Welcome! to the CodeX™ HL7 FHIR Accelerator
Birds of a Feather

May 12, 2022
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CodeX@hl7.org

https://www.hl7.org/codex/
https://confluence.hl7.org/display/COD/CodeX+Home
Welcome!

• **Introduction to CodeX**
  • The HL7 FHIR Accelerator Community building valuable, mCODE-based implementations to improve cancer care and research.

• **Our first FHIR IG: mCODE standard**
  • The common language for cancer data collection and sharing.

• **Community**
  • Community of Practice. Members. Implementers.

• **Use Cases**

• **Membership and Governance**
  • Join us!

• **Appendices**
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 and beyond.
What is a FHIR Accelerator?

“. designed to assist communities .. across the global health care spectrum in the 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/

HL7 FHIR Accelerators
Cancer, in the United States

- 39% lifetime risk
- #2 cause of death
- $209 B cost per year
Most of the nearly 15 million individuals living with cancer in the U.S. have **Electronic Health Records (EHRs)**

**EHR data challenges:**
- Distributed
- Significant variation
- Unstructured
- High Burden
- Difficult to access and share

[Swivel-chair interoperability](https://365.himss.org/sites/himss365/files/365/handouts/552576986/handout-SC3_FINAL.pdf)

Credit: Tcheng
Cancer and Health Equity

- Cancer is one of the most common and deadliest diseases in the United States.²
- Disproportionately affects people of color and other populations:
  - African American patients have had the highest all-cancer mortality rate of any racial or ethnic group for the past 40 years
  - American Indian and Alaska Native patients have higher likelihoods of being first diagnosed with cancer at advanced stages than other populations
  - Compared to non-Hispanic whites, Hispanic patients have disproportionately higher rates of disease associated with specific kinds of cancers
  - Populations living in nonmetropolitan rural counties have higher annual, age-adjusted, all-cancer mortality rates than populations in metropolitan counties and nonmetropolitan urban counties
CodeX Health Equity Webinar (January 27, 2022)
https://confluence.hl7.org/display/COD/Health+Equity+Webinar+2022

Reed V. Tuckson, MD, FACP
Tuckson Health Connections, LLC
Better, standardized data means improved ...

- Treatment quality
- Diversification in clinical trials
- Ability to analyze standardized RWD across populations
- Monitoring of safety and efficacy of approved therapies
- Public health surveillance
- Prior authorization processes in oncology
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
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/2HGpPZ3
#MITREhealth Learn more: health.mitre.org/mcode/

https://www.youtube.com/watch?v=AKkIpOnuSCE&feature=youtu.be
ASCO Volunteer Team (met 2018 - 19)
Identified core mCODE data elements necessary to address use cases

Dr. Robert S. Miller
Medical Director
ASCO CancerLinQ

Dr. Wendy S. Rubinstein
Division Director, Clinical Data Management and Curation
ASCO CancerLinQ

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
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

**mCODE STU2:** [http://hl7.org/fhir/us/mcode/](http://hl7.org/fhir/us/mcode/)
<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft (0)</td>
<td>the resource or profile (artifact) has been published on the current build. This level is synonymous with Draft</td>
</tr>
<tr>
<td>FMM 1</td>
<td>PLUS the artifact produces no warnings during the build process and the responsible WG has indicated that they consider the artifact substantially complete and ready for implementation. For resources, profiles and implementation guides, the FHIR Management Group has approved the underlying resource/profile/IG proposal</td>
</tr>
<tr>
<td>FMM 2</td>
<td>PLUS the artifact has been tested and successfully supports interoperability among at least three independently developed systems leveraging most of the scope (e.g. at least 80% of the core data elements) using semi-realistic data and scenarios based on at least one of the declared scopes of the artifact (e.g. at a connectathon). These interoperability results must have been reported to and accepted by the FMG</td>
</tr>
<tr>
<td>FMM 3</td>
<td>PLUS + the artifact has been verified by the work group as meeting the Conformance Resource Quality Guidelines; has been subject to a round of formal balloting; has at least 10 distinct implementer comments recorded in the tracker drawn from at least 3 organizations resulting in at least one substantive change</td>
</tr>
<tr>
<td>FMM 4</td>
<td>PLUS the artifact has been tested across its scope (see below), published in a formal publication (e.g. Trial-Use), and implemented in multiple prototype projects. As well, the responsible work group agrees the artifact is sufficiently stable to require implementer consultation for subsequent non-backward compatible changes</td>
</tr>
<tr>
<td>FMM 5</td>
<td>the artifact has been published in two formal publication release cycles at FMM1+ (i.e. Trial-Use level) and has been implemented in at least 5 independent production systems in more than one country</td>
</tr>
</tbody>
</table>

