Leaps, Bounds, and FHIR Accelerators

How CodeX is Empowering the Future of Cancer Data Interoperability

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EHR data challenges:

- Significant variation
- Unstructured data
- High Burden

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)
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

- Minimal set of critical data elements
- Standardized for collection and sharing
- Recommended by top oncologists
- Supports multiple cancer use cases
- Improves cancer care and research
mCODE™ Initial Collaborators

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®
The Path to Meaningful Interoperability

FHIR establishes the high-level syntax and interfaces for exchange

Argonaut / US Core / USCDI standardize foundational patient data

Da Vinci and Carin formalize targeted exchange frameworks

Discipline focused modeling provide the detail needed for semantic interoperability
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

Develop open standards and open source

A community and platform to accelerate interoperable data modeling and implementation around mCODE, leading to step-change improvements in cancer care and research.
New Use Cases Domains of Interest

0. Basic mCODE Extraction
1. Real World Data Trials
2. Evidence-Based Care
3. Patient Data Management
4. Payment Models
5. Registry Reporting
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
Use Cases Targeted to Improve Cancer Care and Research
New Use-Case-Based Projects in Discovery
Around Which to Grow the Community Further and Faster

1. EHR Endpoints for Clinical Trials
2. Empowering Patients to Find Clinical Trials
3. Registry Reporting
4. Oncology Clinical Pathways Navigation
5. Radiation Therapy Data for Care Coordination
6. Clinical Cancer Data Exchange (Providers/Payers)
7. Alternative Payment Model Data Reporting
8. Drug Value Based Agreements
Empowering Patients to Find Clinical Trials
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.
- Open data standards and open APIs that support clinical trial matching will organize and improve existing and future trial matching services.
- Comparing a patient’s mCODE++ data to mCODE++ descriptions of trials would enable more automated matching.

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.
Reimagining CAR-T Registry Reporting
Researchers have an improved base of CAR-T patient data

Proposed Process:
- Define the necessary structured data elements by comparing registry forms for CAR-T patient reporting with the mCODE set.
- Utilize existing FHIR endpoints in the registry and cancer center to build an application, questionnaire, etc.
- Collect and structure necessary elements from cancer center using solution at pilot site, reporting back to registry in low burden standardized way.

Registries and clinical sites leverage extended mCODE elements to more easily package and report necessary CAR-T patient data.

Registries require a low-burden approach to data reporting from clinical sites.
Final Thoughts
Every patient’s journey can improve all future care
Please contact us if interested in learning more about mCODE and CodeX

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Questions
Appendix
Oncology Clinical Pathways are evidence-based treatment protocols for delivering cancer care. This initiative uses mCODE elements in producing computable pathways, which provide key decision support in the selection of treatment options.

**ICAREdata™**

EHR-based clinical trials endpoints collection:

Develop and validate data elements that define clinical utility (treatment response, toxicity, change in treatment, deviation from clinical pathway).

**Compass**

Demonstrate 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**

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Building a Trusted Network of Health Systems
Providing requirements and Testing Solutions

mCODE

MAYO CLINIC
Kaiser Permanente
UCSF
Intermountain Healthcare
MD Anderson Cancer Center

St. Joseph Mercy Ann Arbor
Saint Joseph Mercy Health System
Trinity Health

Trinity Health

Massachusetts General Hospital
Dana-Farber Cancer Institute
Brigham and Women’s Hospital
Penn
St. Elizabeth Healthcare

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ICAREdata
**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

- Increase oncology research data pool
- Improve clinical trial efficiency
- Reduce clinical trial costs
- Inform therapeutics development
- Inform regulatory decision-making
- Inform data-driven patient care

**ICAREdata Approach**

- 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
- Serve as mCODE pilot for clinical oncology research
Support the collection of high-quality real-world data, based on mCODE to enable clinical oncology research

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

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

Data collected on all patients as part of routine cancer care

Every patient’s journey improves all future care

Data-driven patient care

RWD-based clinical oncology research

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An agile and iterative approach grounded by implementation

1. Create a guiding coalition of health systems, specialty societies, and leaders
2. Work with clinicians and patients to develop the requirements
3. Identify data elements through use cases that demonstrate tangible impact
4. Focus on core data elements that are cross cutting to use cases
5. Execute targeted implementation pilots at the point of care
6. Enable early adoption and scale by engaging industry and health systems