A Clinical Recruiting Management System for Complex Multi-Site Clinical Trials Using Qualification Decision Support Systems

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Abstract

A clinical recruiting management system with qualification decision support systems was developed to increase the efficiency of screening and evaluation of participants during a recruiting process whereby recruiting for various protocols are conducted at multiple sites by different groups with process interdependencies. This system is seamlessly integrated into our enterprise-scale Human Research Information System (HuRIS), encompassing research participants’ electronic health records (EHR), with real-time access to the clinical trial data.

Introduction

Participant recruitment in clinical research settings—similar to drug discovery and development settings—is a complex process that makes up a significant part of the entire protocol workflow process. A reductionist approach calls for improvement of individual sub-processes in the protocol life cycle in order to achieve a safe, risk-free optimization.

Our clinics concurrently conduct various research studies related to substance abuse. The challenges of recruiting the required number of volunteers in accordance with regulations and standards as well as the requirements of the study at hand is compounded when recruiting is conducted in a decentralized fashion by different groups at various physical locations with process interdependencies whereby different stages of recruiting is conducted at different locations. A solution was required to increase the efficiency of the recruiting process and to handle a set of protocols running concurrently at multiple recruiting centers by various groups of researchers.

Methods

We developed the Clinical Recruiting Management (CRM) system to address the aforementioned challenges. CRM provides recruiting templates for maintenance of checklists of a protocol or a group of protocols which share the same screening process. A recruiting template of a protocol defines the tasks of the required medical, psychological, and laboratory evaluation. Since the required tasks vary from one protocol to another, the recruiting templates provide clinical staff with a checklist that reminds them of the steps to be completed for the designated protocol.

CRM keeps track of the recruiting progress of potential participants. Starting from their first contact, all the screening activities become part of the participants’ clinical research records, which are fully integrated into HuRIS. This enables documentation of the status of the required tasks and serves as evidence for evaluating participant-protocol qualifications.

CRM integrates decision support systems for assisting in the qualification process. Our approach provides for creating screening criteria sets used to dynamically generate a list of protocols a participant could be qualified for, along with the reasons associated with each disqualification. The interface allows researchers to review the outcome of the analysis for a specific participant and override the automated assignment. Comments or customized questionnaires can be added to the qualification decision for designated studies. Once a participant is determined to be eligible, the systems immediately allow for scheduling an appointment. The decision support systems are also used to analyze the collected data across multiple participants, and to simulate various qualification scenarios. By investigating the high-frequency disqualification criteria, researchers can amend the design of their protocols and maximize the recruiting rates of participants.

Discussion and Conclusion

Using CRM with qualification decision support systems in a multi-protocol multi-center clinical research setting, we have successfully increased the efficiency of our recruiting process, resulting in over 10,000 phone screens and 2,300 eligible participants annually. Moreover, with the seamless integration into HuRIS, CRM leverages the power of a wide variety of the native components of HuRIS and our clinical research data repository, as well as the secure communications across multiple sites.

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