THE CANCER DATA SUMMIT
SMARTER DATA FOR THE FIGHT AGAINST CANCER

OUTERNET PASSCODE: like bark farm skill
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>1:00</td>
<td>Welcome</td>
<td>John Halamka and Steve Bratt</td>
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<td>1:10 - 1:40</td>
<td>Overview of Oncology Standards for Health Records</td>
<td>Andre Quina</td>
</tr>
<tr>
<td>1:40 - 2:00</td>
<td>From Clinical Requirements to FHIR</td>
<td>May Terry</td>
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<td>2:00 - 2:30</td>
<td>mCODE Model</td>
<td>Robert Miller and Mark Kramer</td>
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<td>2:30 - 3:00</td>
<td>Break</td>
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<td>3:00 - 3:35</td>
<td>mCODE Pilots</td>
<td>Mary Pulvermacher and Margaret Van Meter</td>
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<td>3:35 - 4:15</td>
<td>mCODE Implementation</td>
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<td>4:15 - 4:45</td>
<td>CodeX</td>
<td>Carole Flamm, Steve Bratt, and Greg Shemancik</td>
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<td>5:00 - 6:30</td>
<td>Reception</td>
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Overview of Oncology Standard Health Records

Andre Quina
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
The FHIR Standard

F - Fast (to design & implement)
H - Healthcare (the domain)
I - Interoperability (the goal)
R - Resources (data building blocks)

- A data exchange standard with significant momentum
- Leverages lessons learned from other industries
- Integrates successful web-based technologies
- Significant industry participation and focus
HEALTHCARE INTEROPERABILITY

The ability to deliver effective healthcare to all depends on the ability to share information and collaborate in providing care.

Interoperability comes from *agreements* about how our systems will *exchange*, *parse*, *interpret* and *act* upon shared information.
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.

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

CANCER

- Patients
- Providers
- Research
- Payers
- Vendors
- Government/Regulatory

Patient  Treatment
Disease  Outcome
Genomics  Lab/Vital
Vision: Enabling a Learning Health System

Every patient’s journey can improve all future care
mCODE Collection and Integration

**Goal:** Demonstrate the low burden collection and use of mCODE at the point of care

- Evaluate mCODE collection methods and workflow integration
  - Traditional data entry
  - Voice interfaces
  - Targeted NLP

- Assess clinician burden: cognitive load and time

- Map, expose, secure, and validate an mCODE API

**mCODE Site Integration**

1. Data Model and FHIR IG
2. Clinical Workflow Integration
3. EHR data and API Mapping
4. Data Exchange and Trust
5. Validation and Testing
ICAREdata Study

Goal: Validate mCODE outcome elements’ suitability for oncology research and clinical trial execution

Phase 1: Validate that ICAREdata method provides high-quality data
  – Partner with clinical sites to collect real-world data (RWD) and compare it to oncology clinical trial data for 2 clinical trials: PATINA and PALLAS

Phase 2: Demonstrate that ICAREdata prospective collection of RWD can support clinical oncology research
  • Establish a set of mCODE-enabled research sites through the Alliance
  • Incorporate ICAREdata and mCODE into clinical trial protocols
    • Alliance A071701 (Brain Mets) trial
    • Alliance A021703 SOLARIS (Vitamin D) Trial
  • Demonstrate that research-quality RWD can support clinical trial endpoints
**Goal:** Pilot mCODE and demonstrate its ability to advance cancer care through comparative effectiveness and shared decision making

Compass is a SMART-on-FHIR application that:

- Uses patient’s mCODE elements from the EHR to match to similar cancer cases in the CancerLinQ database.

- Provides a rich platform for clinician-patient shared decision-making.

Real-world treatment options

Side effects

Outcomes
Goal: Leverage Patient’s Right to Access and FHIR APIs to demonstrate an mCODE-enabled architecture for patient data management.

