App
Membership Information
## CodeX Membership Categories

[https://confluence.hl7.org/display/COD/CodeX+Membership+Options](https://confluence.hl7.org/display/COD/CodeX+Membership+Options)

<table>
<thead>
<tr>
<th>Level</th>
<th>Annual Membership Fees</th>
<th>Operating Committee Vote</th>
<th>Sponsor Partner Operating Committee Membership</th>
<th>Participate in Use Case Leadership Calls</th>
<th>Invited to Use Case Workgroup Calls</th>
<th>Pledge Resources</th>
<th>Access to Use Case Artifacts</th>
<th>Provide Feedback</th>
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<tr>
<td>Premier*</td>
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<td>Developer/Implementer**</td>
<td>None</td>
<td>By Invite Only</td>
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**Notes:**

- *Premier and Principal Members may nominate partner organizations to join the Operating Committee (proxy membership) and must be approved by the Steering Committee.
- **Developer/Implementer Members must be approved by the Steering Committee based on their commitment to contribute resources to implement CodeX products and support Use Cases.** Developer/Implementer Members with >$50M in annual revenue will be asked to join as a paying Member after the first year of membership. Companies with revenues <$50M may continue as Developer/Implementer Members for as long as they are contributing to CodeX work.
- All CodeX Members sign the standard Statement of Understanding/Member Agreement. This document is the standard used by HL7 and is similar to the document signed within other HL7 FHIR Accelerators.
- Membership as a Founder was open to those who joined at the Premier level before the end of 2020.
- To create a variety of participation and perspectives, health systems may participate in CodeX pilots free of charge. Health systems that want to participate in CodeX decision-making may seek to join as paying, Government or Sponsored Members.
ASCO Volunteer Team (met 2018 - 19)
Identified core mCODE data elements necessary to address use cases

1. Doug Blayney – Stanford U – BrCa, quality
2. Jim Chen – Ohio State U – bioinformatics, precision med
3. Edward Ambinder – Mt Sinai - informatics
4. Elmer Bernstam – U Texas - informatics
5. Pamela Crilley – Cancer Treat Ctrs Amer – heme malignancies
6. Gregg Franklin – U New Mexico – radiation onco
7. Vinay Gudena – Cone Health Center - BrCa
8. Kevin Hughes – Mass General – surgery, BrCa, genetics
9. Sean Khozin – FDA – regulatory, thoracic
10. Paul Kluetz – FDA - regulatory
12. Rich Moldwin – College Amer Pathologists – pathology, informatics
13. Loretta Nastoupil – MD Anderson - lymphoma
14. Travis Osterman – Vanderbilt U – informatics, lung
16. Steve Piantadosi – ACTO – clinical trials, biostats
17. Anna Schorer – OncoLogic - informatics
18. Keith Thompson – Montgomery Cancer Ctr - oncology

A volunteer-led, staff-driven, cross-ASCO project to assemble a core set of structured data elements for the oncology EHR
Cancer Care: Variable Outcomes and Costs

County level breast cancer mortality
from the National Center for Health Statistics (NCHS). JAMA (2017)

Cost of stage 1 breast cancer
from 2013-2014 Truven MarketScan commercial claims data. AJMC (2017).

<table>
<thead>
<tr>
<th></th>
<th>25th percentile</th>
<th>50th percentile</th>
<th>75th percentile</th>
<th>95th percentile</th>
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