Introduction to mCODE™ and the CodeX™ HL7 FHIR Accelerator

June 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
• Call to Action
• MITRE
Cancer, in the United States

39% lifetime risk

#2 cause of death

$147 B cost per year
Most of the nearly 15 million individuals living with cancer in the U.S. have Electronic Health Records (EHRs).

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

Only **3%** of adult cancer patients participate in clinical trials that gather high-quality data.

**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).
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.

<table>
<thead>
<tr>
<th>Accessible</th>
<th>Inaccessible</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓ Demographics</td>
<td>X Disease response</td>
</tr>
<tr>
<td>✓ Conditions</td>
<td>X Adverse events</td>
</tr>
<tr>
<td>✓ Procedures</td>
<td>X Hormone Receptors</td>
</tr>
<tr>
<td>✓ Encounters</td>
<td>X Tumor Markers</td>
</tr>
<tr>
<td>✓ Medications</td>
<td>X Pathologic / Clinical Staging</td>
</tr>
<tr>
<td>✓ Devices</td>
<td>X Tumor Size</td>
</tr>
<tr>
<td>✓ Labs / Vitals</td>
<td>X Nodal Status</td>
</tr>
<tr>
<td>✓ Allergies</td>
<td>X Metastatic Status</td>
</tr>
<tr>
<td>✓ Smoking Status</td>
<td>X Body Site</td>
</tr>
<tr>
<td>✓ Care Plan/Team</td>
<td>X Histology, morphology, behavior</td>
</tr>
<tr>
<td>✓ Clinical Notes</td>
<td>X Karnofsky / ECOG scores</td>
</tr>
<tr>
<td>✓ Immunizations</td>
<td>X Chemotherapy dose and cycle</td>
</tr>
<tr>
<td></td>
<td>X Radiation technique and fractions</td>
</tr>
<tr>
<td></td>
<td>X Patient reported outcomes</td>
</tr>
</tbody>
</table>
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.
mCODE Collaboration

ASCO® AMERICAN SOCIETY OF CLINICAL ONCOLOGY
MITRE
ASTRO™
ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY
NIH NATIONAL CANCER INSTITUTE
CancerLinQ®
Dana-Farber®
Cancer Institute
BRIGHAM AND WOMEN’S HOSPITAL
Intermountain Healthcare
logica® information at the speed of life
HL7® International
FHIR®

Common Oncology Data Elements extensions
mCODE 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/
“Cancer patients are willing to share their data in hopes of finding solutions, not just for themselves but for patients in the future.”

**Smarter Data for the Fight Against Cancer**

http://www.hl7.org/CodeX
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 is adapting the successful Da Vinci project for legal, organizational, funding, governance models.

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 to augment mCODE when needed
- Build reference implementations
- Provide test datasets in mCODE and extensions
- Execute pilots to demonstrate feasibility and value
- Enable early adoption and scale by engaging health systems and industry
Vision: Patient Data Collected Once to Support 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
- St. Joseph Mercy Ann Arbor
- Trinity Health
- Massachusetts General Hospital
- Dana-Farber Cancer Institute
- Brigham Health
- 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

Organizations participating in the CoP (as of May 2020)
- Alliance for Clinical Trials in Oncology
- American Society of Clinical Oncology
- ASTRO
- Brigham and Women’s Hospital
- Cancer Insights
- Center for International Blood & Marrow Transplant Research
- Centers for Disease Control and Prevention
- Cerner
- Dana Farber Cancer Institute
- Duke University Health System
- Elsevier
- Epic
- Foundation Medicine
- Intermountain Medical Center
- JKM Software
- Kaiser Permanente
- MaineHealth
- Mayo Clinic
- Memorial Sloan Kettering Cancer Center
- Trinity Health/Saint Joseph Health System
- Princess Margaret Cancer Center
- Quantum Leap Health Collaborative
- University of California San Francisco Medical Center
- University of Michigan Medicine
- University of Texas Southwestern Medical Center
**CodeX Members** (June 2020 – first 6 months of operation)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Member Type</th>
<th>Founder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alliance for Clinical Trials in Oncology Foundation</td>
<td>Premier</td>
<td>★</td>
</tr>
<tr>
<td>ASTRO</td>
<td>Premier</td>
<td>★</td>
</tr>
<tr>
<td>Cancer Insights</td>
<td>Developer/Implem</td>
<td></td>
</tr>
<tr>
<td>Center for International Blood and Marrow Transplant Research (CIBMTR)</td>
<td>Premier</td>
<td>★</td>
</tr>
<tr>
<td>EMD Digital</td>
<td>Premier</td>
<td>★</td>
</tr>
<tr>
<td>HL7</td>
<td>Premier</td>
<td>★</td>
</tr>
<tr>
<td>MITRE</td>
<td>Premier</td>
<td>★</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Premier</td>
<td>★</td>
</tr>
</tbody>
</table>

