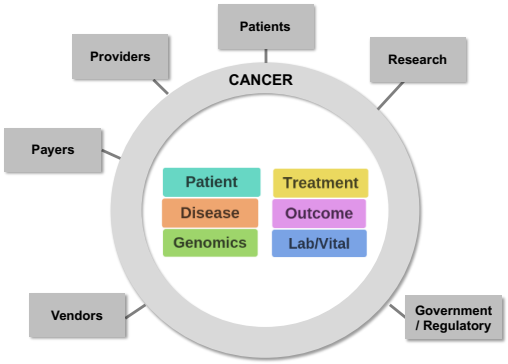
Integrated Clinical Trial Matching for Cancer Patients and Providers
"Blue Button Pilot Project"

Interoperable clinical trial matching services, accessible to all patients and providers at the point of care

Background

Presently, there are a number of barriers for patient participation in clinical trials[1]. Matching patients with trials require a challenging amount of manual entry and / or manual review of trials and frequently this is not integrated into existing clinical workflows. As a result, patients eligible to participate in a clinical trial may not be identified or asked to enroll. Secondly, many patients do not have a local trial available for their cancer at the institution where they are being seen, and providers do not have means to easily identify trials for their patients that are conducted outside the treating healthcare institution. Consequently, only about 27% of cancer patients will have the option to enroll in a local clinical trial at the institution they are being treated at. Furthermore, approximately 20% of cancer clinical trials fail due to insufficient patient enrollment.



The minimal Common Oncology Data Elements (mCODE) standard is designed to enable clinicians to capture a critical set of information for each cancer patient in a way that can be collected, analyzed, and shared quickly and more easily by oncology stakeholders. The American Society of Clinical Oncology, CancerLinQ, the Alliance for Clinical Trials in Oncology, the U.S. Food and Drug Administration, and the MITRE Corporation are collaborating to develop and launch mCODE. mCODE is being established as the standard Fast Healthcare Interoperability Resources (FHIR)-based data element set that will be captured for all cancer patients. These elements are essential for analyzing patient characteristics, treatments, and outcomes across patients and practices to improve treatment and care coordination.

While the "m" in mCODE stands for minimal, there are many potential ways to adapt and extend mCODE for specific use cases such as patient data management, registry reporting, payment models, and more. To help identify, prioritize, and implement new use cases, MITRE and HL7 collaboratively launched the CodeX™ FHIR Accelerator. CodeX™ employs a multi-stakeholder process to rapidly address high-priority oncology use cases using mCODE that can be implemented on a national basis.

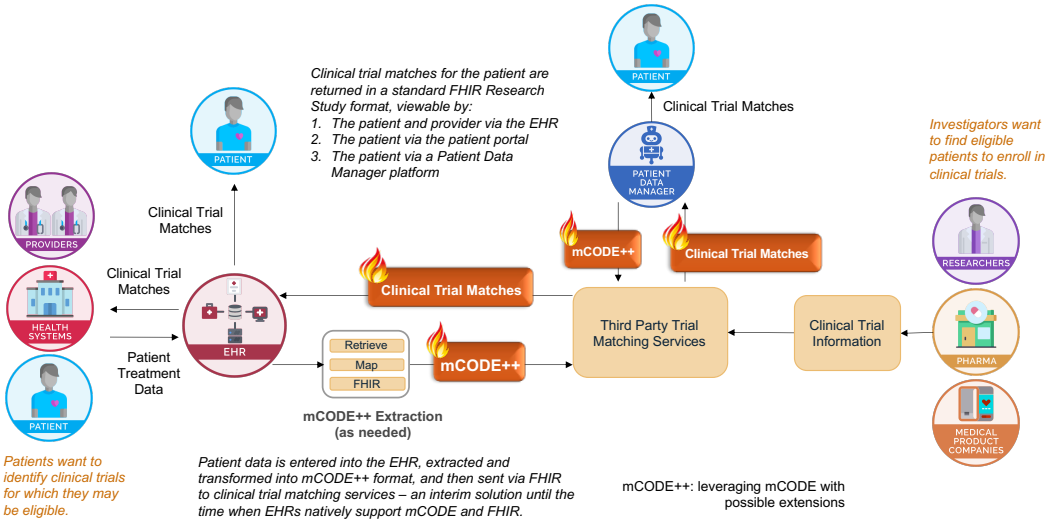
The MITRE Corporation and the American Cancer Society Cancer Action Network (ACS CAN) are championing a use case on Integrated Clinical Trial Matching for Cancer Patients and Providers under CodeX™. This use case aims to make clinical trial participation equitable and easy for all patients and providers. Our approach is to develop mCODE-based open data standards and open APIs that enable interoperable, scalable, and accessible clinical trial matching services that are integrated into existing clinical workflows. This use case will drive awareness of and commitment to use these standards in the industry and improve clinical trial matching for patients and their care teams.