- **What is it?**
  - Patient owned/controlled health data
  - Aggregated view of all health encounters from collected patient data receipts
  - Surrogate access for shared decision making and coordinated care

- **How can it be used?**
  - Personalized patient care
  - Participation in clinical research
  - Determination of benefit eligibility
  - Cost/benefit tradeoff analysis
Next Steps: Focus on Establishing a Community

- Engage critical stakeholders in targeted implementation-focused use cases
- Leverage existing mCODE activities and partnerships to establish the community
- Significantly multiply adoption and impact
Governance Structure

- **EXECUTIVE COMMITTEE**
  - Approve use cases for development, assemble and manage Core Committee
- **TECHNICAL REVIEW GROUP**
  - Review use cases. Convened, resourced, and managed by the EC
- **WORKING GROUPS**
  - The user groups assembled in response to use cases do the work of developing and testing new data elements

**Coalition**
- Use case sponsors, advisors content experts, pool of potential Working Group members

**Curation of mCODE**
- Comparative Effectiveness
- ICAREdata Clinical Trials
- Pathways
- Additional Projects
CodeX: A New HL7 FHIR Accelerator

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 (IGs) and other documents.

Other FHIR Accelerators:

CodeX is following the successful Da Vinci approach to legal, organizational, funding, and governance models.

http://www.hl7.org/about/davinci/members.cfm
Vision for New HL7 FHIR Accelerator

The CodeX Objective
To build a community and a national platform for interoperable cancer data modeling and implementation

Stakeholders collaborate to:

- Prioritize use cases around interest and potential 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
**CodeX Domains of Interest to Prospective Members**

*Use cases within domains will be shaped by CodeX members*

1. **Real World Data**
2. **Evidence-based Care**
3. **Patient Data Management**
4. **Payment Models**
5. **Registry Reporting**
“Every patient’s journey can improve all future care”
From Clinical Requirements to FHIR

May Terry
A Quick Story of FHIR Modeling

A reference lab wants to standardize the transmission of a specific type of lab report from paper-based form to structured data that can be exchanged to other provider EHRs.

An informaticist works with a group of lab experts to identify relevant lab information to create a FHIR implementation guide for this use case…
What You Get…

- **FHIR Implementation Guides (IG)**
  - traditionally targeted for technical implementers
  - not clinically friendly

- Sometimes clinicians have to wait for developed prototypes before realizing it's not what was asked.
Information Models

- Fit for purpose
- Complete to satisfy use cases
- *Unambiguous to your primary stakeholders*
Requirements to FHIR IG Process

An **Agile** process of iterations between each phase.

Clinical SMEs are involved in every phase
Defining Use Cases and Drivers

▪ What's driving the need for the model?
  – Clinical workflow improvement, regulatory, other

▪ Who are the target actors?
  – Patients, physicians, nurses, researchers, payors, etc.

▪ Use Case Scenarios
  – Write in plain-text
  – Create an example persona for context
  – Cite Clinical Sources, where applicable

▪ Avoid modeling solutions in early phases
Gathering Relevant Clinical Information

- Who's needed:
  1. Subject Matter Experts (SMEs)
  2. An objective facilitator

- Encourage use of **clinical (SME) speak**.
  - Include how many (cardinality), optionality, and example representation

- Cite Clinical Sources, where applicable (not existing models)
  - e.g.: AJCC Staging Manual 8th Ed., NCCN Guidelines, and CAP Synoptic Report
Gathering Relevant Clinical Information (cont'd)

- Consider mind-mapping for conceptual models.
  - Freemind, XMind, Coggle, plain ol' whiteboarding, etc.

- Logical Models to be created after clinical SME buy-in with the conceptual model.

- Create a Data Dictionary – logical model elements to clinical information cross-walk
Translate Information into Data Elements

- Create a "Rosetta Stone" Data Dictionary to clinical information cross-walk

<table>
<thead>
<tr>
<th>Data Element Name</th>
<th>Domain</th>
<th>Related Clinical Information Name(s)</th>
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<tbody>
<tr>
<td>problemName</td>
<td>Problem</td>
<td>co-morbid condition</td>
</tr>
<tr>
<td>problemStartDate (NEW)</td>
<td>Problem</td>
<td>co-morbid condition</td>
</tr>
<tr>
<td>problemStopDate (NEW)</td>
<td>Problem</td>
<td>co-morbid condition</td>
</tr>
<tr>
<td>medicationName</td>
<td>Medication</td>
<td>current list of medications</td>
</tr>
<tr>
<td>medicationStartDate (NEW)</td>
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</tr>
<tr>
<td>medicationStopDate (NEW)</td>
<td>Medication</td>
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</tr>
<tr>
<td>medicationStatus (NEW)</td>
<td>Medication</td>
<td>current list of medications</td>
</tr>
<tr>
<td>prognosticFactorName</td>
<td>CancerDiagnosis</td>
<td>ER status, PR, status, HER2 status</td>
</tr>
<tr>
<td>prognosticFactorResult (NEW)</td>
<td>CancerDiagnosis</td>
<td>ER status, PR, status, HER2 status</td>
</tr>
</tbody>
</table>
Develop the FHIR IG

