Introduction to mCODE™ and the CodeX™ HL7 FHIR Accelerator

March 2020

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Contents

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

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

• mCODE / CodeX Use Cases

• CodeX Membership Information

• Cancer Data Summit

• MITRE
Cancer, in the United States

- 39% lifetime risk
- #2 cause of death
- $147 B cost per year
Only 3% of adult cancer patients participate in clinical trials that gather high-quality data.

45% increase in cancer drugs in development over the past ten years with 87% as targeted therapies.

Most of the nearly 15 million individuals living with cancer in the U.S. have Electronic Health Records (EHRs).

**EHR data challenges:**
- Significant variation
- Unstructured
- High Burden
- Difficult to access and share
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>
<th>Max</th>
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</thead>
<tbody>
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<td>Drug spending</td>
<td>$4005</td>
<td>$1519</td>
<td>$27,330</td>
<td>$79,359</td>
<td>$173,572</td>
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<tr>
<td>(n = 1385)</td>
<td></td>
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<tr>
<td>Radiology spending</td>
<td>$282</td>
<td>$1048</td>
<td>$6136</td>
<td>$23,698</td>
<td>$14,982</td>
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<tr>
<td>(n = 459)</td>
<td></td>
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<tr>
<td>Surgery spending</td>
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<td>$963</td>
<td>$9732</td>
<td>$14,982</td>
<td>$14,982</td>
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<tr>
<td>(n = 915)</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Scan spending</td>
<td>$547</td>
<td>$1354</td>
<td>$2921</td>
<td>$6823</td>
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<tr>
<td>(n = 231)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
minimal Common Oncology Data Elements

Every patient’s journey improves all future care
This is Julia.

She’s 65 years old and is diagnosed with breast cancer.

**Accessible**
- ✓ Demographics
- ✓ Conditions
- ✓ Procedures
- ✓ Encounters
- ✓ Medications
- ✓ Devices
- ✓ Labs / Vitals
- ✓ Allergies
- ✓ Smoking Status
- ✓ Care Plan/Team
- ✓ Clinical Notes
- ✓ Immunizations

**Inaccessible**
- X Disease response
- X Adverse events
- X Hormone Receptors
- X Tumor Markers
- X Pathologic / Clinical Staging
- X Tumor Size
- X Nodal Status
- X Metastatic Status
- X Body Site
- X Histology, morphology, behavior
- X Karnofsky / ECOG scores
- X Chemotherapy dose and cycle
- X Radiation technique and fractions
- X Patient reported outcomes

The Current State of FHIR-Enabled Interoperability for Breast Cancer
The Path to Meaningful Interoperability

FHIR establishes the high-level syntax and interfaces for exchange

Argonaut and USCDI standardize foundational patient data

Da Vinci and Carin formalize targeted exchange frameworks

Discipline focused modeling provides detail needed for semantic interoperability
minimal Common Oncology Data Elements

- Small, stable set of critical data elements
- Recommended by top oncologists
- Applicable across key cancer use cases
- Standardized for collection and sharing, using FHIR
- Leading to better cancer care and research

mCODE Release 1 STU1:
http://hl7.org/fhir/us/mcode/
HL7 FHIR Implementation Guide: minimal Common Oncology Data Elements

This illustration is not a formal part of the mCODE specification. Names and structural relationships shown here may not precisely correspond to the data dictionary and FHIR profiles.
Smarter Data for the Fight Against Cancer

http://www.hl7.org/CodeX
A New HL7 FHIR Accelerator

A community and platform to accelerate interoperable data modeling and implementation around mCODE, leading to step-change improvements in cancer care and research

http://hl7.org/CodeX
CodeX announced at HL7/Atlanta (September 17, 2019)
Currently talking with prospective Founding Members

CodeX Website: http://www.hl7.org/CodeX
What is a FHIR Accelerator?
The HL7 FHIR Accelerator Program is designed to assist implementers across the health care spectrum in the creation of FHIR Implementation Guides or other informative documents.

