Integrated Clinical Trial Matching for Cancer Patients and Providers
Clinical trial matching at the point of care, interoperable matching services, accessible to all patients

Background

Today, most new cancer treatments come out of clinical trials. However, while over half of patients indicate that they are interested and able to participate in a clinical trial\(^1\)-\(^3\), only about 8 percent of all cancer patients enroll in clinical trials\(^1\). This disparity between patients interested in trials vs. patients enrolled in trials is largely due to the limited ability for patients and providers to identify trials in a manner that is efficient, easily accessible and integrated within existing clinical workflows. As a result, valuable information contained in the medical records of 92 percent of oncology patients is nearly impossible to leverage to improve clinical care or clinical research.

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™. Most cancer patients who enroll in clinical trials learn of these opportunities from their providers or from study staff, but most hospitals do not run trials. Furthermore, existing provider and patient-facing tools for clinical trial matching typically require a challenging amount of manual clinical data entry and / or manual review of trials. This use case aims 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.

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 oncology academic medical centers and community 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 via traditional matching process vs. automated matching via mCODE-enabled matching services using minimum eligibility criteria

The minimum eligibility criteria used for matching⁴ include:

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

⁴ The minimum eligibility criteria was defined by a workgroup convened by the American Cancer Society – Cancer Action Network (provide reference).
Key measures include:
1. Evaluate the quality of matches, including whether trials identified via 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 oncology community 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) to guide MITRE in structuring a minimal set of eligibility criteria for selected trials to align with mCODE
3. Make available an oncologist (or comparable clinical SME) to manually match patients to clinical trials

If the initial pilot is successful, 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 to trials outside their treating institution and ability to meet clinical trial enrollment targets. This phase of the pilot would entail engaging with the EHR vendor to support EHR integration and piloting the patient – clinical trial matching capability.

Current Partners
- American Cancer Society – Cancer Action Network (co-champion)
- The MITRE Corporation (co-champion)
- TrialScope (matching service)
- BreastCancerTrials.org (matching service)
- Cancer Insights (patient 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 Generic Playbook: https://confluence.hl7.org/display/COD/mCODE+Generic+Playbook