- Various FHIR profiling and IG creation tools available.
  - CIMPL, Trifolia, Forge, HL7 IG template spreadsheet

- Documentation
  - Introductory material that is understandable by multiple stakeholders
    - Non-technical: clinicians and project leaders
    - Technical: integrators and software developers
  - Include original use case scenarios

- Data Dictionary to clinical information cross-walk

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Develop the FHIR IG (cont’d)

- Consider search parameters and operations
  - Is this implementation read-only? read/write?
  - How would I query for the information that I need?
  - What types of filtering is needed for the requested data?

- Create FHIR examples for each profile
  - Must include a narrative which reflects the structured representation

- Create a Capability Statement (if applicable)
  - Let implementers know what their reference implementation should support for messaging
Validate the FHIR IG

- Create examples that can successfully validate against FHIR profiles

- Set up a Reference Implementation server to test the capability statement, additional FHIR profile examples, search parameters, and operations

- Pressure test the Implementation Guide
  - FHIR Connectathons
  - Pilot sites
**FHIR IG Process Summary**

1. **Define use case**
   - Purpose
   - Drivers
   - Use case scenario
   - Persona

2. **Gather relevant clinical information**
   - Clinical Information inventory
   - Concept Model (Mind Map)
   - Logical Model

3. **Translate information into data elements**
   - Data Dictionary to Clinical Information Cross-Walk (*Rosetta stone*)

4. **Develop FHIR IG**
   - Include:
     - Documentation
     - Data Dictionary

5. **Validate FHIR IG**
   - Examples
     - FHIR reference implementation

6. **Release for Trial Use**
   - Early Pilots
   - Connectathons
Purpose: To develop and maintain standard computable data formats, known as minimal Common Oncology Data Elements (mCODE), to achieve data interoperability and enable progress in clinical care quality initiatives, clinical research, and healthcare policy development.

www.mCODEinitiative.org
Clinical Challenges and Opportunities With Current Electronic Health Records: Practicing Oncologists’ Perspective

Debra Patt, Philip Stella, and Linda Bosserman

Oncology clinicians have five main roles: diagnosis, care planning and management, physical examination, procedures, and the development and use of evidence to continuously improve health outcomes. As we work to incorporate rapidly expanding knowledge into our practice, we must also consider and adapt to multiple and often conflicting demands.

American Medical Association collaborations report that 80% of burnout is due to organizational factors, with the major contributors being high workloads, workflow inefficiencies, increased time spent in documentation, loss of meaning in work, and isolation to name a few.
“Current EHR problems boil down to 6 problems”
- Data Entry
- Discrete data elements
- Reports and dashboards
- Workflow processes
- Interoperability
- Design engineering
mCODE: The Problem and Our Mutual Goals

- Oncology practice is hobbled by being primarily captured as non-computable data
  - Staging, biomarkers, progression, outcomes, adverse events, etc.
  - Transforming unstructured data to structured format via curation is unsustainable
- EHR frustration is a major source of practice stress
- ASCO is well-positioned to lead an initiative to address oncology data challenges
- A corpus of high value data elements needs to be selected by clinicians who are supported by informaticists
  - Engagement is essential to minimize data entry burden

Goals

- Identify a core set of data elements to populate the oncology EHR
- Concentrate on important use cases
  - clinical care/coordination, quality improvement, clinical trial matching, research
- Inform EHR vendor design decisions
mCODE Project Personnel

- **ASCO staff leads**
  - Drs. Robert Miller and Wendy Rubinstein (CancerLinQ)
  - Additional staff from CancerLinQ, Clinical Affairs-QOPI, CENTRA, Policy & Advocacy-HIT policy

- **Volunteer leads**
  - Drs. James Chen (Ohio State) and Douglas Blayney (Stanford)

- **Volunteer participants with an array of expertise and backgrounds:**
  - Clinical oncology (solid tumor + heme malignancies) including radiation and surgical oncology
  - Pathology
  - Genomics/precision medicine
  - Biostatistics
  - Community practice & academia
  - Oncology informatics
  - Standards and interoperability
  - Quality
  - Regulatory issues
There have been multiple collaborative efforts in the past, for a variety of use cases (and sometimes no definitive use case specified)

- Many appear to be one-time publications (“gathering dust”)
- Some are being actively supported and/or developed – e.g., CDISC, USCDI, FHIR

Adoption has been limited and most efforts have not been transformative!