Current FHIR Accelerators:

- CodeX follows the successful Da Vinci project for legal, organizational, funding, governance models.
  [http://www.hl7.org/about/davinci/members.cfm](http://www.hl7.org/about/davinci/members.cfm)
Approach

Gather an influential community that **collaborates to:**

- Prioritize *use cases* around interest and impact
- Create new *data models* and *FHIR IGs*, augment mCODE
- Build *reference implementations*
- Execute *pilots* to demonstrate feasibility and value
- Enable early *adoption* and *scale* by engaging health systems and industry
Vision: Same Core Data Supporting Many Use Cases
Data are collected and shared via the mCODE standard, and CodeX extensions
Use Case Domains

0. Basic mCODE Extraction
1. Real World Data Research
2. Evidence-Based Care
3. Patient Data Management
4. Payment Models
5. Registry Reporting
Building a Trusted Network of Health Systems
Defining Requirements and Testing Solutions

- Mayo Clinic
- Kaiser Permanente
- UCSF
- Intermountain Healthcare
- MD Anderson Cancer Center
- ThedaCare
- Rush University Medical Center
- Saint Joseph Mercy Health System
- Trinity Health
- Massachusetts General Hospital
- Dana-Farber Cancer Institute
- Brigham and Women’s Hospital
- Penn
- Geisinger
- St. Elizabeth Healthcare
CodeX / mCODE Community of Practice

A group of health systems and supporting organizations, working together within the CodeX HL7 FHIR Accelerator.

**Goal:** Develop and share best practices for implementing mCODE and extensions into production EHRs and other systems.

- Latest developments on mCODE, CodeX, and cancer data exchange
- Develop and share best practices for clinical workflows, data modeling, and exchange
- Ask questions and learn from the experience of other community members
Summary of Use Case Projects Underway or in Discovery

mCODE™

More details in a later section
Use-Case-Based Projects Currently Underway

**ICAREdata™**
Evaluates EHR-based clinical trials endpoints collection by defining and validating data elements that define clinical utility (treatment response, toxicity, change in treatment, deviation from clinical pathway).

**Compass**
Demonstrates the use of mCODE elements to allow providers and patients to make informed, shared, data-driven decisions and provide data back to generate new knowledge.

**Camino**
Uses mCODE elements to produce computable pathways, providing key decision support in the selection of treatment options in Oncology Clinical Pathways, evidence-based treatment protocols for delivering cancer care.
New CodeX Use-Case-Based Projects in Discovery

0. mCODE Extraction
1. EHR Endpoints for Clinical Trials
2. Empowering Patients to Find Clinical Trials
3. Registry Reporting
4. Radiation Therapy Data for Care Coordination
5. Oncology Clinical Pathways Navigation
6. Clinical Cancer Data Exchange (Providers/Payers)
7. Alternative Payment Model Data Reporting
8. Drug Value Based Agreements

Active
Proposed
## Summary of CodeX Use Cases in Discovery

[https://confluence.hl7.org/display/COD/CodeX+Use+Cases](https://confluence.hl7.org/display/COD/CodeX+Use+Cases)  
*(as of March 2020)*

<table>
<thead>
<tr>
<th>Use Case</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>mCODE Extraction</td>
<td>Enable EHRs and other systems to provide cancer patient data that conforms to the standard defined by the mCODE FHIR IG.</td>
</tr>
<tr>
<td>EHR Endpoints for Clinical Trials</td>
<td>Reduce and potentially eliminate manual and/or duplicate data entry into case report forms (CRF).</td>
</tr>
<tr>
<td>Empowering Patients to Find Clinical Trials</td>
<td>Improve capability for patients to find clinical trials for which they may be eligible.</td>
</tr>
<tr>
<td>Registry Reporting</td>
<td>Enable low-burden, standardized reporting of cancer data from cancer centers to registries that are aggregating data for different reasons.</td>
</tr>
<tr>
<td>Radiation Therapy Data for Care Coordination and Data Reuse</td>
<td>Enable sharing of critical radiation therapy summary data for care coordination or data reuse (research, quality measurement, payer-required reporting).</td>
</tr>
<tr>
<td>Oncology Clinical Pathways (OCP)</td>
<td>Enable clinicians to use an oncology clinical pathway application that accurately navigates to recommended treatments using structured data in the EHR.</td>
</tr>
<tr>
<td>Clinical Cancer Data Exchange (CCDE)</td>
<td>Enable automatic exchange of clinical oncology data recorded by providers, to payers.</td>
</tr>
<tr>
<td>Alternative Payment Model Data Reporting</td>
<td>Facilitate clinical practice reporting to registries and payer repositories governed by oncology payment models, such as chemotherapy episodes.</td>
</tr>
<tr>
<td>Drug Value-Based Agreement (VBA)</td>
<td>Operationalize drug value-based agreements for clinicians, payers, and pharma through collection of real world data in EHRs.</td>
</tr>
</tbody>
</table>
Membership Information
CodeX Member Benefits

