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

What if we could learn from the experiences of the other 97% of patients?

There are many barriers to collecting and sharing valuable patient data, including the inconsistent use or absence of data standards and the difficulty of transforming how we receive, access, and share patient information in a complex and non-interoperable healthcare system. Every interaction between a clinician and a cancer patient has the potential to provide data that could be used to improve care for that particular patient, as well as for all who follow.

A multi-stakeholder community is forming to address the need to obtain high-quality, computable data for cancer care and research. The community is called CodeX – the Common Oncology Data Elements eXtensions project within the HL7 Fast Healthcare Interoperability Resources (FHIR) Accelerator program.

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.

**The Objective of CodeX**

To build a community and platform that accelerates interoperable cancer data modeling and implementation, leading to better cancer care and research

**Objectives**

CodeX is assembling patients, providers and health systems, researchers, regulators, payers, and electronic health record vendors and information technology innovators to:

- Revolutionize cancer patient data collection, data sharing, and care by developing high-quality FHIR Implementation Guides, Reference Implementations, and pilots that demonstrate value
- Leverage the capabilities of mCODE, adding the additional data elements needed for new use cases
- Exchange data through electronic health record (EHR) and other systems in an interoperable way
- Streamline data collection to unburden workflows, while protecting patient privacy

**Use Case Domains**

- Community of Practice
- Real World Data
- Evidence-based Care
- Patient Data Management
- Payment Models
- Registry Reporting
- Additional Use Case 1
- Additional Use Case 2

Use cases within each Domain are shaped by CodeX

**Leveraging mCODE**

- CodeX will speed the development and interoperability of new data models and systems necessary for better cancer research and care, leveraging the mCODE data model
- Extensions around mCODE would be based on priority use cases
- Some extensions may require new data elements that would be proposed to move into mCODE
Governance Structure

The Steering Committee, representing all of the key stakeholders, will prioritize CodeX activities, approve use cases and projects, contract for project managers and technical experts, monitor progress, report status to the CodeX members and decide which products should go to HL7 for formal standardization.

The Operating Committee, representing CodeX members, will propose use cases, project plans and deliverables, artifacts for standards development, and requests for funding for consideration by the Steering Committee. The Operating Committee will also facilitate staffing of projects with in-kind personnel contributed by founders, members, and implementers.

<table>
<thead>
<tr>
<th>Level</th>
<th>Annual Membership Fees</th>
<th>Operating Committee Vote</th>
<th>Sponsor Partner 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>
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<tr>
<td>Developer/Implementer</td>
<td>In kind only</td>
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</table>

Community of Practice (CoP)

The Community of Practice is a discussion forum within CodeX where health systems and supporting organizations develop and share best practices for implementing mCODE and extensions into production EHRs and systems. Participation in CoP teleconferences is free for all participants.

Resourcing

- Resources will come from in-kind contributions of developers and supported by member fees.
- The project management team will establish budgets for use cases and monitor execution.
- Funds will be used at the direction of the CodeX Steering Committee to support management of and experts for projects.

Role of HL7

- Administrator and financial manager for CodeX
- Permanent role for an HL7 board member on Steering Committee.
- Establishes a clear path for work to enter standards development via input/engagement with the responsible HL7 WG.
- Selective balloting/publication of CodeX developed FHIR Implementation Guides.
- Participation in HL7 FHIR Connectathons.

Implementation Approach

- CodeX projects will develop FHIR Implementation Guides (IGs), Reference Implementations (RIs) and other artifacts.
- IGs and RIs will be tested at connectathons (or related industry FHIR developer forums), and piloted in coordination with the CodeX members and other organizations.
- IGs and RIs developed collaboratively within CodeX are available royalty-free. Systems developed outside of CodeX are welcome to leverage CodeX products for free and may be used as part of connectathons and pilots under whatever licensing terms the owners choose.

Management and Technical Support for Members

- **Project** management and coordination of the overall program and of individual use-case-based projects.
- Technical architecture, modeling, tooling, and training to help members develop and test data models and FHIR IGs

For More Information

Interested in joining CodeX or learning more? Please contact: Greg Shemancik, gshemancik@mitre.org, or Steve Bratt, sbratt@mitre.org