Ultimately, the goal of this use case is to ensure opportunities for patients to consider clinical trial participation regardless of where they are initially treated and to identify a larger pool of patients eligible to participate in trials.

[1] Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer, April 11, 2018, https://www.fightcancer.org/policy-resources/clinical-trial-barriers

This will enable recruitment of a more diverse set of patients into trials with a cohort representative of the population of cancer patients. It will also enable clinical trials to meet enrollment targets sooner and lead to more clinical trials being completed in a timely, cost effective and efficient manner. This will ultimately result in greater and faster knowledge generation that can lead to better outcomes for all patients with cancer.

MITRE and ACS CAN, in collaboration with additional partners, have developed a proof of concept implementation of an mCODE-enabled, clinical trial matching capability. The team is seeking engagement and partnership with an academic medical center with a network of affiliated community oncology practices, community cancer centers, or regional health centers to pilot the proof of concept implementation via retrospective and prospective studies.



Integrated Clinical Trial Matching for Cancer Patients and Providers Pilot Objectives

1. Demonstrate the value of mCODE-enabled, interoperable matching services to empower patients and their providers to identify clinical trials
2. Evaluate the ability of a minimal set of eligibility criteria to support efficient matching of patients with clinical trials

Technical Approach

The initial pilot will be a retrospective study focused on matching patients with clinical trials. Specific activities include:

1. Identifying a cohort of patients and associated clinical trials
2. Curating mCODE records for these patients
3. Matching patients with clinical trials:
    a. Manually via clinician / researcher / patient
    b. Automatically via multiple mCODE-enabled matching services
4. Comparing the results of the manual matching using traditional matching process vs. automated matching via mCODE-enabled matching services using minimum eligibility criteria

The minimum eligibility criteria used for matching[2] include:

- Cancer type
- Cancer subtype
- Biomarker status
- Stage
- Presence of metastases
- Age
- Treatments

Key measures include:

1. Evaluate the quality of matches, including whether trials identified using traditional matching processes are included in the results based on automated matching using the minimum eligibility criteria
2. Quantify the level of effort saved via automated matching in comparison to traditional matching processes

The Ask

We are seeking engagement and partnership by a health center (ideally an academic medical center with a network of affiliated community oncology practices, community cancer centers, or regional health centers) to help design and guide the retrospective study.

The health center would:

1. Make available a data analyst to help retrospectively curate a defined set of patient records for initial cohort into mCODE to extract mCODE from patient health records. The data analyst would collaborate with MITRE to map mCODE to the health centers internal data models. MITRE provides the mCODE subject matter expertise and tools to support the curation process.
2. Make available an oncologist (or comparable clinical SME) that can advise a trained person (e.g., a student identified by the health center with a medical background) to manually match patients to clinical trials.

Upon successful completion of the retrospective pilot, we aspire to expand to a prospective pilot that integrates with existing Electronic Health Record systems, recruiting patients and providers into the pilot and evaluating the ability to match patients who otherwise do not have onsite trial options to trials outside their treating institution.

Potential Value to a Health Center

This pilot providers an opportunity for health center to help shape an interoperable, scalable and accessible approach for patients and providers to identify the right clinical trials. By joining the pilot, health centers can be an early adopter and implementer of mCODE standard not only to drive greater patient participation and matches for clinical trials but also enable additional use cases beyond clinical trial matching. Also, we plan to publish the results of the pilot via a peer-reviewed journal publication in collaboration with the health system. We invite health centers to be part of this journey and reshape the landscape of clinical trial matching for patients and providers.

[2] The minimum eligibility criteria was defined by a workgroup convened by the American Cancer Society – Cancer Action Network (provide reference).

Current Partners

- American Cancer Society – Cancer Action Network (co-champion)
- The MITRE Corporation (co-champion)
- TrialScope (trial matching service)
- BreastCancerTrials.org (trial matching service)
- Cancer Insights (patient and provider oncology platform)

Additional Resources

- CodeX™ Overview: https://confluence.hl7.org/display/COD/CodeX+Home
- Integrated Clinical Trial Matching for Cancer Patients and Providers Overview: https://confluence.hl7.org/pages/viewpage.action?pageId=66938394
- mCODE FHIR Implementation Guide (with data dictionary): http://hl7.org/fhir/us/mcode/
- mCODE Generic Playbook: https://confluence.hl7.org/display/COD/mCODE+Generic+Playbook