New areas of focus:

- Promote cancer data interoperability – develop APIs, combat information blocking, accelerate data exchange among health systems, enhance patient access
- Reduce administrative and reporting burden for clinicians
- Improve data quality for ASCO CancerLinQ

21st Century Cures Act
Review of Prior Work

- ASCO-NCI-NCCCP Clinical Oncology Requirements for the EHR “CORE” (2009)
- HL7 CDA Implementation Guide: Clinical Oncology Rx Plan & Summary
- NCI Cancer Data Standards Registry and Repository (caDSR)
- ASCO 2018 LDP group “Oncovitals” project supporting transitions in care
- Tumor registry (NAACCR) standards
- HL7 Genomics FHIR Implementation Guide
- HL7 Breast Cancer FHIR Implementation Guide
- US Core Data for Interoperability (USCDI)
Timeline

Convene expert panel for clinical and technical input
  • Jul - Aug 2018

Develop draft data spec from 2 use cases
  • Sep - Dec 2018

Review public comments and adjust spec
  • Jan - Mar 2019

Detailed modeling work - CLQ and MITRE
  • Mar - Apr 2019

mCODE™ data dictionary v0.9 approved
  • Apr 2019

Data dictionary/ FHIR IG officially released
  • June 1, 2019
mCODE™ Initial Proposal

Patient
- age
- gender
- race
- ethnicity
- KPS/ECOG
- Family History
- demographics
- vital status
- co-morbidities
- exposures
- germline mutations
- allergies

Disease
- site
- size
- laterality
- histology
- grade
- tumor markers
- molecular markers
- metastatic sites

Treatments
- radiation
- treatment intent
- drug name
- dose/route
- treatment plans
- palliative care
- XRT fields
- reason for stopping rx
- clinical trial status
- surgery
- biopsy
- line of rx
- # cycles
- XRT dose
- provider info
- physical exam
- lab results
- imaging
- encounters

Outcomes
- best response
- adverse events
- disease status at end of rx
- cause of death
- progression
- PROs
- disease status at end of rx
- cause of death
- PROs
mCODE™ Consensus Prioritization

**Patient**
- Date of birth
- Gender
- Race
- Ethnicity
- KPS/ECOG
- Family History
- Demographics
- Co-morbidities
- Germline mutations
- Exposures
- Allergies

**Disease**
- Site
- Size
- Laterality
- Histology
- Grade
- Tumor markers

**Genomics**
- Molecular markers
- Metastatic sites

**Treatments**
- Radiation
- Treatment intent
- Drug name
- Dosage/route
- Treatment plans
- Palliative care
- Clinical trial status
- XRT fields
- Reason for stopping Rx

**Outcomes**
- Best response
- Disease status at end of Rx
- Cause of death
- Vital status
- PROs
- Adverse events
- Progression
- XRT dose
- Line of Rx
- # cycles
- Clinical trial status
- XRT fields
- Selected lab results
- Imaging
- Encounters
- Provider info
- Physical exam
- Selected lab results
mCODE Governance Structure

**Decision-making:** Approve use cases for development, assemble and manage TRG

**Advisors to EC:** Use case sponsors, content experts, pool of potential Working Group members

**Maintains mCODE data dictionary:** Initial review of use cases. Convened, resourced, and managed by the EC

**Working Groups:** User groups assembled in response to use cases approved by EC to do the work of developing and testing new data elements

---

- **Executive Committee**
- **mCODE Council**
- **mCODE Technical Review Group (TRG)**
- **Intermountain Health Comparative Effectiveness Pilot**
- **ICARE data Clinical Trials pilot**
- **mCODE Summit**
- **Other projects and events**
mCODE Guiding Principles

• Highly collaborative
• Iterative use case development
• Maintenance is reductionist and parsimonious
• Developed and maintained by its users
• Non-commercial data standard
How Do Data Elements Get into mCODE?

