# 2021 Cambia Grove Innovator Fellowship Program

*Executive Summary: The CodeX FHIR Accelerator Project and the Value Metrics Framework*

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## About the Accelerator

The Common Oncology Data Elements eXtensions (**CodeX**) is one of six FHIR Accelerator projects, and is specifically focused on interoperability solutions that stand to improve both care and research for people with cancer. Given the tremendous and pervasive challenges to optimizing and leveraging oncology data, the importance of CodeX cannot be understated. Central to the CodeX Project is the mCODE Implementation Guide, which is developing standards for **m**inimal **C**ommon **O**ncology **D**ata **E**lements. In other words, what are the cornerstone pieces of oncology data which—if standardized—would lead to improved care and more rigorous research. The use case explored during the 2021 Innovators Fellowship pertained to the use of mCODE and a delineated set of eight Optimized Patient Data Elements (OPDE) and associated APIs to assess whether these elements improve patient matching for cancer clinical trials. The OPDEs were tested in several pilot studies for their ability to support eligibility determination for trials while reducing reliance on manual data entry/management. Such efforts are essential to increasing clinical trial accrual and providing equitable opportunities for patients to be offered participation in trials.

## Methods and Interviews

The CodeX Integrated Trial Matching project team convenes regularly, hence, the meetings were a secondary source of input for this project, along with two in-depth key informant interviews and virtual data collection via emailed Q&A with two other key stakeholders. In all, interviewees included an oncologist, a cancer researcher/startup founder, an expert in cancer trial data, and a leader from the cancer advocacy/policy space. The interviews explored the value creation opportunities afforded by mCODE and deployment of a data- and API-enabled trial matching capability. It should be noted that while the Fellowship and key informant interviews were occurring, the CodeX community was in the process of completing several pilot-tests of the ability for the OPDE to facilitate clinical trial eligibility, and insights from the pilots are incorporated into the summary of themes below.

## Common Themes and Insights

***Dimension of the Value Metrics Framework***
*Abrasion*
***Accuracy***
*Clinical*
*Efficiency*
*Financial*
*Foundational*
*Market*
*Security*

All of the interviewees were united around the value proposition for bolstering the capability to match patients to trials more effectively, equitably, and efficiently. Aligning their insights to the domains of the value metrics framework (Box), the elements that arose most often were **Abrasion and Efficiency**. Many matching algorithms and clinical trial matching services exist, some of which are unique to a particular tumor type or an institution (i.e., comprehensive cancer center such as MD Anderson, Sloan-Kettering, or Dana-Farber)—organizations that are comparatively well-resourced. But for patients receiving cancer care in a community health system, access to trials is less common, due in part to limited resources and time to undertake chart abstraction needed to both find and match patients to potential trials. The extent to which workflow-related efficiencies can be realized by eliminating the need for manual data entry of common data elements would provide tremendous additional value to a broader array of cancer care providers.

An important feature of the CodeX community is its ability to convene disparate stakeholders. This was important to the interviewee representing a policy and advocacy perspective, insofar as it creates a sense of shared ownership of the issue and the solutions, even though each participant may have a unique area of expertise. As the interviewee described it,

> *"This fits with our organization's extant model of convening different stakeholders to find common cause and solutions. We recognize the necessity of data standards—the Blue Button equivalent for cancer clinical trials—and our motivation is to get more oars in the water to propel the use case forward."*

## Potential Barriers to Implementation

An area needing additional in-depth consideration is the **integration** of the mCODE data standards and OPDE into electronic health record systems, as every EHR installation is unique to its health system. Given competing demands for customizing and updating EHRs at any particular time, the value of integrating OPDEs needs a very compelling business case that resonates with the clinical provider and the health system IT leadership. Moreover, the clinical care teams must have high confidence in the **reliability** of the trial matching results. The pilot studies undertaken by CodeX are addressing this directly and determining whether certain data elements are more or less available and reliable for identifying potential matches between patients and trials.

As was noted by all interviewees, the key hill to climb will be spreading these capabilities in community cancer care providers. Notionally, no one disputes the importance of trials as a means of providing cancer patients with the highest standard of care, but the distance between ideal state and current state remains vast. An interviewee with experience as a researcher and startup founder aptly observed,

> *"Adoption and implementation of mCODE is going to require seamless integration into the clinical workflow. There is no conversation on adoption and/or implementation without workflow integration."*

## Conclusion

Optimizing the data infrastructure and health care system infrastructure for cancer clinical trial accrual is a challenge that has persisted for decades. The complexity of cancer and the ever-growing array of treatment modalities will not change, and if anything will only grow more complicated as cancer biology discoveries unfold. To this end, interrogating and applying data standards to hasten the ability to identify appropriate trials will only grow in importance. While isolating one component of this equation—identification of the eight OPDEs—will not reduce complexity in and of itself, any process that will ease the burden on systems and engage patients in their cancer care experience is of paramount importance. As the CodeX/mCODE work matures, it will be critical to bring additional stakeholders together to build a larger base of support and settings to test the performance of the data standards. Finally, members of the CodeX community have centered this work on **equity**. The pivotal importance of increasing availability of cancer clinical trials to ***everyone*** is a key underpinning to the value of this work, and should be reflected in the Value Metrics framework.

Eisenberg, P., P. Kaufmann, E. Sigal, and J. Woodcock. 2012. Developing a Clinical Trials Infrastructure in the United States. *NAM Perspectives.* Discussion Paper, National Academy of Medicine, Washington, DC. https://doi.org/10.31478/201205g