Introduction to mCODE™ and the CodeX™ HL7 FHIR Accelerator

Steve Bratt sbratt@mitre.org
Greg Shemancik gshemancik@mitre.org
December 2019
Contents

- Introduction to mCODE
- HL7 FHIR accelerator (CodeX)
- Cancer Data Summit
- Opportunities and Next Steps

© 2019 The MITRE Corporation. All rights reserved.
MITRE: Solving Problems for a Safer World

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

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

**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

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

*Every patient’s journey improves all future care*
Cancer

- 39% lifetime risk
- #2 cause of death
- $147 B cost per year

© 2019 The MITRE Corporation. All rights reserved.
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.

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

© 2019 The MITRE Corporation. All rights reserved.
mCODE™, or Minimal Common Oncology Data Elements, is a data standard that can be widely adopted. It holds promise to greatly increase high-quality data for all cancer types.

Through mCODE™, every patient’s journey can improve all future care, and provide ...

- SAFER CARE
- BETTER THERAPIES
- IMPROVED OUTCOMES
- LOWER COST
mCODE ™ minimal Common Oncology Data Elements

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

mCODE balloted in HL7 in Aug-Sep:
Initial Collaborators

- ASCO
- MITRE
- CancerLinQ
- ASTRO
- Alliance for Clinical Trials in Oncology
- FDA
- NIH
- Dana-Farber Cancer Institute
- Brigham and Women's Hospital
- Intermountain Healthcare
- HSPC
- HL7 International
- FHIR
Balloted in HL7 Aug-Sep 2019
Standard for Trial Use based on FHIR R4

© 2019 The MITRE Corporation. All rights reserved.
mCODE-Enabled Projects

**ICAREdata™**

EHR-based clinical trials endpoints collection:
Validate mCODE data elements that define clinical utility (treatment response, toxicity, change in treatment, deviation from pathway)

**Compass**

Shared patient – clinician decision making:
Demonstrate use of mCODE elements to allow providers and patients to make informed, data-driven treatment decisions and provide data back to generate new knowledge
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>observed for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>primary tumor</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>
<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>
</tbody>
</table>

Sample Resulting Structured Phrase*

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

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-disease not responding</td>
<td></td>
</tr>
<tr>
<td>Yes-due to AE/toxicity</td>
<td></td>
</tr>
<tr>
<td>Yes-pre-planned therapy transition</td>
<td></td>
</tr>
<tr>
<td>Yes-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

* Blue font denotes controlled vocabularies
### Comparing outcomes and side effects from matched patients

<table>
<thead>
<tr>
<th>Overall survival rates</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1yr</td>
<td>5%</td>
</tr>
<tr>
<td>2yr</td>
<td>75%</td>
</tr>
<tr>
<td>5yr</td>
<td>90%</td>
</tr>
</tbody>
</table>

#### Data elements

- **Comparing outcomes and side effects from matched patients**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>1yr</th>
<th>2yr</th>
<th>5yr</th>
<th>1yr</th>
<th>2yr</th>
<th>5yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormonal therapy &amp; chemotherapy</td>
<td>97%</td>
<td>95%</td>
<td>90%</td>
<td>5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>96%</td>
<td>94%</td>
<td>90%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hormonal therapy</td>
<td>96%</td>
<td>89%</td>
<td>80%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### mCODE

Data elements

- **Matching to similar patients in CancerLinQ database**
Public report coming within a month
Smarter Data for the Fight Against Cancer

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 following the successful Da Vinci project for legal, organizational, funding, governance models
http://www.hl7.org/about/davinci/members.cfm
A New HL7 FHIR Accelerator

Building a community and platform to accelerate interoperable data modeling and implementation around mCODE, leading to step-change improvements in cancer care and research.
CodeX announced at HL7/Atlanta (September 17, 2019)
Currently talking with prospective Founding Members

CodeX Website: [http://www.hl7.org/CodeX](http://www.hl7.org/CodeX)

Approach

Gather stakeholders collaborate to:

- Prioritize use cases around interest and impact
- Create new data models and FHIR IGs, extending around the mCODE core
- Build Reference Implementations
- Execute pilots in the field to demonstrate feasibility and value
- Open standards and open source*

* Models, IGs, APIs and other artifacts developed collaboratively by members working within CodeX projects will be available royalty-free. Systems developed outside of CodeX are welcomed to leverage all CodeX products for free and may be used as part of connectathons and pilots under whatever licensing terms the owners choose.
CodeX Domains of Interest to Prospective Members