- Use case proposal brought forward by stakeholder group
  - Make call for use cases
    - mCODE Technical Review Group (TRG)
      - Use case intake evaluation & recommendation to Exec Committee (EC)
        - No new elements required
      - Relevant mCODE data elements are shared with stakeholder group
      - TRG periodically evaluates data elements and makes recommendations for necessary updates
        - New elements required
        - Stakeholders develop required elements
          - OR, if necessary, EC establishes a new WG to develop required elements
            - New elements proposed
              - TRG reviews new elements and reconciles them with existing mCODE, submits to EC for approval
                - EC approves new elements
                  - New elements are added to mCODE
        - TRG periodically evaluates data elements and makes recommendations for necessary updates

Recent Developments

- **FHIR DSTU 2**: April/June 2019
  - mCODE™ v0.9

- **FHIR R4**: July 2019
  - mCODE™ v0.91

- **Aug - Sept 2019**
  - HL7® International
  - Ballot
  - Standard for Trial Use
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.
### Structure of mCODE v0.91

#### 6 domains:

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<th>Domain</th>
<th>27 FHIR profiles:</th>
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<tr>
<td>Lab/Vitals</td>
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<td>8</td>
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<td>Disease</td>
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<td>25*</td>
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<td>Outcome</td>
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Counts do not include:
- Elements required by FHIR and US Core
- Lab tests that are part of CBC, CMP

*19 unique elements (staging method reported with each TNM Category)
mCODE™ Approved as HL7 Standard for Trial Use

G O O D
N E W S!
## Ballot Results (Sept. 9, 2019)

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<th>Abstain</th>
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<td>Government/Non-Profit</td>
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<td>Provider</td>
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<td><strong>Totals</strong></td>
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<td><strong>16</strong></td>
<td><strong>59</strong></td>
<td><strong>22</strong></td>
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*50 affirmative votes needed to pass
FHIR Connectathon, Sept. 2019

- Organized by MITRE and led by May Terry
- Participation from:
  - **Vendors:** Varian, Flatiron, Penrad
  - **GO/NGO:** CSIRO (Australia), Cancer Care Ontario (Canada), Center for International Blood and Marrow Transplant Research (US), Institute for Personalized Medicine (Germany)
- Notable accomplishments:
  - Cancer Care Ontario translated their lung surgery form to mCODE and FHIR
  - CIBMTR mapped their Transplantation Form to mCODE
  - CSIRO translated one of their genetics forms to mCODE and uploaded it to a test server
  - Varian successfully imported an STU3 version of mCODE ECOG performance assessment to their decision support software

https://confluence.hl7.org/display/FHIR/2019-09+mCODE+Cancer+Interoperability+Track
Path to mCODE Version 1.0

- mCODE v1.0 cannot be published until all ballot comments are addressed
  - 80 Affirmative comments
  - 47 Negative comments

- Comment areas:
  - Alignment with other Implementation Guides (genomics, vital signs)
  - Desire for international version
  - Lab structures and codes
  - Reducing FHIR extensions
  - Suggested content (e.g. cytogenetics)

- Target date: February 2019 (next HL7 meeting)
2020: Expanding and Maturing the mCODE Ecosystem

- **Extending the reach**
  - Supplements driven by CODEx
    - International version

- **Strengthening the core**
  - Define actors, workflows
  - Define conformance requirements
  - Provide mappings to related standards
  - Develop testing tools

- **Facilitating adoption**
  - Implement updates from ballot and pilots
  - Relate inputs to mCODE data structures
  - Define consent/privacy/security requirements
THE CANCER DATA SUMMIT
SMARter DATA FOR THE FIGHT AGAINST CANCER
mCODE Pilots
mCODE Pilot: ICAREdata

Mary Pulvermacher
Need: High-quality Data on all Cancer Patients

Only 3% of adult cancer patients participate in clinical trials

Understudied populations
- Age 15-19 and > 65
- Underrepresented minorities
- Residents of rural communities
- Patients with co-morbid conditions
- Uninsured patients

1.7M New Cancer Patients each year in US
**ICAREdata® Study**

**EHR-based clinical trials endpoints collection**

**Goal**

Support the collection of high-quality real-world data (RWD), based on mCODE, to enable clinical oncology research.

**ICAREdata Approach**

- Serve as **mCODE pilot** for clinical oncology research.
- **Partner with clinical trials** to demonstrate prospective collection of RWD can support clinical oncology research.
- Use ICAREdata method to **collect key outcome data** not yet well represented in EHRs.

