The CodeX™ HL7 FHIR Accelerator

Birds of a Feather Discussion
January 18, 2022
Contents

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

• Introduction to the mCODE
  • The standard language for cancer data collection and sharing

• Strategy

• Use Cases

• Join Us!
HL7 FHIR Accelerator

A Member-driven community accelerating interoperable data modeling and implementation around the FHIR HL7 standard, leading to substantial improvements in health care and research in cancer and beyond

http://hl7.org/CodeX
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**

(Starting soon)
People’s lives are depending on what we do and what this data tells us.

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

minimal Common Oncology Data Elements

Every patient’s journey improves all future care
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/2HGpZ3

MITREhealth Learn more: health.mitre.org/mcode/

https://www.youtube.com/watch?v=AKkIpOnuSCE&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.

DEBI WILLIS
CEO and Founder of PatientLink Enterprises and a Cancer Survivor

Smarter Data for the Fight Against Cancer

http://www.hl7.org/CodeX
Data are collected and shared via the mCODE standard, and CodeX extensions.
CodeX is a growing, active community of stakeholders, working together to ...

**Prioritize**
- *Use cases* around interest and impact on patient care and research

**Build**
- New *FHIR IGs* needed to supplement *mCODE*
- *Implementations and updates to products*

**Execute**
- *Pilots* in the *field* to demonstrate feasibility and value, and enabling early adoption and scale
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
(December 2021)  
**CodeX Founders ★**

<table>
<thead>
<tr>
<th>PREMIER</th>
<th>PRINCIPAL</th>
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<tbody>
<tr>
<td>AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE</td>
<td>American Society for Radiation Oncology</td>
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<td>ASTRO</td>
<td>UnitedHealthcare</td>
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<td>MITRE</td>
<td>Cancer Action Network</td>
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<td>Alliance for Clinical Trials in Oncology</td>
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<th>BENEFACCTOR</th>
<th>GOVERNMENT AGENCY</th>
<th>SPONSORED MEMBER</th>
<th>DEVELOPER/IMPLEMENETER</th>
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<tr>
<td>CIBMTR</td>
<td>Centers for Disease Control and Prevention</td>
<td>Canadian Organization of Medical Physicists</td>
<td>Cancer Insights</td>
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<td>Telligen</td>
<td>Michigan Cancer Surveillance Program</td>
<td>Organization canadienne des physiciens médicaux</td>
<td>MASSIVE BIO</td>
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<td>Trajectory</td>
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<td>NaviHealth</td>
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<td>PRINCIPIA HEALTH SCIENCES</td>
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<td>Quantum Leap Healthcare Collaborative</td>
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<td>Clinical Information Specialists</td>
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## Building an Engaged Network of Health System Solutions

| Brigham and Women’s Hospital | The Ohio State University | The University of Chicago Medicine | Oncoclinicas  |
| City of Hope | The University of Michigan | University of California San Francisco | Taiwan Cancer Registry |
| Dana Farber Cancer Institute | Trinity Health | University of Pennsylvania | Netherlands Cancer Registry |
| Duke University | UNC Lineberger Comprehensive Cancer Center | University of Texas Southwestern | UC Los Angeles |
| Heartland Cancer Research | University of Michigan | Veterans Health Administration |  |
| Massachusetts General Hospital | University of Pennsylvania | University of Texas Southwestern |  |
| Mayo Clinic | University of Michigan |  |  |
| MD Anderson Cancer Center | University of Pennsylvania |  |  |
| Metro-Minnesota Community Oncology | University of Michigan |  |  |
| Missouri Baptist | University of California San Francisco |  |  |
| Northwell Health | University of Texas Southwestern |  |  |
| Rush University Medical Center | Veterans Health Administration |  |  |
| Saint Joseph Mercy Health System | University of Michigan |  |  |

## Scaling through Industry Implementations

| CancerInsights | Elsevier | Jitterbit | NeuralFrame | Roche |
| Clinical Pipe | Epic | MassiveBio | Nuance | Semedy |
| Elekta | Flathiron | Mettle Solutions | PatientLink | Syntropy |
| | IQVIA | Microsoft | Pfizer | Trial Scope |
| | | | | TrailJectory |
| | | | | Varian |
| | | | | Wemedoo |
Summary of Use Case Projects Underway or in Discovery

https://confluence.hl7.org/display/COD/CodeX+Use+Cases
CodeX Use-Case-Based Projects