In addition to contributing to a platform for interoperable data to improve cancer care and research, CodeX members …

▪ Work with leading cancer care organizations to *transform clinical knowledge* to FHIR-based models, develop reference implementations and pilots
▪ *Drive use cases* and projects
▪ Operate under the umbrella of the world’s premier open health IT standards organization (HL7)
▪ *Gain early access* to and achieve deeper understanding of future standards and how to implement
▪ Benefit from overarching and use-case-based project management
▪ Sponsor another organization to become a CodeX member*

* Depends on membership level. See later slide.
## CodeX Membership Categories

<table>
<thead>
<tr>
<th>Level</th>
<th>Annual Membership Fees</th>
<th>Operating Committee Vote</th>
<th>Sponsor Operating Committee Membership</th>
<th>Opportunity to Provide PMO Staff</th>
<th>Pledge Resources</th>
<th>Access to Use Case Artifacts</th>
<th>Provide Feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Founder</strong> (early adopters – join by 1 July 2020)</td>
<td>$ 35,000</td>
<td>1</td>
<td>2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Premier</strong></td>
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<td>2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Sponsor</strong></td>
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<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td><strong>Member</strong></td>
<td>$ 20,000</td>
<td>1</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Organization sponsored by Premier or Sponsor member</td>
<td>Free</td>
<td>1</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Developer/ Implementer</strong></td>
<td>Free</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Gov’t Agencies</strong></td>
<td>Free</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Community of Practice</strong></td>
<td>Free</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
CodeX Organizational Plan
To be finalized by initial members

- CodeX Steerung Committee
- CodeX Operating Committee (person from each member)
- Project Management
- Architecture (interoperability, consistency)
- Support (training, reqs, modeling, FHIR, implementation, pilots)

- Use-Case-Based Project #1
- Use-Case-Based Project #2
- Use-Case-Based Project #N

mCODE Council

- Proposed, new mCODE elements
- Oncology Expertise

FHIR IGs sent to HL7 Work Groups as agreed by CodeX
Identifying CodeX Use-Case-Based Projects

CodeX members will prioritize and recommend use cases for development based on:

- Potential Value
- Speed
- Community Commitment

**Discovery**
- Identify use cases of interest
  - Potential Members & Partners
  - Thought Leaders
  - mCODE Council

**Use Case Backlog**
- Use Case 1
- Use Case 2
- Use Case N

**Selection**
- Collaborate to refine value proposal, workflow, scope

**Planning**
- Solidify project plan and kick-off work
  - PLAN
    - Target outcomes
    - Roadmap/timeline
  - TEAM
    - Champion
    - Key partners

**Execution**
- Develop models/IGs
- Reference Implementations/Pilots

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Impact
- Value Alignment

Viability
- Community Drive, Speed
More Detail on Use Case Projects Underway or in Discovery
**mCODE Extraction**

**Problem:** mCODE compliant data stored in EHRs must be made available to support downstream requirements.

**Target Outcome:** patient mCODE data is available to any workflow in standard, HL7 FHIR resources.

Note: This use case focuses on the patient looking for clinical trials. Healthcare providers looking for trials on behalf of their patients and/or investigators trying to enroll patients in a trial will be addressed in separate use cases.
EHR Endpoints for Clinical Trials

- Establish a network of research sites and data collection infrastructure
  - Demonstrate real-world data strategy for clinical trials based on mCODE
  - Extend ICAREdata to additional trials with new data needs
  - Create data elements in addition to mCODE needed to complete most CRFs

- New applications, e.g.
  - RWD to support patients searches for trials and enrollment
  - Rare disease trials
**EHR Endpoints for Clinical Trials**

- **Investigators leverage clinical treatment data captured in the EHR to derive and/or compute clinical trial endpoints.**
  - Eliminates (or reduces) the need for manual entry of duplicate data into case report forms (CRFs).
  - If the trial requires data stored outside the EHR (e.g., patient-reported outcomes, laboratory data, etc.), ideally this data can also be expressed in a standard, computable manner via mCODE and extensions.

