Designing Clinical Trials to Improve Diversity, Equity and Inclusion (DEI): A Machine Learning Approach to Evaluate Clinical Trial Criteria

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Description of the Presentation

The US Census Bureau estimates that non-Hispanic white Americans represent ~61% of the US population [1]. However, non-Hispanic whites of European ancestry comprise more than 90% of the population in clinical trials. This imbalance in clinical research inclusion leads to limitations in clinical guidelines and products, with serious adverse health consequences for excluded populations. Despite awareness and recent efforts to rectify this problem, numerous obstacles persist, partly due to the inherent complexity of trial design and the lack of appropriate tools that clinical trial researchers can use to identify the specific components responsible for the lack of representation [2].

In this project, we propose a machine learning (ML) approach with natural language processing and deep learning methods to analyze the inclusion and exclusion criteria in a large corpus of clinical trial data from ClinicalTrials.gov to identify those criteria that reduce/increase diversity in patient recruitment. Embedding the ML model in a user-oriented software platform, we aim to demonstrate how it can facilitate increase in patient recruitment diversity for multiple stakeholders, including clinical trial designers, researchers, patient advocacy groups and potentially the FDA. Factors contributing to the underrepresentation of minorities and vulnerable disease populations in clinical trials are complex. Our machine learning tool will aim to both identify and optimize variables in a multi-dimensional solution space to identify and mitigate some of these factors. We use breast cancer as an illustrative use case for prototyping, as it is a disease with a well-characterized disparity in mortality and trial representation. However, the basic models and technology platform will be easily scalable and generalizable to other conditions.

Our presentation will introduce the imbalance issues in clinical trial inclusion and its consequences, highlighting research indicating the impact of lack of DEI on patients, health systems and society. We will discuss the reasons why identifying the specific components responsible for the lack of representation is a complicated task with the current tools available for trial design. Our solution addresses the DEI challenge from both the clinical and patient perspectives - helping clinicians design better inclusion/exclusion criteria by evaluating their impact on diversity in recruitment so that the criteria can be modified to improve diversity, and creating a trial recommendation system to make it easier for patients and health professionals to find and assess potentially relevant trials during clinical encounters. We will briefly discuss the technology and models used to create the system, focusing on the performance of the ML models, the results for the breast cancer use case, and feedback on the system prototype from real users (clinicians and patients).

Presentation Outline

1. **Problem and Consequences:** Lack of DEI in clinical trials
2. **Status Quo and Challenges**: Discussion of existing processes and bottlenecks
3. **Proposed Solution:** Discussion of system and technical components
4. **Results:** Performance of ML models, use case demonstration, user feedback from prototyping
5. **Future Scope:** Opportunities for extensions, scalability and generalizability

1. Ma, M. A., Gutiérrez, D. E., Frausto, J. M., & Al-Delaimy, W. K. (2021). Minority Representation in Clinical Trials in the United States: Trends Over the Past 25 Years. *Mayo Clinic Proceedings*, *96*(1), 264–266.
2. https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html, accessed on November 30, 2022.