**Clinical Trial Partners**

- **Clinical Trials:** Partnering with clinical trials to collect and test ICAREdata questions.
- **Clinical Sites:** Partnering with selected clinical sites participating in these trials to:
  - Collect ICAREdata at point of care:
    - **Cancer disease status** *(in mCODE v0.9.1)*
    - **Cancer treatment plan change** *(Possible mCODE addition or extension)*
  - Share mCODE/ICAREdata via automated interface.
ICAREdata® Study Phase 1
Validate can prospectively collect high-quality data

Phase 1 Clinical Site Partners

- DANA-FARBER CANCER INSTITUTE
- ST. JOSEPH MERCY ANN ARBOR
- ThedaCare
- St. Elizabeth HEALTHCARE
- metro-minnesota MMCORC community oncology research consortium

Phase 1 Clinical Trial Partners

- PALLAS
- PATINA

Phase 1 Approach

- At partnering sites, for patients in the trial, clinicians collected Cancer Disease Status as structured phrases in patient clinical note
- ICAREdata team evaluated correspondence between this RWD and clinical trial data

Phase 1 Results

- Successfully partnered with 2 clinical trials and 5 clinical sites to show complete agreement when disease is absent
  - 96% concordance with 95% probability
- ICAREdata Phase 1 results led to NCI funding for ICAREdata Study Phase 2
### ICAREdata® Study Phase 2
EHR-based clinical trials endpoints collection

**ICAREdata Approach**

- Serve as mCODE pilot for clinical oncology research
- Incorporate ICAREdata into 2+ Alliance clinical trials to collect and test ICAREdata questions
- Partner with selected clinical sites participating in these trials
- Use ICAREdata method to collect key outcome data not yet well represented in EHRs
  - Cancer disease status *(In mCODE v0.9.1)*
  - Cancer treatment plan change *(Possible mCODE addition or extension)*
- Share mCODE/ICAREdata via automated interface

**Potential Clinical Site Partners**

- MGH/MASSACHUSETTS GENERAL HOSPITAL
- UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM
- DANA-FARBER CANCER INSTITUTE
- MAYO CLINIC
- Geisinger
- THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
- UCSF Health
- KAISER PERMANENTE
- Trinity Health
- RUSH UNIVERSITY MEDICAL CENTER
- BRIGHAM AND WOMEN’S HOSPITAL
ICAREdata® Study Phase 2 Clinical Trial Partners

EHR-based clinical trials endpoints collection

A071701 – Brain Mets Trial
( Genomically-guided Treatment Trial in Brain Metastases )

- **PI:** Priscilla Brastianos, MD
- **Type:** Phase II trial
- **Trial Activation:** Aug 2019
- **Hypothesis:** Targeted therapies will demonstrate efficacy in patients harboring the appropriate mutations
- **Patient Accrual:** 8 cohorts, 21 patients/cohort + 2 additional per cohort
- **Timeline:** 3-5 years
- **ICAREdata collection:**
  - Cancer disease status
  - Cancer treatment plan change

A021703 – Vitamin D Trial
(Randomized double-blind phase III trial of vitamin D3 supplementation in patients with previously untreated metastatic colorectal cancer)

- **PI:** Kimmie Ng, MD, MPH
- **Type:** Phase III randomized trial
- **Trial Activation:** Sept 2019
- **Hypothesis:** Confirm role of high-dose vitamin D3 supplementation in treatment of metastatic colorectal cancer
- **Patient Accrual:** 400 patients
- **Timeline:** 5 years
- **ICAREdata collection:**
  - Cancer disease status
  - Cancer treatment plan change

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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(s) 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>#imaging</td>
<td></td>
</tr>
<tr>
<td>#metastatic tumor(s)</td>
<td>#responding</td>
<td>#pathology</td>
<td></td>
</tr>
<tr>
<td></td>
<td>#stable</td>
<td>#symptoms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>#progressing</td>
<td>#physical exam</td>
<td></td>
</tr>
<tr>
<td></td>
<td>#not evaluated</td>
<td>#tumor marker</td>
<td></td>
</tr>
</tbody>
</table>

Sample Resulting Structured Phrase*

#cancer disease status observed for #primary tumor(s) was #progressive disease based on #imaging and #symptoms
#cancer disease status for #metastatic tumor(s) was #not evaluated

* Blue font denotes controlled vocabularies

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

Cancer Treatment Plan Change

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

ICAREdata Question Format

<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>

Sample Resulting Structured Phrase*

#cancer treatment plan change #yes-disease not responding #cancer treatment plan change #no change in treatment plan
ICAREdata® Phase 2 Data Collection
Example Using Epic

