Needs Assessment of a Cohort Exploration Tool for Clinical Research Coordinators at a Large Academic Medical Center

Thomas Kingsley MD MPH MS[1,2], Sunyang Fu PhD[3], Huan He PhD[3], Michael Lin[4], Robert Gehrke[4], Carmen Vodislav[4], Sijia Liu PhD[3], Andrew Wen MS[3], David Strauss MBA[1], Dania Helgeson[1], Kathryn Cook[4], Alex Ryu MD[1], Hongfang Liu PhD[3]

[1] Department of Medicine Mayo Clinic, Rochester Minnesota
[2] Department of Quantitative Health Sciences, Rochester Minnesota
[3] Department of Artificial Intelligence & Informatics, Rochester Minnesota
[4] Center for Clinical Translational Sciences, Rochester Minnesota

Introduction

Clinical trials (CTs) are essential to the translational pipeline of bench-to-bedside, but unfortunately, are a rate-limiting step. CTs have major challenges that desperately require innovation to address them. Several of the challenges include (1) cost, (2) duration, and (3) study failure[1-4]. For instance, the average cost to develop a new drug is between 1.5 and 2.0 billion dollars and takes an average of 10 to 15 years, and this does not even account for the cost of failed trials[5, 6]. Two-thirds of all clinical trials fail to meet their recruitment goals, and one-third are never completed once started [4]. A proposed cause of the high cost, long duration, and study failure is difficulty in finding study participants based on trial eligibility criteria. Potential participant medical data is stored in large databases, where the vast majority of that data is unstructured, like the electronic health record (EHR) [4, 7]. It is often the task of clinical research coordinators (CRCs) to sift through this unstructured data to find those elusive eligible participants. It can be summarized as an information extraction problem. On the surface, this may seem easy to solve with currently available technology.

However, many have tried in the past decade, like IBM's Watson for oncology trial matching, and have been unsuccessful [8]. Our team conducted a needs assessment surveying CRCs at Mayo Clinic, a large academic medical center. The results of the survey clearly pointed to the need for a user-centric solution and, subsequently, the design and development of a Precision Extraction and Analysis for Cohort Exploration (PEACE) tool. We briefly discussed how this survey then led to designing and developing PEACE. The results of our needs assessment will be essential to most academic hospitals and clinical trial sites because they emphasize the challenge of finding participants based on eligibility criteria and the need for a user-centric technologic solution.

Methods

Our team designed a survey for individuals identified as Clinical Research coordinators at Mayo Clinic. These individuals were identified through an internal human resource database. Two identical emails inviting participation in the study were sent approximately six weeks apart. The survey was designed, administered, and data was stored using an institutional account to REDCap LLC software.

Results

We present only questions from the survey that was part of the need assessment. The survey was sent to 758 individuals, 242 individuals responded, and 240 individuals completed the survey with a completed response rate of 32%. Below we present the selected questions that fulfilled our needs assessment and gap analysis and provided the impetus to develop PEACE.

Question 1: As a Research Coordinator or similar position, what parts of patient accrual do you participate in as part of your job? (Select all that apply)

Table 1. The answers to Question 1.

Answer	Total Count & Percentage of Respondents
Searching the electronic health record (EHR or Epic) for patients that meet clinical trial or study criteria	181, 76.1%
Searching other data sources (non-EHR or Epic) for patients that meet clinical trial or study criteria	62, 26.1%
Enrolling patients into clinical trials or studies once they have been identified	211, 88.7%
Data entry and organization	210, 88.2%
Other	67, 28.2%

Question 1b (of those who selected part of their time is for searching patients in the EHR):

What percentage of your total time do you spend searching the EHR (Epic) for patients to enroll in clinical trials?

The median stated 30% of their time. The 25th and 75th percentile stated 20% and 50%, respectively. The 95th percentile stated 75%.

Question 1c (of those who selected they search other data sources other than the EHR for patients):

What percentage of your total time do you spend searching other data sources for patients to enroll in clinical trials?

The median stated 15% of their time. The 25th and 75th percentile stated 10% and 33.750%, respectively. The 95th percentile stated 55.80%.

Question 2:

If there was a tool (software) that allowed you to enter in the inclusion and exclusion criteria for research studies and accurately identify patients by searching Mayo Clinic data would this be helpful in your job?

There were 239 who responded to this question, and 87.4% responded yes and 12.6% responded no.

Question 2b (those that responded yes to question 2):

How much time do you think such a tool would save you on average in a given day?

Table 2. The answers to Question 2b.

Answer	**Total Count & Percentage of Respondents**
Greater than 12 hours	17, 8.2%
More than 8 hours but less than or equal to 12	16, 7.7%
More than 4 hours but less than or equal to 8 hours	36, 17.3%
More than 2 hours but less than or equal to 4 hours	58, 27.9%
More than 30 minutes but less than or equal to 2 hours	62, 29.8%
Less than or equal to 30 minutes	19, 9.1%

Discussion

The results of our needs assessment survey of CRCs show that most spend some part of their effort looking for patients based on eligibility criteria, and of those, the vast majority believe (1) a tool (software) to help find patients would be helpful and, (2) one-third of respondents would save more than 4 hours per day if such a tool existed. This led to the development of PEACE, which is a full-stack solution.

The back end is a search engine with natural language processing for unstructured data that ranks patients based on their likelihood of meeting trial eligibility criteria. The front end is a user interface that allows for easy user reviewing of patients that resulted from the search query and annotation of unstructured data. This feature allows for scalability and iterative solution improvement as a function of time and use. However, to be effective, CRCs must find immediate value in PEACE to adopt it. Therefore, a user-centric approach was taken, reflected in our survey, design, and development team having broad stakeholders, especially CRCs.

References

1. Collier, R., Rapidly rising clinical trial costs worry researchers. Canadian Medical Association Journal, 2009. 180(3): p. 277-278.
2. Wong, C.H., K.W. Siah, and A.W. Lo, Estimation of clinical trial success rates and related parameters. Biostatistics, 2019. 20(2): p. 273-286.
3. Bentley, C., et al., Conducting clinical trials—costs, impacts, and the value of clinical trials networks: A scoping review. Clinical Trials, 2019. 16(2): p. 183-193.
4. Nipp, R.D., K. Hong, and E.D. Paskett, Overcoming Barriers to Clinical Trial Enrollment. American Society of Clinical Oncology Educational Book, 2019(39): p. 105-114.
5. Beck, J.T., et al., Artificial Intelligence Tool for Optimizing Eligibility Screening for Clinical Trials in a Large Community Cancer Center. JCO Clinical Cancer Informatics, 2020(4): p. 50-59.
6. Sertkaya, A., et al., Key cost drivers of pharmaceutical clinical trials in the United States. Clinical Trials, 2016. 13(2): p. 117-126.
7. Sampson, R., et al., An integrated approach to improve clinical trial efficiency: Linking a clinical trial management system into the Research Integrated Network of Systems. Journal of Clinical and Translational Science, 2022. 6(1): p. 1-20.
8. Harrer, S., et al., Artificial Intelligence for Clinical Trial Design. Trends in Pharmacological Sciences, 2019. 40(8): p. 577-591.