Enabling Clinical Trial Feasibility and Patient Finding Through the Use of the OMOP CDM

Mui Van Zandt[2], Jason Hsu[1], Alex Nguyen[1], Gyeol Song[2], Sabrina Cheema[2], Michael Krupnick[2]
[1] Taipei Medical University, [2] IQVIA

Background

Client trial feasibility and finding the right patients for a trial can be challenging. Some of those challenges are having enough information to find and keep the right potential patients, such as a clear diagnosis, overstretched health-care providers and infrastructure[1]. Another challenge with recruitment is better understanding of how well a patient meets the inclusion/exclusion of the trial since many of this information can sit within both structured and unstructured data, such as pathology reports and notes.

Cancer clinical trial recruitment is hindered even further. Studies shows that 56% of patients will not have a local trial available for their cancer, 17% will be ineligible due to exclusion criteria, many eligible patients will not be asked by their providers to enroll, and only 27% of cancer patients will have the option to enroll in a local clinical trial[2]. Having the right information and data points available for researchers will help resolve some of the barriers above. However, data captured within hospital center and community centers can pose their own challenges. Access to the right quality information can be hindered by inconsistencies in data formats, limiting data sharing and reuse across institutions. Unstructured data sources such as pathology reports contain valuable clinical information that is underutilized due to technological limitations. Existing data models, like the OMOP Common Data Model, can offer standardized structures for data, but require further tools for transforming unstructured data.

Methods

This project, a collaboration between Taipei Medical University and IQVIA, aims to apply the OMOP common data model on top of an oncology network to help address some of the challenges to enhance the quality and efficiency of clinical research feasibility and patient finding. The main objective of this project is to develop a universally applicable data format and a system for extracting and transforming data for cancer research. These tools will enable the conversion of unstructured data into structured formats, integrating into the internationally recognized OMOP model, thereby facilitating cross-institutional clinical research and data sharing.

This collaboration will be broken up into multiple phases:

- Phase 1: Develop and refine NLP algorithms to automatically extract key clinical information from unstructured data sources like pathology reports and map them to the standard vocabulary
- Phase 2: Establish a system to convert both the structured and unstructured data over to the OMOP CDM
- Phase 3: Deploying the Data Quality Dashboard to ensure high quality conversion
- Phase 4: Install oncology patient finding and screening tool to enable sites to easily find the right patients for a trial and track them as they move along the eligibility process

Results

As this project is ongoing, no results have been generated, but the hopes to showcase how the OMOP CDM can be used to standardize many of the structured and unstructured elements.

Conclusion

Given the continuous development of this project, there is no conclusion at this time. With higher quality data, this can lead to more accurate identification of patients for a trail increasing the success rate of patient recruitment and trial retention. The hope is to showcase to the OHDSI community how the OMOP CDM can be utilized for use cases within the clinical trial space where there is an overlap between real world analysis and clinical trial feasibility.

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References

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1. Jessica B. Langbaum, Julie Zissimopoulous, Rhoda Au, Nairanjan Bose, Chris J. Edgar, Evan Ehrenberg, etc., Recommendations to address key recruitment challenges of Alzheimer's disease clinical trials, https://doi.org/10.1002/alz.12737.
2. Fightcancer.org, Barriers to Patient Enrollments in Therapeutic Clinical Trials for Cancer – A Landscape Report, https://www.fightcancer.org/sites/default/files/National%20Documents/Clinical-Trials-Landscape-Report.pdf.