- **Participating Clinical Sites**
  - Implement low-burden way to collect data not yet well represented in the EHR
    - For Epic sites, use SmartPhrases with SmartData Elements
    - Working with Epic on enterprise solution
  - Identify patients on participating clinical trials

- **Participating Clinicians**
  - For patients on the trial, at each patient visit, document ICAREdata questions via Epic SmartPhrase
    - Cancer disease status
    - Cancer treatment plan change

- **Result**
  - #phrase persisted in EHR clinical note with data stored in Epic (via SmartData Elements)
ICAREdata® Study Data Sharing

Clinical Site

Point of Care

Clinician documents at point of care

- Data routinely in patient EHR
- Outcome data not yet well represented in EHR

Patient
Electronic Health Record (EHR)

For patients in partnering clinical trials
- mCODE data extracted from EHR
- Packaged into message and shared using defined standards

ICAREdata Infrastructure

Secure Storage
and Analysis

Standard health record for oncology

Built on FHIR standard for exchanging health information

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## ICAREdata® Study Contact Information

<table>
<thead>
<tr>
<th>Name</th>
<th>ICAREdata Study Role</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>
The Current Clinical Landscape of Oncology

- Rapid evolution of medications to treat cancers
  - Cancer drugs made up 27% of FDA drug approvals in 2018
- New protocols alter the sequencing of existing treatments
  - Surgery, chemotherapy, radiation
- Limitations of published literature
  - Rare diseases
  - Stringent entry criteria
  - Older and younger patients
  - Reliance on subgroup analysis
  - Publication bias
  - “Straw man” or outdated control arm

Common Scenario

- 73-year-old woman triple-negative breast cancer. Lumpectomy revealed 1.8 cm tumor without spread to lymph nodes. She presents to discuss additional treatment options.

NCCN Guidelines Version 3.2019
Invasive Breast Cancer

Tumor >1 cm \(\rightarrow\) Adjuvant chemotherapy\(^{aa,dd,nn}\) (category 1)

\(dd\) There are limited data to make chemotherapy recommendations for those >70 y of age. See NCCN Clinical Practice Guidelines for Older Adult Oncology.
How Are Treatment Decisions Currently Made?

- Family & Friends
- Internet
  - “What do I value?”

- Patient
  - Preferences
    - Communication
    - Statistics
      - Recommendations

- Doctor
  - Published studies
  - Guidelines Pathways
  - “My last patient...”

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Wouldn’t It Be Great If…

…we could harness real-world data to help patients and their doctors choose the treatment that is “right” for them?

▪ Aggregate data that is already being collected
▪ Provide patients and their physicians with recent real-world data about survival rates and side effects associated with each type of therapy

– 73-year-old woman triple-negative breast cancer

▪ e.g., among 450 similar patients, chemotherapy improved 5-year survival by 4% (from 71% to 75%) with a 15% risk of severe fatigue requiring hospitalization and a 7% risk of severe neuropathy
Goal of Compass Pilot

Demonstrate the use of mCODE data models to allow providers and patients to make informed, shared, data-driven decisions and provide data back to generate new knowledge.
Compass Development to Date

- Early involvement of stakeholders in design
  - Patients, nurse navigators, oncologists

- Intermountain Healthcare and MITRE informatics and modeling experts have reviewed FHIR profiles and made minor adjustments to underlying specifications in a collaborative way

- High priority data elements are available for use with FHIR profiles in Cerner
  - Data not yet consistently entered into Cerner by physicians

- Working on seamless integration of Compass within Cerner environment

- User acceptance testing with oncologists completed, feedback solicited
  - Majority are enthusiastic about using Compass with patients
Metastatic Breast Cancer Example

Tumor markers show HER2 + Breast cancer subtype.

Patient has developed metastatic disease.
The current patient is matched to similar cases for comparison of treatments and outcomes.