Many other organizations from – including health systems, vendors, payers, government agencies and more – are actively discussing use cases of interest and CodeX membership.
Summary of Use Case Projects Underway or in Discovery

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

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.
CodeX Use-Case-Based Projects

0. mCODE++ Extraction
1. EHR Endpoints for Cancer Clinical Trials (future extensions of ICAREdata)
2. Integrated Trial Matching for Cancer Patients and Providers
3. Cancer Registry Reporting
4. Oncology Clinical Pathways
5. Radiation Therapy Treatment Data for Cancer
7. Alternative Payment Model Data Reporting for Cancer
8. Drug Value Based Agreements for Cancer

Active Community Development
Active Community Planning
In Discovery

CodeX Common Oncology Data Elements Extensions
# 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 Cancer Clinical Trials</td>
<td>Reduce and potentially eliminate manual and/or duplicate data entry into case report forms (CRF).</td>
</tr>
<tr>
<td>Integrated Trial Matching for Cancer Patients and Providers</td>
<td>Improve capability for patients to find clinical trials for which they may be eligible.</td>
</tr>
<tr>
<td>Cancer 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 Treatment Data for Cancer</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>Oncology Clinical Pathways: Prior Authorization Support</td>
<td>Enable automatic exchange of clinical oncology data recorded by providers, to payers.</td>
</tr>
<tr>
<td>Alternative Payment Model Data Reporting for Cancer</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 for Cancer</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>
<td>$ 45,000</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>
<td>$ 30,000</td>
<td>1</td>
<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></td>
<td>X</td>
<td>X</td>
<td>X</td>
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<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></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></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>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
CodeX Organizational Plan
To be finalized by initial members

- **mCODE Council**
  - Proposed, new mCODE elements
  - Oncology Expertise

- **CodeX Operating Committee** (person from each member)
  - CodeX Steering Committee
  - 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**

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  |  Community Commitment  |  Speed

**Discovery**
- Identify use cases of interest

**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

Use Case Backlog
- Use Case 1
- Use Case 2
- ... Use Case N
Accessible to the Public
https://confluence.hl7.org/display/COD/CodeX+Home

Objective

**CodeX (Common Oncology Data Elements eXtensions)** is an HL7 FHIR Accelerator that is building a community to accelerate interoperable data modeling and applications leading to step-change improvements in cancer patient care and research.

CodeX members are achieving interoperability by integrating the **mCODE** (minimal Common Oncology Data Elements) FHIR Implementation Guide — a standard language for cancer data — into existing and new applications. As a part of this effort, CodeX will also develop extensions to mCODE as needed for Use-Cases-based projects to be successful.

For background, see the more detailed overview. To stay up to date on all CodeX news, subscribe to the general mailing Listserv below.

Use Cases

A number of potential CodeX Use Cases are now in the Discovery phase. These are Use Cases that promise to substantially improve cancer care and research through community alignment around the use of mCODE and necessary extensions for the sharing of standardized, structured cancer data. Current and prospective CodeX members are reviewing and building out Use Cases that will become the first CodeX projects.
More Detail on Use Case Projects Underway or in Discovery

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

The Extractor provides a bridge to retrieving data from EHRs and providing them as mCODE++ via FHIR – an interim solution until the time when EHRs natively supported mCODE and FHIR.

Patient mCODE++ data is available in any workflow in standard, HL7 FHIR resources.

- Integrated Trial Matching for Cancer Patients and Providers
- Cancer Registry Reporting
- Radiation Therapy Treatment Data for Cancer
- Oncology Clinical Pathways
- Oncology Clinical Pathways: Prior Authorization Support
- EHR Endpoints for Cancer Clinical Trials

mCODE++: mCODE, with possible extensions
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 Cancer Clinical Trials

Researchers need computable and obtainable clinical trial endpoints without added burden.