Discovery -> Planning -> Execution

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

- mCODE++ Extraction
- EHR Endpoints for Cancer Clinical Trials (future extensions of ICAREdata)
- Integrated Trial Matching for Cancer Patients and Providers
- Cancer Registry Reporting
- Radiation Therapy Treatment Data for Cancer

- Prior Authorization in Oncology
- Oncology Clinical Pathways
- Risk Evaluation and Mitigation Strategies (REMS)
- Genomics
- Cardiovascular Disease

------- Stages -------

Discovery  Planning  Execution
• **Register for the Webinar**

  Jan 27, 2022 01:00 PM in Eastern Time (US and Canada)

  Featured Speakers:

  Reed V. Tuckson, MD, FACP
  Managing Director, Tuckson Health Connections, LLC

  JaWanna Henry, MPH, MCHES
  Public Health Analyst, Office of the National Coordinator (ONC)

  Chuck Mayo, PhD
  Professor, Director of Clinical Informatics & Analytics in the Department of Radiation, University of Michigan

  Su Chen, MD
  Clinical Director, CodeX & Health Clinical Principal, MITRE

  Muhammad Beg, MD
  Internal Medicine | Medical Treatment of Pancreatic Cancer @UT Southwestern Medical Center (utswmed.org)

  Jamil Rivers
  Founder, Chrysalis Initiative

• **Read the White Paper**
Health Equity and Health Disparities in Cancer Care
Adding outcome objectives to use case(s) in 2022

**Health Equity** is the attainment of the highest level of health for all people. (NCI)

**Health Disparities:** Although cancer incidence and mortality overall are declining in all population groups in the United States, certain groups continue to be at increased risk of developing or dying from particular cancers.

Leverage the **Gravity** Accelerator’s work to identify barriers of people and groups and design interventions.
PATIENT ENROLLMENT BARRIERS VARY BY LOCATION

Step 1: Are trials available locally?  
Step 2: Are patients pre-screened?  
Step 3: Is patient eligible?  
Step 4: Is patient asked to enroll and provided support/education?  
Step 5: Does patient enroll?

Research-Optimized Site*

Clinical Trial
Many trials open
Systematic pre-screening of patients.
Criteria
Eligibility requirements prevent many patients from consideration.
Eligible patients are asked to enroll and provided support/education.
More than 50% of asked eligible patients enroll.

Clinical Trial
Interested patients that are not matched at their institution can search elsewhere using matching tools/services.

Non-Research Focused Site*

Clinical Trial
Few trials open
Trials may only come up if provider or patient asks.
Criteria
Eligibility requirements prevent many patients from consideration.
Non-research focused sites often do not have dedicated staff to answer patient questions or provide resources.
Few patients enroll.

*Comparisons are illustrative only, and individual sites vary.

Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer, American Cancer Society – Cancer Action Network (2018)
https://www.fightcancer.org/policy-resources/clinical-trial-barriers
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
Matching Phase 1: Key Takeaways

▪ How effective are mCODE data as a filter?
  – 8 mCODE elements appear effective in filtering potential clinical trial matches for breast cancer patients to a reasonable number, with few missed trials and manageable number of false positives.

▪ Are certain elements more discriminatory?
  – Age, Cancer Type, Metastases and Prior Treatments are key.
  – Biomarker and Stage = next most valuable additional data.

▪ Are these data structured in the patient record?
  – Age and cancer type = typically structured.
  – Metastasis, past treatments, performance status, subtype, stage = inconsistently structured.
  – Biomarkers = typically unstructured.
Matching Phase 2: Prospective Study (2022)

- Enroll 400+ patients who are looking for potential clinical trials
- Patient Data Managers
- Health sites and their EHR systems
- Matching services

**Example research questions:**
- How are the quality of matches?
- How many patients with true matches consent to enrollment at another health system?
- How many patients follow-through with additional screening?
- How easy is it for providers/patients/health IT staff to use this capability?
Let’s find some clinical trials

Search with data populated from your record, or change to find matching trials

Matching Services
- BreastCancerTrials.org
- Trajectory
- Trialscope

Zip Code: 02215
Travel Distance (miles): 100
Age: 40

Cancer Type: Breast
Cancer Subtype: invasive ductal carcinoma

Metastasis: Lymph Node: Lung
Stage: IV
ECOG Score: 1
Karnofsky Score

Biomarkers:
- ER Positive
- PR Positive
- HER2 Positive
- Add biomarker...

Radiation:
- Radiation Therapy
- Add radiation...

