Accrual to Clinical Trials (ACT) - a SHRINE User Interface Refresh to Search for 125+ Million Lives

Anupama Maram, MS¹, Griffin M. Weber, MD, PhD¹
¹Harvard Medical School, Boston, MA

Introduction
Multi-site clinical trials often require identifying and locating a statistically significant number of patient subjects, yet a majority of these studies are unable to meet their initial recruitment goals. The Accrual to Clinical Trials (ACT) network is a nationwide federation of Clinical and Translational Science Award (CTSA) institutions that share aggregate patient counts from electronic health record data. The network consists of local installations of Informatics for Integrating Biology at the Bedside (i2b2) EHR data repositories that are linked by the Shared Health Research Information Network (SHRINE) platform. The SHRINE platform includes a web-based query tool that allows researchers to construct complex Boolean queries to obtain real time aggregate count of patients at participating hospitals who meet a given set of inclusion and exclusion criteria. Because of the national scope of the ACT network, researchers have access to patient sets with regional diversity helping with clinical trial cohort discovery and study feasibility. To date, the network connects 41 CTSA sites and contains data on more than 125 million patients¹. The existing SHRINE user interface (UI) was derived from and closely resembles i2b2 code that is over 12 years old. In order to serve the needs of a larger researcher audience who are unfamiliar with i2b2, the SHRINE/ACT team at Harvard Medical School are developing a more intuitive, user-friendly UI with modern usability standards of design, look-and-feel, and accessibility.

Discussion
The expansion of the user community driven by continued growth of the ACT network to over half of the CTSA consortium, and the availability of a large number of patient records, necessitates a new UI and user experience for SHRINE/ACT to be as intuitive as possible for novice users while conveying complex query construction and eliminating the need for extensive training.

Working with the assumptions listed in Figure 1, the development team underwent a series of internal and external analysis including 1. A review of 100 selected studies from https://clinicaltrials.gov to categorize the degree of difficulty of inclusion and exclusion criteria as it relates to constructing Boolean logic 2. Producing a landscape analysis of existing tools, both open source and proprietary, to learn how similar efforts have developed modern web user interfaces, including: transSMART, TriNetx, LEAF (UW) and Glowing Bear (Hyve) and 3. Working collaboratively with the i2b2/TransSMART Foundation User Interface working group, various ACT working groups, and conducting focus groups to gain insights into creating a more intuitive workflow while ensuring that the resulting web client is positioned to meet SHRINE/ACT’s growing needs. The system demonstration will unveil the new UI developed by iterative prototyping and rapid user feedback focusing on novice users.

Conclusion
Producing a new SHRINE/ACT web client that is well understood by the user community involves collaboration with prospective and current users, incorporating feedback, and validating assumptions to encourage the research use case of the ACT network.

References

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