

# Towards High Efficiency Eligibility Assessment for Clinical Trial Accrual

Huan He, PhD<sup>1</sup>, Andrew Wen, MS<sup>1</sup>, Sunyang Fu, PhD<sup>1</sup>, Sijia Liu, PhD<sup>1</sup>, Kurt Miller, MS<sup>1</sup>, Michael Lin<sup>2</sup>, Robert Gehrke<sup>2</sup>, Carmen Vodislav<sup>2</sup>, Kathryn Cook<sup>2</sup>, David Strauss, MBA<sup>3</sup>, Dania Helgeson MS<sup>3</sup>, Thomas Kingsley, MD, MPH<sup>3,4</sup>, Alexander Ryu, MD<sup>3</sup>, Hongfang Liu, PhD<sup>1</sup>

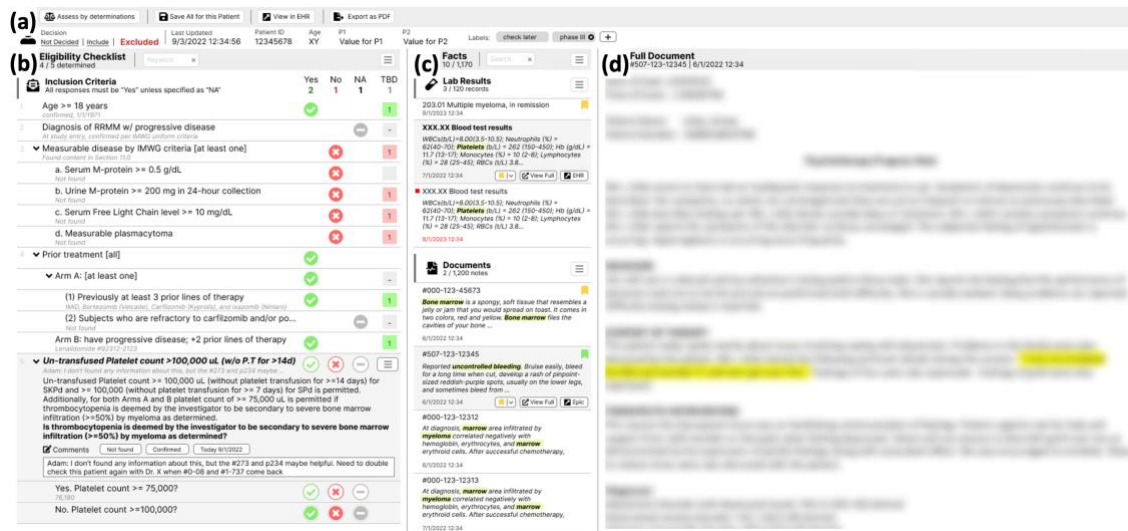
<sup>1</sup> Department of Artificial Intelligence and Informatics, Mayo Clinic, Rochester, MN, USA

<sup>2</sup> Center for Clinical and Translational Science, Mayo Clinic, Rochester, MN, USA

<sup>3</sup> Department of Medicine, Mayo Clinic, Rochester, MN, USA

<sup>4</sup> Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN, USA

**Background:** Recently, the use of electronic health records (EHRs) has been proposed to address the challenges of patient recruitment for clinical trial accrual<sup>1</sup>. The rich information included in the EHR, such as patient demographics, past medical history, laboratory results, and clinical reports, would significantly support increasing the effectiveness and efficiency of clinical trial accrual. However, due to the complexity of the criteria and the amount of data, manual patient evaluation is inefficient. To address this issue, we propose applying human-computer interaction design principles to guide the design of the user interface (UI) for eligibility assessment.



**Figure 1.** The visual design of our proposed tool, including (a) patient view showing decision, demographics, and labels for a specific patient, (b) the eligibility checklist view showing the details of criteria and determinations, (c) the document list view showing the matched items, and (d) the document viewer showing the full text content.

**Design Principles:** To understand the workflow and system requirements, we conducted several rounds of interviews with clinical research coordinators who have extensive clinical trial accrual experiences. Based on their comments, we summarized the design principles to guide the UI development, including **1) reducing the cognitive overhead**. As no EHR system modules are yet directly dedicated to supporting eligibility assessment, the user must memorize various criteria information, build relevant keywords, and search clinical facts in the EHR system to evaluate each criterion. Repeating this process on each criterion and each patient is time-consuming and can lead to cognitive overload, which may further affect the quality of the recruitment. Therefore, the UI should provide sufficient information for users to make judgments and avoid context switching; **2) be consistent with user expectations**. The UI solution should not reinvent terminology, workflow, or patterns that are misaligned with users' expectations. We designed a three-panel layout to support the three major tasks: checking the criteria, browsing the facts, and examining the details. Each panel has a similar layout to existing tools. **3) low physical effort**. We try to minimize the steps in each task so that the user can complete a task without any "unnecessary" operations.

**Future work:** At present the prototype shown in the figure is only available in our internal site for initial evaluation. We will release an open-source prototype with sample dataset to collect feedback and improve the design. In addition, we plan to conduct case studies based on real clinical trial projects to validate the visual design.

## References

1. Devoe C, et al. Use of Electronic Health Records to Develop and Implement a Silent Best Practice Alert Notification System for Patient Recruitment in Clinical Research: Quality Improvement Initiative. *JMIR Medical Informatics*. 2019 Apr 26;7(2):e10020.