Surgery:
- Bilateral mastectomies
- Add surgery...

Medications:
- Cyclophosphamide
- Methotrexate
- Fluorouracil
- Anastrozole
- Faslodex
- Ibrance
- Erbublin
- Add medication...
<table>
<thead>
<tr>
<th>Clinical Trial Finder</th>
</tr>
</thead>
</table>

**Alyssa971 Goodwin327**  
Female  40 yrs

**New Search**

**Filters**

**SORT BY**
- Match Likelihood
- Distance

**FILTER BY**

**RECRUITMENT STATUS**
- Recruiting  19
- Closed to Accrual  13
- Completed  6
- Terminated  2

**TRIAL PHASE**
- Phase 1  23
- Phase 2  10

**STUDY TYPE**
- Interventional  39
- Observational  1

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**We found 5 matching trials...**

<table>
<thead>
<tr>
<th>Recruiting Status</th>
<th>Study Title</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruiting</td>
<td>Keytruda plus Abraxane Before Surgery for Stage II-III Hormone Positive, HER2 Negative Breast Cancer</td>
<td>High-likelihood match 82.1 miles  Feb 23, 2017 - Jan 2023</td>
</tr>
<tr>
<td>Recruiting</td>
<td>Olaparib &amp; Sapacitabine for People with Advanced Breast Cancer &amp; an Inherited BRCA1/2 Mutation</td>
<td>High-likelihood match 12.9 miles  Oct 1, 2018 - Jun 22, 2025</td>
</tr>
<tr>
<td>Recruiting</td>
<td>Ipatasertib, Hormone Therapy and Ibrance for Metastatic Breast Cancer (TAKTIC)</td>
<td>Possible match 49.2 miles  May 30, 2019 - Jun 30, 2024</td>
</tr>
<tr>
<td>Recruiting</td>
<td>Saccituzumab Govitecan and Talazoparib for Women With Metastatic Triple Negative Breast Cancer</td>
<td>No match 12.9 miles  Oct 9, 2019 - Aug 31, 2024</td>
</tr>
<tr>
<td>Recruiting</td>
<td>Neratinib and Xeloda for Metastatic HER2+ Breast Cancer</td>
<td>No match 32.5 miles  Dec 13, 2017 - Dec 2022</td>
</tr>
</tbody>
</table>
Structuring Eligibility Criteria in mCODE
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

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**Phase 1**
Validation of the Methodology
- Disease Status
  - 5 sites, 2 trials

**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

- 96% Concordance with 95% probability when disease absent
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>not evaluated</td>
</tr>
<tr>
<td>imaging</td>
<td>pathology</td>
<td>symptoms</td>
<td>physical exam</td>
</tr>
<tr>
<td></td>
<td>lab results</td>
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</tr>
</tbody>
</table>

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

*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*

**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

<table>
<thead>
<tr>
<th>Cancer Treatment Plan Change…</th>
<th>&lt;treatment change?&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>No change in treatment plan</td>
<td></td>
</tr>
<tr>
<td>Yes-disease not responding</td>
<td></td>
</tr>
<tr>
<td>Yes-due to AE/toxicity</td>
<td></td>
</tr>
<tr>
<td>Yes-planned change</td>
<td></td>
</tr>
<tr>
<td>Yes-due to patient request</td>
<td></td>
</tr>
<tr>
<td>Yes-due to other</td>
<td></td>
</tr>
</tbody>
</table>
ICAREdata Approach

**Collect Data**
Clinician documents ICAREdata questions in EHR during patient visit using Epic Smart Tools

**Implement ICAREdata Questions**
Build Epic Smart Tools to enable ICAREdata collection in the EHR
- Cancer disease status
- Cancer treatment plan change

**Site User Interface**
- Cancer Disease Status
- Cancer Treatment Plan Change
- Epic EHR

**Install ICAREdata Extraction Client**
- Site Host Machine
- EHR Database
- FHIR Message

**Secure Storage and Analysis**
- FHIR Messaging Service
- Data Processing Service
- Analytics

**ICAREdata Infrastructure**
- Clinician
- Site IT Staff
- MITRE provided
ICAREdata® Phase 2 Clinical Trial Partners
Trial protocol & consent incorporate ICAREdata; more trials under consideration

A071701 Brain Mets Trial
PI: Priscilla Brastianos, MD
Type: Phase II trial
Trial Activation: Aug 2019
Timeline: 3-5 years
Accrual Goal: 150 patients