This provides opportunity for shared decision-making.
Remaining Challenges from a Clinical Perspective

- Data entry at point of care
- More CancerLinQ data to draw from
- Physician understanding strengths and weaknesses of data
- Ability for physician to filter relevant data
- Presenting data in a way that resonates with both physicians and patients
- Integrating use of Compass into physician workflow during a busy clinic day
mCODE Implementation
THE CANCER DATA SUMMIT
SMARTER DATA FOR THE FIGHT AGAINST CANCER

EDUCATION SESSION

Carole Flamm
Steve Bratt
Greg Shemancik

CodeX
Contents

- HL7 FHIR Accelerators
- Da Vinci
- CodeX
- Use case domains of interest
- Membership opportunities and organization
- Questions
- Preview of Cancer Data Summit, Day 2
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.
Da Vinci Project Challenge

To ensure the success of the industry’s shift to Value Based Care

By providing FHIR based solutions for provider to payer and provider to provider exchanges

- Pre-Collaboration / Controlled Chaos:
  Develop rapid multi-stakeholder process to identify, exercise and implement initial use cases.

- Collaboration:
  Minimize the development and deployment of unique solutions. Promote industry wide standards and adoption.

- Success Measures:
  Use of FHIR®, implementation guides and pilot projects.
Provider Members:
Dallas Children's Health, MultiCare, OHSU, Providence St. Joseph Health, Rush University Medical Center, Sutter Health, Texas Health Resources, Weil Cornell Medicine

Payer Members:
Anthem, BCBSA, BCBSAL, BCBSM, BCBST, BC Idaho, Cambia Health, Cigna, CMS, GuideWell, HCSC, Humana, Independence, United Healthcare

Vendor Members:
Allscripts, Athenahealth/Virence(aka GE Centricity), Casenet, Cerner, Cognosante, eCW, Edifecs, Epic, HealthLX, InterSystems, Juxly, Optum, Surescripts, ZeOmega

Partners:
HIMSS, NCQA

Project Process
- Define requirements (clinical, business, technical and testing)
- Create Implementation Guide (IG)
- Create and test Reference Implementation (RI) (prove the IG works)
- Pilot the solution
- Deploy the Solution
Use Case Focus Areas

Quality Improvement
- Data Exchange for Quality Measures
- Gaps in Care & Information

Coverage
- Coverage Requirements Discovery
- Documentation Templates and Rules
- Prior-Authorization Support

Process Improvement
- Clinical Data Exchange
- Payer Data Exchange
- Payer Data Exchange: Formulary
- Payer Data Exchange: Directory
- Payer Coverage Decision Exchange
- Patient Cost Transparency
- Risk Based Contract Member Identification
- Chronic Illness Documentation for Risk Adjustment

Member Access
- Alerts / Notifications
- Patient Data Exchange
- Performing Laboratory Reporting

Use Case Status
- May ballot STU and for comment
- In early September ballot (July) as STU
- September ballot as STU
- Currently targeted for early or regular January 2020 ballot
- Use cases in discovery (some may be balloted in January 2020)

More information available at: http://www.hl7.org/about/davinci/use-cases.cfm
A New HL7 FHIR Accelerator

Building a community and platform for interoperable cancer data modeling and implementation, leading to better cancer care and research

- Research
- Patients
- Health Systems
- Regulators
- Payers
- Industry
- Innovators
- Registries

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builds an implementation community and extended value around

starting with compelling use cases and ending with tested, implementable products
Gather stakeholders and collaborate to:

- Prioritize use cases around interest and potential 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
Priority Use Cases Domains
Others to be defined by CodeX members

- mCODE Implementation
- Real World Data
- Evidence-based Care
- Patient Data Management
- Payment Models
- Registry Reporting

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CodeX Member Benefits

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.
CodeX Organizational Plan
Gather communities of interest and capabilities

- mCODE Council
  - FHIR IGs sent to HL7 Work Groups as agreed by CodeX
  - Proposed, new mCODE elements
  - Implementation support

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

- CodeX Steering Committee
  - Cancer Advisory Board
  - Project Management
  - Architecture (interoperability, consistency)
  - Support (training, reqs, modeling, FHIR, implementation, pilots)

- CodeX Operating Committee (person from each member)

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CodeX is Live! ..
and talking with prospective Founding Members

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

How To Get Involved:
Interested in joining CodeX or learning more? Please contact Greg Shemancik gshemancik@mitre.org and Steve Bratt sbratt@mitre.org
Path of the Cancer Data Summit

Vision for Smarter Data in the Fight Against Cancer

Where Are We Now? Data Interoperability for Cancer Care and Research

What Could Cause mCODE to Fail?

Making the Vision a Reality by 2022

Solutions and Pathways to the Future

Next Steps and Call to Action
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](http://www.mitre.org)
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SMARTER DATA FOR THE FIGHT AGAINST CANCER