Through mCODE++, researchers obtain clinical trial endpoints captured through an EHR with lower burden.

Patient data is entered into collection systems, extracted and transformed into mCODE++ format as needed, and then sent via FHIR to trials managers – an interim solution until the time when these systems natively support mCODE and FHIR.

mCODE++: leveraging mCODE with possible extensions
ICAREdata®
Integrating Clinical Trials And Real-world Endpoints data

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
Goal 100% Patients

Data collected on all patients as part of routine cancer care

Learning Health System

Research Quality Real-World Data (RWD)

Standard data elements

ICAREdata® - ICAREdata Integrating Clinical Trials And Real-world Endpoints data

RWD-based clinical oncology research

Every patient’s journey improves all future care

Data-driven patient care

#data
#data
#data
## 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>complete response</td>
<td>stable disease</td>
<td>imaging</td>
</tr>
<tr>
<td>metastatic lesion</td>
<td>partial response</td>
<td>progressive disease</td>
<td>pathology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>not evaluated</td>
<td>symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>physical exam</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>markers</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>No</td>
</tr>
<tr>
<td>Yes - disease not responding</td>
<td>Yes - disease not responding</td>
</tr>
<tr>
<td>Yes - due to AE/toxicity</td>
<td>Yes - due to AE/toxicity</td>
</tr>
<tr>
<td>Yes - pre-planned therapy transition</td>
<td>Yes - pre-planned therapy transition</td>
</tr>
<tr>
<td>Yes - patient request</td>
<td>Yes - patient request</td>
</tr>
<tr>
<td>Yes - due to other</td>
<td>Yes - due to other</td>
</tr>
</tbody>
</table>

**Sample Resulting Structured Phrase***

#Treatment change  #yes-disease not responding
Integrated Trial Matching for Cancer Patients and Providers

Providers want to find clinical trials suitable for their patients.

Patients want to identify clinical trials for which they may be eligible.

Investigators want to find eligible patients to enroll in clinical trials.

Patient data is entered into the EHR, extracted and transformed into mCODE++ format, and then sent via FHIR to clinical trial matching services – an interim solution until the time when EHRs natively support mCODE and FHIR.

mCODE++: leveraging mCODE with possible extensions
Cancer Registry Reporting

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

Registries receive standardized reporting of cancer data through mCODE ++ that enables successful communication to other sectors.

**mCODE++ Extraction (as needed)**

Patient data is entered into the EHR, extracted and transformed into mCODE++ format, and then sent via FHIR to registries – an interim solution until the time when EHRs natively support mCODE and FHIR.

mCODE++: leveraging mCODE with possible extensions
Radiation Therapy Treatment Data for Cancer

FHIR mCODE++ radiation treatment data extraction from radiation oncology EHR module and sent to EHR. Through mCODE++, radiation therapy treatment summary data is available for clinical care, surveillance and evaluation.

mCODE++ Extraction (as needed)

Patient data is entered into Rad Onc EHRs, extracted and transformed into mCODE++ format as needed, and then sent via FHIR to health system EHRs – an interim solution until the time when these systems natively support mCODE and FHIR.

mCODE++: leveraging mCODE with possible extensions
Old Use Case Domain-Oriented Slides
(there’s probably some good stuff we can use here)
Establish a community to enable evidence-based care delivery and shared decision making using mCODE

- Health systems, payers, patients, vendors

Focus on improving care and reducing costs

- Computed pathway conformance to reduce variation and automate prior auth
- Comparative effectiveness to enable shared decision making
Comparing outcomes and side effects from matched patients

Matching to similar patients in CancerLinQ database

<table>
<thead>
<tr>
<th>Name</th>
<th>Invasive ductal carcinoma of breast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis</td>
<td>18 Dec 2018 (age 51)</td>
</tr>
<tr>
<td>Laterality</td>
<td>Right</td>
</tr>
<tr>
<td>Tumor Histology</td>
<td>ductal carcinoma</td>
</tr>
<tr>
<td>Histological Grade</td>
<td>2 (moderately differentiated)</td>
</tr>
<tr>
<td>Clinical Stage</td>
<td>IA</td>
</tr>
</tbody>
</table>