A021703 Vitamin D Trial
PI: Kimmie Ng, MD, MPH
Type: Phase III randomized trial
Trial Activation: Sept 2019
Timeline: 5 years
Accrual Goal: 400 patients

A031902 CASPAR
PI: Arpit Rao, MD (Co-chair Charles Ryan, MD)
Type: Phase III randomized trial
Trial Activation: Jan 2021
Timeline: 5 years
Accrual Goal: 964 patients

A011801 COMPASS
PI: Ciara O’Sullivan, MB, BCh, BAO
Type: Phase III randomized trial
Trial Activation: Jan 2021
Timeline: 7-14 years
Accrual Goal: 1031 patients

A021806 Pancreatic Trial
PI: Cristina R. Ferrone, MD
Type: Phase III randomized trial
Trial Activation: July 2020
Timeline: 6 years
Accrual Goal: 352 patients

ICAREdata® Companion Protocol Partnering Trials

A021602 CABINET – Randomized, double-blinded phase III study of cabozantinib versus placebo in patients with advanced neuroendocrine tumors after progression on everolimus

A031701 ICONIC – A phase II study of ipilimumab, cabozantinib, and nivolumab in rare genitourinary cancers

A031702 PD1GEE – PD-inhibitor (nivolumab) and ipilimumab followed by nivolumab vs. VEGF TKI cabozantinib with nivolumab: A phase III trial in metastatic untreated renal cell cancer

A031801 RadiCal – A phase II randomized trial of radium-223 dichloride and cabozantinib in patients with advanced renal cell carcinoma with bone metastasis

Embedded Language

<table>
<thead>
<tr>
<th>Study #</th>
<th>PI</th>
<th>Title</th>
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<tr>
<td>A011801</td>
<td>Ciara O’Sullivan</td>
<td>COMPASS HER2 trials examining escalating and de-escalating therapy in HER2-positive breast cancer: Optimizing treatment in residual disease (COMPASS HER2 RD): a double-blinded, Phase III randomized trial</td>
</tr>
<tr>
<td>A021703</td>
<td>Kimmie Ng</td>
<td>SOLARIS</td>
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<tr>
<td>A021806</td>
<td>Cristina Ferrone</td>
<td>A phase III trial of perioperative versus adjuvant chemotherapy for resectable pancreatic cancer</td>
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<td>A031902</td>
<td>Arpit Rao</td>
<td>CASPAR</td>
</tr>
<tr>
<td>A071701</td>
<td>Priscilla Brastianos</td>
<td>Brain Mets</td>
</tr>
</tbody>
</table>
Sets Stage for Future Generalization Studies

**Every cancer patient’s outcomes are captured**

Enables unprecedented application of clinical trial results

**Questions we will answer**
- Are clinical trial results generalizable to broader populations, particularly underrepresented populations?
- If not, what are the sources of differences if observed?
- What are the different patterns of use of newly approved treatment?
- What is the treatment effectiveness and toxicity in more diverse populations outside of clinical trials?

**All patients will benefit from improved care**

Clinical Trial Cohort: ~8%
Trial-Eligible, Not Participating Cohort: ~15%
Not Trial-Eligible Cohort: ~21%
No Trial Available: ~56%

Joseph M. Unger, Riha Vaidya, Dawn L. Hershman, Lori M. Minasian, Mark E. Fleury,
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)

We are here

Phase 0
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.

Phase 1
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.

Phase 2
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.
Technical Architecture - MedMorph Based

UCSF's De-Identified Patient Data Repository

Backend Services App

Knowledge Artifact Repository

Translator Service

CIBMTR

CA State Registry

MCSP

CDC

Registry Reporting Architecture
Health System & PHA Partners
Tentative
Reported for testing purposes only
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 January 2022)

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

Multi-Phased Approach

We are here

Phase 0
Standards Development – mCODE radiotherapy

Phase 1
Proof of Concept – End of treatment summary
Informal IHE-RO XRTS Connectathon – December 13-15th (Results pending)

Phase 2
Proof of Concept – In-progress treatment summary
Upcoming IHE-RO or HL7 Connectathon – targeting May 2022

Phase 3
Pilot Study – End-to-end workflow of treatment summary
FHIR profile development – Phase 1