*Facilitating capture of high-quality data at the point of care is critical.*
Support the collection of high-quality real-world data, based on mCODE to enable clinical oncology research.

**CLINICAL TRIAL**

Clinician  Patient

Clinical Trial Care Events [3% PATIENTS]

Clinical Trial Data

Data collected only on patients in clinical trials (97% cancer patients not represented)

**ICAREdata®**

Clinician  Patient

All Care Events

Research Quality Real-World Data (RWD)

Data collected on all patients as part of routine cancer care

**Learning Health System**

Every patient’s journey improves all future care

RWD-based clinical oncology research

Data-driven patient care
ICAREdata Outcome Questions

**ICAREdata**: Develop and validate mCODE-based outcome measures

## 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;lesion evaluated&gt;</th>
<th>&lt;status value&gt;</th>
<th>&lt;reason value&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>primary tumor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>metastatic lesion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>complete response</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>partial response</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>stable disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>progressive disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>not evaluated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>imaging</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pathology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>symptoms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>physical exam</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>markers</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sample Resulting Structured Phrase***

#Cancer disease status observed for #primary tumor was #progressive disease based on #imaging and #symptoms

* Blue font denotes controlled vocabularies

## Treatment change

**Clinical Assessment**
Based on your evaluation today, are you making a change in treatment?

**ICAREdata Question Format**

<table>
<thead>
<tr>
<th>Treatment change...</th>
<th>&lt;treatment change?&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>- disease not responding</td>
<td></td>
</tr>
<tr>
<td>- due to AE/toxicity</td>
<td></td>
</tr>
<tr>
<td>- yes-pre-planned therapy transition</td>
<td></td>
</tr>
<tr>
<td>- patient request</td>
<td></td>
</tr>
<tr>
<td>- yes-due to other</td>
<td></td>
</tr>
</tbody>
</table>

**Sample Resulting Structured Phrase***

#Treatment change #yes-disease not responding
Empowering Patients to Find Clinical Trials

Problem: Existing patient-facing tools for trial matching typically require a challenging amount of manual clinical data entry to provide matches.

Target Outcome: Develop open data standards and open APIs that enable interoperable, scalable, and accessible trial matching services.

Providers want to find clinical trials suitable for their patients.

Patients want to identify clinical trials for which they are eligible.

Investigators want patients to enroll in clinical trials.

EHR-Based Data

Patient-Accessible Data

Existing and Future Patient – Clinical Trial Matching Services

Eligibility Criteria

Clinical Trial Information

mCODE++: leveraging mCODE with possible extensions

Note: This use case focuses on the patient looking for clinical trials. Healthcare providers looking for trials on behalf of their patients and/or investigators trying to enroll patients in a trial will be addressed in separate use cases.
Registry Reporting

**Problem:** Data collection and aggregation puts a high burden on reporters and registries. Variability in patient data collection negatively impacts overall understanding of patient care.

**Target Outcome:** Enable low-burden, standardized reporting of cancer data from cancer centers to registries that are aggregating data for different reasons.

Registries require a low-burden approach to data reporting from clinical sites.

- **EHR-Based Data**
- **Patient Interaction**
- **FHIR Endpoints with Automated Solution**

mCODE++: leveraging mCODE with possible extensions.

- Treatment Data
- RESEARCHERS (Treatment effectiveness research)
- REGULATORS (Public health monitoring efforts)
- Payers (Accountable care arrangements)
Radiation Therapy Treatment Summary

**Problem:** Radiation therapy treatment details are not readily available in systems other than radiation oncology EHR modules.

**Target Outcome:** Develop, test and deploy open data standards that enable interoperable, multi-purpose exchange of radiation treatment summary data for care coordination and data reuse.
1st Cancer Data Summit
October 3-4, 2019, Mclean, VA
MITRE: Solving Problems for a Safer World

**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

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

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

**Objectivity & independence**
**Long-term strategic partner**
**Deep technical expertise**
**Sensitive data**
**Close to inherently governmental function**
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.

Learn more www.hl7.org/codex/