*Co-morbidity profile may be 2"
FHIR Shorthand (FSH) Seminar:
Getting Started with New Tools to Create
Swimmingly Slick Implementation Guides

Learn how to create FHIR Implementation Guides (IG)
• Comprehensive overview of FHIR IG authoring basics using FSH
• Access self-service educational content and embedded videos

May 24-25th
• LIVE Zulip support

May 26th Open Q&A Forum 2-3 PM ET
• Speakers: Mark Kramer, Chris Moesel, Max Masnick, May Terry, Saul Kravitz

Registration & Course Info:
https://fshschool.org/courses/
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**


DEBI WILLIS
CEO and Founder of PatientLink Enterprises and a Cancer Survivor
THE PATIENT CANCER JOURNEY

Newly Diagnosed Breast Cancer

1. Mammography
   - BREAST MASS
   - mCODE Record

2. Biopsy & Staging Visits
   - BREAST CANCER
   - Collecting mCODE Genomics

3. Treatment Plan Visit
   - Drug Safety
   - Insurance

4. Radiation Therapy
   - PRIOR AUTH

5. Trial Matching
   - REGISTRY

6. Enrolled in Trial

7. Surveillance Visits
   - NO EVIDENCE OF DISEASE

- Patient
- Providers
- Oncologist
- Research
- Radiation Clinic
- Genomic Laboratory
- Registry

Health System
Data are collected and shared via FHIR and use-case specific FHIR Implementation Guides, like the mCODE standard, and CodeX supplements.

Enabling every patient’s journey to improve all future care.
1. **Welcome!**  .. an energetic **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 **FHIR IGs** (like mCODE) and supplements, and implement these into real **products**, systems and new workflows

4. **Execute** .. **Pilots** in the field with future **users** to **demonstrate impact** and feasibility, and enable rapid adoption and scaling
Community
CodeX™ / mCODE™ Community of Practice

A group of health systems, specialty societies, government agencies, pharmaceutical manufacturers, researchers, EHRs and supporting organizations, participating in a monthly public forum focused on real-world applications of mCODE.

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

https://confluence.hl7.org/display/COD/mCODE+Community+of+Practice
# CodeX Members
(April 2022)

## CodeX Founders

<table>
<thead>
<tr>
<th>PREMIER</th>
<th>PRINCIPAL</th>
</tr>
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<tbody>
<tr>
<td>AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE</td>
<td>AMERICAN SOCIETY FOR RADIATION ONCOLOGY</td>
</tr>
<tr>
<td>ASTRO</td>
<td>UnitedHealthcare</td>
</tr>
<tr>
<td>ALLIANCE FOR CLINICAL TRIAL RESEARCH</td>
<td>Cancer Action Network</td>
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<table>
<thead>
<tr>
<th>BENEFACtor</th>
<th>GOVERNMENT AGENCY</th>
<th>SPONSORED MEMBER</th>
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<tbody>
<tr>
<td>MITRE</td>
<td>HL7 International</td>
<td>American Cancer Society</td>
</tr>
<tr>
<td>EVERNORTH</td>
<td>Syntropy</td>
<td>Cancer Organization of Medical Physicists</td>
</tr>
<tr>
<td>Ontada</td>
<td>Pfizer</td>
<td>Organization coopérative des physiciens médicaux</td>
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</table>

<table>
<thead>
<tr>
<th>DEVELOPER/IMPLEMENTER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer Insights</td>
</tr>
<tr>
<td>patientlink</td>
</tr>
<tr>
<td>Varian</td>
</tr>
</tbody>
</table>
Use Cases
Use Case Development and Transition Guidelines
https://confluence.hl7.org/display/COD/Use+Case+Transition+Guidelines