Use cases within domains will be shaped by CodeX members
CodeX Organizational Plan
Gather communities of interest and capabilities

- mCODE Council
  - Proposed, new mCODE elements
  - Implementation support
- Use-Case-Based Project #1
- Use-Case-Based Project #2
- Use-Case-Based Project #N
- Oncology Advisory Board
- Project Management
  - Architecture (interoperability, consistency)
  - Support (training, reqs, modeling, FHIR, implementation, pilots)
- CodeX Operating Committee (person from each member)
- CodeX Steering Committee
  - FHIM IGs sent to HL7 Work Groups as agreed by CodeX

© 2019 The MITRE Corporation. All rights reserved.
In addition to contributing to a platform for interoperable data to improve cancer care and research, CodeX members can ... 

- Under the umbrella of the world’s premier open health IT standards organization (HL7)
- Overarching and use-case-based project management
- Drive use cases and projects
- Early access to and deeper understanding of future standards and how to implement
- Work with world leading companies, their experts and tools to define use cases, transform clinical knowledge to FHIR-based models, develop reference implementations and pilot
- Sponsor another organization to become a CodeX member*

* Depends on membership level. See later slide.
Proposed Membership Fees

Annual membership fees are based on estimated cost of developing and testing FHIR IGs and Implementation Guides for selected use cases, and the estimated complexity of use cases.

<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 Resource</th>
<th>Access to Use Case Artifacts</th>
<th>Provide Feedback</th>
</tr>
</thead>
<tbody>
<tr>
<td>Founder (early adopters – join by specified date)</td>
<td>$35,000</td>
<td>1</td>
<td>2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Premier</td>
<td>$45,000</td>
<td>1</td>
<td>2</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Sponsor</td>
<td>$30,000</td>
<td>1</td>
<td>1</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Member</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>Developer/Implementer</td>
<td>In kind only</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
Use Case Domains

Detailed use cases and participants within each Domain will be defined by CodeX members. Descriptions and organizations in the following slides are not final.
Priority Use Cases Domains
Others to be defined by CodeX members

0. Community of Practice
1. Real World Data
2. Evidence-based Care
3. Patient Data Management
4. Payment Models
5. Registry Reporting
**CodeX mCODE Community of Practice**

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

Goal: To improve cancer care and research by developing and sharing best practices for implementing mCODE and extensions into production EHRs and other systems.

Participation in CoP teleconferences (roughly monthly) is free and open to all interested parties. Participants can expect to:

- Stay apprised of the latest developments for mCODE, CodeX, and cancer data exchange
- Develop and share best practices for clinical workflows, data modeling, and exchange
- Have a venue to ask questions and learn from the experience of other community members
mCODE Implementation
- Workflow definitions
- Mapping EHR/apps into FHIR APIs
- Access (authorization, scope push/pull, queries)
- Validation

Grow broader community to support ICAREdata RWD trials
- Model development and implementation
- Vendors, medical centers, pharmaceuticals

Establish a network of research sites and data collection infrastructure
- Extend ICAREdata to additional trials
- Demonstrate real-world data strategy for clinical trials based on mCODE
Evidence-based Care

- 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**
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 (i.e., mCODE)

- **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 in alignment with mCODE

$510,563$ 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)
  - Commission on Cancer: National Cancer Database
  - CDC National Program of Cancer Registries
  - ASCO CancerLinQ

- Improve timeliness and accuracy of data while reducing reporting costs
Relationship between CodeX, HSPC and HL7

**CodeX**
- Common Oncology Data Elements
- Agile Project Operations & Governance
- Clinical Use Cases
- Clinical Field Testing
- Implement in Applications
- Open Source Software Repository
- Use
- Future projects
- App developers
- EHR vendors
- Researchers
- Etc.

**HSPC:**
- Clinical review, coordination, and governance
- Cross-domain curated model repository
- Application of models in interop app marketplace

**HL7:**
- Technical review
- Standardization, if desired

**Open HSPC/CIIC Model Repository**
- Use
How To Get Involved:
Interested in joining CodeX or learning more?
Please contact Greg Shemancik gshemancik@mitre.org and Steve Bratt sbratt@mitre.org

© 2019 The MITRE Corporation. All rights reserved.
MITRE’s mission-driven teams are dedicated to solving problems for a safer world. Through our federally funded R&D centers and public-private partnerships, we work across government to tackle challenges to the safety, stability, and well-being of our nation.

Learn more www.mitre.org