

## **Integrating AI-Enabled Clinical Trial Matching into Operations**

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### **1. Background**

The Ohio State University, The James Comprehensive Cancer Center (OSUCCC) is an NCI-designated cancer center with an estimated 400 active industry, cooperative group, and investigator-initiated clinical trials. Matching more patients to clinical trials is increasingly resource-intensive, given the complexity of contemporary cancer care, the specificity of clinical trials inclusion and exclusion criteria, and the increasing diversity of patients matched and enrolled in trials.

Enrolling patients in research studies is an integral part of the medical center's mission, is a distinguishing factor when patients are seeking care—bringing more patients to the medical center – is part of physician scorecards and is integral to maintaining grants such as the National Cancer Institute's (NCI) Cancer Center Support Grant (CCSG) which provides the Comprehensive Cancer Center designation to the OSUCCC.

Manual screening and identification of patients for clinical trials are extremely time-consuming, inefficient, and with the growing number of clinical trials, not scalable or sustainable. OSUCC clinical trial enrollment exceeded the national average (2021 interventional rate 26 percent, therapeutic rate 14 percent, national average 3 percent). Given this complexity, increasing enrollment from already high numbers would be challenging without introducing technology to aid the effort.

In preparation for the next CCSG grant renewal, CCC leadership began an extensive evaluation of clinical trials matching platforms available. After comprehensive review and vetting over a two-year period, Deep6 AI was selected as the vendor, and their artificial intelligence (AI) -driven clinical trials matching system (CTMS) was implemented at the OSUCCC in January 2023, with the first of seventeen disease teams to incorporate AI and NLP-driven clinical trial matching into the patient screening workflow.

### **2. Goals**

- Train and implement a scalable, sustainable technology solution to increase efficiency in screening and matching patients to clinical trials (Deep6 AI)
- Increase clinical trial enrollment of women, minorities, and underserved patient populations.
- Develop reporting tools to monitor patient accrual and pre-screening effort, staff engagement, and efficiency.
- Implement a disease-agnostic tool that can expand beyond cancer clinical trials.

### **3. Solutions and Methods**

#### **Solution Required for Clinical Trials Matching System**

- **Disease Agnostic:** While there are several oncology-specific platforms, the interest is in having a disease-agnostic platform for use by the entire clinical research enterprise.
- **Patient Identification and Trial Matching:** Two workflows in this software are essential for clinical research staff to utilize. The first workflow, patient identification, would allow staff to build studies (based on inclusion/exclusion criteria) and screen and identify eligible patients for trials. The second workflow, trial matching, would allow staff to find available trials for any

patient or group. The latter workflow is particularly critical for increasing the accrual of minority patients—a key initiative of the OSU WMC (Wexner Medical Center) and the NCI.

- **Allows Research Staff to Build Studies/Cohorts:** One limitation of some similar platforms is that clinical staff can wait a significant amount of time for studies to be built by informatics teams. Additionally, clinical and informatics often have a back-and-forth to review and refine study criteria. Deep 6 AI allows research staff to design and refine their cohorts in a user-friendly interface to cut down on that time and, more precisely, build inclusion/exclusion criteria for OSU studies.
- **Easy User Interface:** OSU seeks to utilize software that will decrease the time spent per patient evaluation and enrollment. Thus, a critical requirement that Deep 6 AI fulfills is a user interface that speeds patient screening by presenting and highlighting patient data related to the inclusion/exclusion criteria across a longitudinal patient record.
- **Incorporates multiple data sources:** Deep 6 AI can incorporate multiple data sources beyond the electronic medical records (EMR), such as genomics, custom databases, cancer registries, CTMS, etc., that may have additional data unavailable from the EMR.
- **Searches Unstructured Data:** Industry and academic research estimates have concluded that up to 80 percent of clinical data is contained in unstructured clinical notes such as pathology or clinician notes. This includes much information that applies to research studies' inclusion/exclusion criteria. To utilize these data in clinical research workflows, OSU requires a software platform to access and comprehend unstructured and structured data to help screen and match patients against OSU's available clinical trials. Two essential features of Deep 6 AI's Natural Language Processing (NLP) are 1) the ability to select the areas to which we wish to apply NLP and 2) to be able to reference the text in which the NLP identified the keywords to view the keywords in context to confirm the finding. Notably, the platform can search genomic data critical to clinical trial matching.
- **Provides partial matches; shows excluded patients and criteria:** Because of complexities in identifying patients for studies and the changing nature of their health/healthcare, it is vital for the platform to show partial matches that may require some additional manual look-up and the excluded patients and criteria.
- **Improved staff efficiency and productivity:** While it will not eliminate human intervention, Deep Six AI's platform and the user interface should significantly decrease staff time in identifying patients for studies.
- **Business model:** The business model is a critical consideration for the institution. Some companies offer "free" or lower-cost software platforms. The companies evaluated can do this because the data from customers is commercialized to generate a revenue stream. Importantly, with Deep Six AI, the customer owns their data. Data is not commercialized.