Members, Potential Members, Thought Leaders

Proposed, new 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
**CodeX Use-Cases**

**Discovery -> Planning -> Execution**

[https://confluence.hl7.org/display/COD/CodeX+Use+Cases](https://confluence.hl7.org/display/COD/CodeX+Use+Cases)

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**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

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**Stages**

Discovery  Planning  Execution

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Prior Authorization in Oncology

Risk Evaluation and Mitigation Strategies (REMS)
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
Mayo Clinic
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 Michigan
University of Pennsylvania
University of Texas Southwestern
Veterans Health Administration
Virginia Commonwealth University
Washington University in St Louis

Oncoclinicas
Taiwan Cancer Registry
Netherlands Cancer Registry
UC Los Angeles

Engaged & Previously Expressed Interest – Engaged in multiple conversations and/or in the process of being Active

Scaling through Industry Implementations

CancerInsights
Cerner
Clinical Pipe
Elekta
Elsevier
Epic
Flatiron
IQVIA
Jitterbit
MassiveBio
Mettle Solutions
Microsoft
NeuralFrame
Nuance
PatientLink
Pfizer
Roche
Semedy
Syntropy
Trial Scope
TrialJectory
Varian
Wemedoo
(Pre-Discovery/Potential) CodeX Use-Cases (1)

New Clinical Domains Exploring Use Cases Concepts

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

- **Cardiovascular - CardX**
  - Hypertension Management
(Pre-Discovery/Potential) CodeX Use-Cases (2)

Early discussions to see if there is sufficient interest

- Structuring inclusion and exclusion trial matching criteria
- Regulatory grade RWE
- Oncology nurse case manager
- Clinical quality measurement
- Internationalization of mCODE (not necessary a "use case", but could be tied to one)
- Oncology Clinical Pathways (hibernating – awaiting community interest)

https://confluence.hl7.org/display/COD/Pre-Discovery+Use+Case+Concepts
mCODE++ Extraction
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
**Multi-Phase Approach**

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

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**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
ICAREdata® Question Summary
Outcome Data Collected by Clinicians at Point of Care

Cancer Disease Status
Clinical Assessment
Based on the data available today (at the time of evaluation), categorize the patient’s disease extent

ICAREdata Question Format

<table>
<thead>
<tr>
<th>cancer disease status</th>
<th>&lt;tumor evaluated*&gt;</th>
<th>&lt;status value&gt;</th>
<th>&lt;reason value&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>primary tumor(s)</td>
<td>no evidence of disease</td>
<td>responding</td>
<td>stable</td>
</tr>
<tr>
<td>metastatic tumor(s)</td>
<td>progressing</td>
<td>undetermined</td>
<td>stable</td>
</tr>
<tr>
<td></td>
<td>imaging</td>
<td>pathology</td>
<td>symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td>physical exam</td>
<td>lab results</td>
</tr>
</tbody>
</table>

Collection Method
Recommended by Epic: via SmartForm in the Problem List

Cancer Treatment Plan Change
Clinical Assessment
Based on your evaluation today, are you making a change in the cancer treatment?

Collection Method
Recommended by Epic: via SmartPhrase in Encounter Note

- No change in treatment plan
- Yes-disease not responding
- Yes-due to AE/toxicity
- Yes-planned change
- Yes-due to patient request
- Yes-due to other

Select one value  Select one or more values  Note: if “not evaluated” selected, then options for reason value do not appear

*Tumor evaluated will not be entered by the clinician for an Epic problem-based collection approach
### Embedded Protocol