**Data elements**

<table>
<thead>
<tr>
<th>Overall survival rates</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 yr</td>
<td>2 yr</td>
</tr>
<tr>
<td>77%</td>
<td>24%</td>
</tr>
<tr>
<td>95%</td>
<td>2%</td>
</tr>
<tr>
<td>90%</td>
<td>4%</td>
</tr>
<tr>
<td>95%</td>
<td>5%</td>
</tr>
<tr>
<td>97%</td>
<td>2%</td>
</tr>
<tr>
<td>51%</td>
<td>25%</td>
</tr>
<tr>
<td>46%</td>
<td>20%</td>
</tr>
</tbody>
</table>

**Surgery & Radiation therapy**
- Lymphedema (14%)
- Skin irritation (5%)

**Hormonal therapy & chemotherapy**
- Nausea & vomiting (25%)
- Hair loss (21%)

**Chemotherapy**
- Nausea & vomiting (20%)
- Neutropenia (12%)

**Hormonal therapy**
- Hot flash (33%)
- Nausea (5%)
Patient Data Management

- Putting the patient at the center of our healthcare system is a fundamental paradigm shift.
- Demonstrate an mCODE-based Patient Data Manager, enabling:
  - Patient ownership and right to access
  - Longitudinal health record
  - Patient-centered research and care
  - Value-added services and APIs
Payment Models

- **Radiation Oncology Alternative Payment Model**
  - Mandatory Centers for Medicare and Medicaid Services (CMS) payment model being developed
  - Engage with health systems, vendors, and payers through a regulatory avenue
  - Large proportion of model reimbursement will be focused on collecting a core set of data

- **Chimeric Antigen Receptor T-Cell Therapy**
  - Breakthrough, personalized cure for cancer
  - Challenges include high cost, uncertain benefit
  - CMS and other payers are exploring coverage with evidence development requiring data

*$510,563$ total expected cost of CAR-T
Registries

- Enable more automated reporting to cancer registries using mCODE APIs
  - NCI Surveillance, Epidemiology, and End Results Program (SEER)
  - ASCO CancerLinQ
  - CIBMTR: CAR-T
  - CDC National Program of Cancer Registries

- Improve timeliness and accuracy of data while reducing reporting costs

* In Development
1st Cancer Data Summit
October 3-4, 2019, Mclean, VA

https://confluence.hl7.org/display/COD/Cancer+Data+Summit+2019
“IT’S AMAZING TO SEE THE PACE FOR CONCEIVING AND LAUNCHING THIS EFFORT. THERE’S A LOT OF MOMENTUM BEHIND IT.”

ANEESH CHOPRA, PRESIDENT OF CAREJOURNEY, FORMER U.S. CTO

Call to Action
We Need Your Help to Ensure that Every Patient’s Journey Informs All Future Care

- Test mCODE version 1.0 and give feedback
- Ask to join the mCODE Council to help build, maintain and promote mCODE
- Join CodeX, the HL7 FHIR Accelerator, to demonstrate and implement mCODE for important use cases
- Participate in CodeX through a special Committee of Practice, where health systems discuss basic implementation of mCODE for care and research
- Suggest and participate in pilots of mCODE in CodeX and ICAREdata
- Share the vision of mCODE in your communications.
Public Resources to Build the Community

**Greg Simon**
- Executive outreach

**CodeX Email List**
- 500 people
- 200 organizations

**Virtual HIMSS20**
- Steve Bratt *(panel, audio)*
- Greg Shemancik *(videos: talk, interview)*

**Materials**
- CodeX Fact Sheet

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https://confluence.hl7.org/display/COD/CodeX+Home
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/](http://www.hl7.org/codex/)
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

*FAR §35.017

Objectivity & independence

Long-term strategic partner

Deep technical expertise

Sensitive data

Close to inherently governmental function

Federally Funded Research and Development Centers: Government-created. Ahead of the curve. Stakeholder convener. Solving the nation’s most complex problems. (FAR §35.017)
ASCO Volunteer Team (met 2018 - 19)
Identified core mCODE data elements necessary to address use cases

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

A volunteer-led, staff-driven, cross-ASCO project to assemble a core set of structured data elements for the oncology EHR