#### **Methods:**

- Rolling implementation of Deep6 AI Clinical Trials Matching platform across seventeen disease teams within the OSUCCC clinical trials office.
  - Training and support done in close collaboration with the vendor.
- Developed standard workflow and tracking for clinical research coordinators (CRC) to review and optimize trial builds in the system.
- Continued development of incorporation of the matching system into day-to-day CRC workflows.
  - This includes honing the process of communication of trial matches with treating physicians and following up on trial presentation to patients and consent outcomes.

## Category: Trial Recruitment and Study Conduct - Work in progress

- Creation of a process manual for the matching system for staff to use as a reference.
- Initial data was captured in Excel to monitor user engagement and matching accuracy.
- Developing data capture of all screening efforts within the new CTMS and manual chart review. (RedCap Form in development)
  - Are research staff identifying and enrolling more patients with the help of the AI-driven clinical trials matching application?
  - Do the clinical trial matching system's AI and NLP identify potentially eligible patients accurately?
  - What are the reasons patients are not consenting? (patient refusal, physician decision, deterioration due to disease, etc.)
  - Does the system capture a more diverse patient population?
- Central oversight of training, administration, and staff engagement
  - Director, Clinical Research Informatics
  - Process Manager, Clinical Trials Office
  - Clinical Trials Office senior leadership

### 4. Outcomes

Patient enrollment and screening method data are pending data capture tools in RedCap.

87 active users across 12 disease teams

242 active clinical trial queries in use

Over 3,000 patients with evidence were screened in the last six months (Aug. 2023-Feb. 2024)

### 5. Lessons Learned and Future Directions

#### Lessons Learned

- Augmented versus AI
- Nuance of eligibility in complex diseases and clinical trials
- Realistic expectations of system capability
- Limitations of the system--scanned records and media, Epic Care Everywhere (outside records)
- Selectivity of trials due to limitations of system and disease characteristics
- Query validation and modification require ongoing study team effort and expertise
  - Increased effort = Increased utility
- Workflow integration must be considered and incorporated into training

#### Future Directions (Application Enhancements)

- Continued enhancements and process improvements made based on feedback from users.
- Increased use of genomics platform integration
- Integration with Advarra OnCore clinical trials management system for efficiently tracking patients identified through AI-enabled clinical trials matching application system enrolled to clinical trials and staff list crossover
- HL7 FHIR integration for Epic EMR for patient-level Trial Recommender
- Addition of a Watchlist
- Better communication capabilities for reviewed patients - the ability to attach comments to a patient record
- More extensive reporting options
- Further improvements for user-friendly interface
- Better ways to capture nuanced data
- Increased enrollment
- Expansion to trials/diseases outside of cancer

*Category: Trial Recruitment and Study Conduct - Work in progress*

- Evaluating other data sources beyond EMR and genomics, including cancer registry data and CTMS (OnCore) data
- Integration with CTMS for trial enrollment status, staff on the protocol
- Integration with EMR via FHIR-enabled interface to allow for a quick review of available clinical trials, aka Embedded Trial Recommender
- Enhanced data integration with the EMR via HL7 FHIR