<table>
<thead>
<tr>
<th>Study #</th>
<th>PI</th>
<th>Title</th>
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</thead>
<tbody>
<tr>
<td>A011801</td>
<td>Ciara O’Sullivan</td>
<td>COMPASS COMPASS HER2 trials examining escalating and de-escalating</td>
</tr>
<tr>
<td></td>
<td></td>
<td>therapy in HER2-positive breast cancer: Optimizing treatment in</td>
</tr>
<tr>
<td></td>
<td></td>
<td>residual disease (COMPASS HER2 RD): a double-blinded, Phase III</td>
</tr>
<tr>
<td></td>
<td></td>
<td>randomized trial</td>
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<tr>
<td>A021703</td>
<td>Kimmie Ng</td>
<td>SOLARIS Randomized double-blind phase III trial of vitamin D3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>supplementation in patients with previously untreated metastatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>colorectal cancer</td>
</tr>
<tr>
<td>A021806</td>
<td>Cristina Ferrone</td>
<td>A phase III trial of perioperative versus adjuvant chemotherapy for</td>
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<tr>
<td></td>
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<td>resectable pancreatic cancer</td>
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<tr>
<td>A031902</td>
<td>Arpit Rao</td>
<td>CASPAR phase iii trial of enzalutamide and rucaparib as a novel</td>
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<td>therapy in first-line metastatic castration-resistant prostate cancer</td>
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<tr>
<td>A071701</td>
<td>Priscilla Brastianos</td>
<td>Brain Mets Genomically-guided Treatment Trial in Brain Metastases</td>
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### Companion Protocol

<table>
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<tr>
<th>Study #</th>
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<tbody>
<tr>
<td>A021602</td>
<td>CABINET – Randomized, double-blinded phase III study of cabozantinib</td>
</tr>
<tr>
<td></td>
<td>versus placebo in patients with advanced neuroendocrine tumors</td>
</tr>
<tr>
<td></td>
<td>after progression on everolimus</td>
</tr>
<tr>
<td>A031701</td>
<td>A phase II study of dose-dense gemcitabine plus cisplatin (ddGC) in</td>
</tr>
<tr>
<td></td>
<td>patients with muscle-invasive bladder cancer with bladder preservation</td>
</tr>
<tr>
<td></td>
<td>for those patients whose tumors harbor deleterious DNA damage</td>
</tr>
<tr>
<td></td>
<td>response (DDR) gene alterations</td>
</tr>
<tr>
<td>A031702</td>
<td>ICONIC – A phase II study of ipilimumab, cabozantinib, and nivolumab</td>
</tr>
<tr>
<td></td>
<td>in rare genitourinary cancers</td>
</tr>
<tr>
<td>A031704</td>
<td>PDIGREE – PD-inhibitor (nivolumab) and ipilimumab followed by</td>
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<tr>
<td></td>
<td>nivolumab vs. VEGF TKI cabozantinib with nivolumab: A phase III trial</td>
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<tr>
<td></td>
<td>in metastatic untreated renal cell cancer</td>
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<tr>
<td>A031801</td>
<td>RadiCaL – A phase II randomized trial of radium-223 dichloride and</td>
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<tr>
<td></td>
<td>cabozantinib in patients with advanced renal cell carcinoma with</td>
</tr>
<tr>
<td></td>
<td>bone metastasis</td>
</tr>
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ICAREdata Site Onboarding Progress  (As of 4/27/2022)

ICAREdata Site Progress

- Data Flowing: 2
- IT Extraction Implemented: 2
- Collecting Data: 7
- Collection Tools Implemented: 8

Number of 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)

Phase 2
- Prospective Study – integration with health site EHR and PDM application
  - Presentation Summary - [https://confluence.hl7.org/display/CO D/Trial+Matching+Meetings](https://confluence.hl7.org/display/CO D/Trial+Matching+Meetings)
ACS CAN Provided Nearly $1 Million in Support From Amgen to Expand Cancer Clinical Trial Enrollment Through Improved Technology and Patient Support

PROJECT WILL TEST INTEGRATION OF TRIAL MATCHING CAPABILITY INTO EXISTING MEDICAL RECORD SYSTEMS, AIMING TO REACH MORE PATIENTS AT COMMUNITY AND MEDICAL CENTERS

March 3, 2022

WASHINGTON, D.C.—The American Cancer Society Cancer Action Network (ACS CAN) has been provided nearly one million dollars in support from Amgen for a pilot program to test a trial eligibility screening intervention intended to increase and diversify patient enrollment in cancer clinical trials. The project will integrate regional cancer clinical trial matching capability into existing electronic health record (EHR) systems and will utilize clinical trial navigators to help patients address logistical and financial
Integrated Trial Matching for Cancer Patients and Providers (Update as of April 2022) (Slide 2 of 2)

