Recruitment Innovation Center: Assessing Institutional Capabilities and Appropriate EHR Recruitment Strategies

Abstract
The ability to support a learning health care system at a national level requires reliable data to inform policy and clinical practice decisions. Controlled intervention trials, which depend on effective recruitment and enrollment, continue to be one of the most recognized sources of data for this effort. The Recruitment Innovation Center (RIC) is developing recruitment and retention strategies to improve the quality of clinical trials, raise awareness of the value of research and increase trial enrollment and health outcomes across America. During the past 12 months the RIC has enabled innovative work by developing methods to support sites who would like to leverage their local electronic health record (EHR), their EHR data, and other informatics tools for recruitment and retention in clinical trials. This panel will examine three interrelated activities and how they can positively impact the challenges of recruitment and retention: EHR driven recruitment strategies; 2) Governance and maturity models for implementation and EHR recruitment; 3) Implementing recruitment strategies in a Cerner/Epic environment.

Keywords: Recruitment technologies, Secondary use of EHR data, Learning healthcare system

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Panel Description
The EHR, because of the breadth and depth of data about potential study participants, has been seen as a logical opportunity to address the issues of recruitment and retention for individual clinical trials. The promise of accessing and using these enterprise systems and associated data sources have been delayed for numerous documented reasons including: individual investigators lacking knowledge of the data source, required tools, governance issues, and implementation requirements of the local EHR data environments. These impacts have been particularly acute for non-informatics investigators who may have never interacted with an IT shop. Recognizing this inherent disparity, the RIC has been providing direct support, expertise and evaluation support. This allows the RIC to provide targeted assistance to individual investigators through the Trial Innovation Network (TIN). This panel will describe three different areas of research which have been used in real world scenarios to evaluate, guide and implement approaches to leverage EHR
data for practical support of recruitment and retention is clinical trials. In addition to presenting data in these areas the panel will participate in a discussion with conference attendees about best practices, successful strategies and how current practice and experience can be shared and leveraged to benefit researchers and participants on a national scale.

**Presentation 1: Developing a Decision Matrix to Assess EHR Driven Recruitment Strategies**
This presentation will highlight the decision matrix which was developed to help assess what EHR specific strategy may be appropriate to use (if any). We will also discuss several categories of EHR driven recruitment: (a) patient/PHR-directed alerts; (b) clinician-directed point-of-care alerts; (c) researcher-directed alerts; (d) registry-driven recruitment; (e) general EHR data queries/cohort identification for asynchronous participant contact; (f) patient-directed kiosk-based alerts. We will include evidence/feedback generated from ~15 studies for which the RIC EHR optimization team has engaged in consultations as well as some of the outputs of those consultations.

**Presentation 2: Assessing existing governance and maturity models of a site prior to implementing an EHR based approach to recruitment**
This presentation will draw upon evidence/feedback generated from the RIC informatics team as well as engagement with RIC awarded studies. The presentation will highlight strategies that have been developed by the RIC EHR Optimization service line to engage with study sites and assess their local IT maturity and governance.

**Presentation 3: Developing EHR specific recruitment tools in a Cerner/Epic environment**
Developing tools that are EHR specific first requires you to identify specific functions within your EHR that can be co-opted or developed for research. Examples of coopted capabilities include: **Notifications:** regarding potential participants for retention and tracking; **Documentation:** Flowsheets, MARs, orders, problem lists; **Subject Recruitment:** patient health record communications, Clinical trial alerts. This presentation will describe creating new opportunities for implementation approaches beyond the standard clinical workflows for game changing approaches and designed optimizations.

**Relevance**
A previous survey of controlled clinical trials research within the United States (US) provided data which described how many trials are being conducted and how many participants are being recruited. The results showed there were 10,974 actively recruiting interventional trials, whose target enrollment exceeded 2.8 million participants, with an average recruitment target size of 259. Another analysis of US clinical trials concluded that 80% of clinical trials fail to meet enrollment timelines and up to 50% of research sites in multi-center trials enroll one or no participants. Many sources have concluded that a major reason contributing to delayed and failed enrollment is lack of awareness within the target patient population.

We believe that a large cross section of the AMIA Informatics Summit attendees include clinician scientists, clinical research information officers (CRIOs), bioinformaticians, biomedical informaticians clinical enterprise administrators, clinical informatics scholars and students and
that members from all of these groups can contribute to the panel discussion and will learn from the moderated exchanges following the presentations.

Discussion Questions

Data strategies utilizing the Electronic Health Record
1. What are current capabilities of your EHR with regards to participant recruitment?
2. Are there resources (people, tools) available to assess the best, or any, strategy for utilizing the EHR for recruitment?
3. Is there an established ‘data pipeline’ from trial development, through approval, to recruitment that includes EHR data?
4. To what extent is re-use of EHR data a subsidized resource? Is this a barrier?

Governance and Maturity Models
1. How would you rate the governance environment at your institution in terms of access to clinical data for research recruitment?
2. Are there institutional guidelines and policies regarding access and use of clinical data for research?
3. What institutional barriers currently exist, with regards data access?

Developing EHR specific recruitment tools
1. Are vendor specific recruitment tools available to your researchers who are not directly involved in providing health care?
2. How effective are multiple alerts for similar patient populations?
3. Are patient directed alerts, as opposed to provider directed alerts, available at your institution?
4. What are some of the barriers to EHR specific recruitment tools?

Participant Agreement

If accepted, each of the panelists listed in this proposal have agreed to attend the conference and participate in the panel/