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

**Planned Course Summary**
- Planned Dose per Volume
- Prescribed Dose per Target Volume

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

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

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

**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

**Planned Fraction**
- Planned Dose per Volume
- Prescribed Dose per Target Volume

**Delivered Fraction**
- Delivered Dose per Volume
- Resumption or complete fraction
- DICOM Reference

**RTTD / XRTS (Plan Summary)**
- Radiotherapy Volume
- Planned Phase

**Delivered Course Summary**
- Body Site
- Diagnosis
- Therapeutic Intent
- Modifiers
- Techniques
- Delivered Number of Sessions
- Delivered Dose per Volume
- Delivered Fractions per Volume

**RTTD / XRTS (Lower Level Delivery Summary)**
- Radiotherapy or Brachytherapy
- Delivered Phase
- Modality
- Technique
- Delivered Number of Fractions
- Delivered Dose per Volume

Include for Session Summary (future)
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.
Da Vinci Standards for Prior Authorization: Schematic View

1. Is there a requirement for PA or specific documentation?
   - YES or NO

2. Coverage Requirements Discovery (CRD)

3. Request templates/rules

4. Receive templates/rules

   - Documentation Templates and Coverage Rules (DTR)

   FHIR-BASED EXCHANGE

   API

   PAYER 1

   API

   PAYER 2

   API

   PAYER 3

Prior Authorization Support

Transformation Layer

Prior Authorization Support

Da Vinci Prior Authorization IGs and Supporting Comment
Prior Authorization in Oncology – Planning Phases
(Updated as of December 2021)

Collaborators

- EVERNORTH
- ASTRO
- varian
- UnitedHealthcare
- ONS
- MITRE
- Mettle SOLUTIONS

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

- 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 0

We are here

Phase 1

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

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 Medicine 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 interest
Membership Information
CodeX Governance and Management

Program Management
Cross-Program Support: CodeX and cross-Accelerator Coordination, Governance, Member Engagement, Architecture, Informatics, Implementation, Education, Communications

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

mCODE Exec Comm

WG & other Accelerators

HL7 International
Lead Strategy & Decision-Making

- Prioritize use cases
- Drive what is standard, design how the standards are implemented and apply your lens for **business and industry impact**
- Stay ahead of regulations

Provide Industry Thought Leadership

- Position yourself and your organization as an **industry thought leader**
- Showcase your organization’s work and progress through member presentations/webinars
- Professional growth opportunities
- Work with leading cancer organizations to transform clinical knowledge to FHIR-based models, develop reference implementations and demonstrate value through pilots

Gain Efficiencies

- **Solve business problems faster and incur less cost** leveraging a community of experts with paid support, including program management and technical support
- Decrease implementation costs through a “build it once and re-use” model to support multiple use cases, workflows, and business partners
- Operate under the umbrella of the world’s premier health IT standards organization (HL7)
Leveraging the mCODE™ standard (minimal Common Oncology Data Elements), CodeX will expand around this core to encompass additional use cases, accelerating opportunities to create a learning health system based on interoperable data and improved patient care.

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

Governance & Oversight

▪ Paying, Government and Sponsored Member have a seat on the Operating Committee

▪ May also run for the decision-making Steering Committee

Use Case Leadership

▪ Serve on Use Case Leadership Teams, where CodeX Members are responsible for developing project plans, engaging partners, and overseeing work that includes transforming domain knowledge to FHIR-based models, implementing these within software and piloting to demonstrate the art of the possible

▪ Recognized as leaders in the quest for Smarter Data in the Fight Against Cancer through CodeX decision-making, thought leadership, conference key notes, press quotes, logos on websites and slides, etc.

Community Building & Access

▪ Premier and Principal Members may sponsor other organizations to become CodeX Members

▪ Learn in a committed community and gain early access to and achieve deeper understanding of FHIR implementation, mCODE and extensions
# CodeX Membership Categories

<table>
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<tr>
<th>Level</th>
<th>Annual Membership Fees</th>
<th>Operating Committee Vote</th>
<th>Sponsor Partner Operating Committee Membership</th>
<th>Use Case Leadership and Decision-Making</th>
<th>Commit Resources</th>
<th>Access and Give Feedback on Use Case Artifacts</th>
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MITRE: Solving Problems for a Safer World

MITRE is a not-for-profit company that operates multiple federally funded research and development centers (FFRDCs)

**Key FFRDC Attributes**

- Federal entities, created by government
- Address problems of considerable complexity
- Analyze technical questions with a high degree of objectivity
- Provide innovative and cost-effective solutions to government problems

**Federally Funded Research and Development Centers:**
Government-created. Ahead of the curve. Stakeholder convener. Solving the nation’s most complex problems. (FAR §35.017)