Collaborators

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
Structuring Eligibility Criteria in mCODE
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).
Radiation Therapy Treatment Data for Cancer
(Update as of May 2022)

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

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

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

We are here
FHIR profile development – Phase 1

RTTD / XRTS (Plan Summary)

- Planned Course Summary
  - Prescribed Number of Sessions
  - Prescribed Dose per Target Volume

Radiotherapy Volume
- Targets or DARTs
- Name
- Technical Identifier
- Type
- Location / Anatomy

Planned Phase
(a series of equivalent fractions to a set of volumes)
- Modality
- Techniques
- Prescribed Number of Fractions
- Prescribed Dose per Volume

Plan
- Modality
- Technique
- Planned Number of Fractions
- Planned Dose per Volume
- DICOM Reference

Delivered Phase
- Modality
- Techniques
- Delivered Number of Fractions
- Delivered Dose per Volume

Delivered Plan
- Modality
- Technique
- Delivered Number of Fractions
- Delivered Dose per Volume
- DICOM Reference

Delivered Fraction
- Delivered Fraction Dose per Volume
- Type of record
- Fraction Number (Phase)
- Fraction Number (Plan)
- Resumption or complete fraction
- DICOM Reference

Prescription (Course Cumulative)
- Cumulative (course)
- Body Site
- Diagnosis
- Therapeutic Intent
- Modality
- Techniques (optional)
- Prescribed Number of Sessions
- Prescribed Dose per Target Volume

Prescription (Phase Cumulative)
- Cumulative (phase)
- Body Site
- Diagnosis
- Therapeutic Intent
- Modality
- Techniques
- Prescribed Number of Fractions
- Prescribed Dose per Target Volume

Prescription (Single Plan)
- Cumulative (no single plan)
- Body Site
- Diagnosis
- Therapeutic Intent
- Modality
- Technique
- Prescribed Number of Fractions
- Prescribed Dose per Target Volume
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

California Cancer Registry

Pilot Activity
Proof of concept

California focused proof of concept with UCSF, CA Cancer Registry, CIBMTR. Testing of CDC's MedMorph architecture implementation and ability to send de-identified data in a registry agnostic way. IG drafted with CDC MedMorph.

Extended Elements and Testing

Expand testing beyond proof of concept by working with additional data domains and further utilizing de-identified data from UCSF. Extend engagement into additional states and health systems to pilot.

Transition From Test to Production

Continue to test as needed, begin integrating architecture with production EHR environment. Integrate into day-to-day reporting with subset of registrars, assessing outcomes. Continue to engage additional states and systems.
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 – Planning Phases
(Updated as of March 2022)

Collaborators

Phase 0

- Framework - Proof of Concept
  - 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

- Rad Onc Prior Auth Pilot for Breast & Prostate Cancer (MVP)
  - 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

- Prior Authorization Pilot
  - 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)
Risk Evaluation and Mitigation Strategies (REMS)

Problem
- Multiple stakeholders play an important role in the REMS administration process, including verification of variable completed REMS requirements and dispensing of the drug with no unified way to coordinate the process and share data amongst one another
- Gaps in data interoperability make REMS communication and coordination burdensome
- REMS is not built into current workflows and the complexity of these programs leads to increased burden for stakeholders and the healthcare system overall

Solution
- Leverage data standards and create a data infrastructure to integrate REMS processes into stakeholder workflows
- Integration will enable prescribers to be alerted to a REMS requirement and complete requirements (training, education, clinical actions), prescriber attestation and pharmacist would be able to easily confirm, in workflow, that REMS requirements have been met prior to dispensing
- Patients receive REMS drugs in a timely manner with minimal effort or burden
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 it’s 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 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
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
Membership and Governance
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 & other Accelerators

HL7 International
## CodeX Membership Categories

<table>
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<tr>
<th>Level</th>
<th>Annual Membership Fees</th>
<th>Operating Committee Vote</th>
<th>Sponsor 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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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.
Quick Confluence Tour
https://confluence.hl7.org/display/COD/CodeX+Home
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 cancer and beyond.

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