Design and Architecture of a Distributed Network Pragmatic Clinical Trial: The PCORnet ADAPTABLE Study

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Abstract

The ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness) study will be the first randomized clinical trial to be executed within PCORnet, the National Patient-Centered Clinical Research Network. Design of the ADAPTABLE data architecture incorporates features of the Distributed Research Network, including innovative use of the PCORnet Common Data Model. The ADAPTABLE study database will amalgamate multiple data sources into an integrated data ecosystem.

Introduction

The ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-term Effectiveness) study will be the first randomized clinical trial to be executed within PCORnet, the National Patient-Centered Clinical Research Network recently initiated by the Patient Centered Outcomes Research Institute (PCORI)(1). The study will randomized 20,000 patients into a pragmatic clinical trial to identify the optimal dosing of aspirin in patients with cardiovascular disease, (2).

ADAPTABLE is a vanguard for the Distributed Research Network (DRN) infrastructure developed by PCORnet to support efficient observational and interventional research, with a focus on pragmatic clinical trials that are embedded into "real world" clinical care(3). PCORnet trials and studies will form a continuous cycle of improvement for data infrastructure.

Methods

Design of the ADAPTABLE data architecture required an assessment of trial objectives against existing PCORnet DRN infrastructure, extensions to incorporate new interventional components, and configuration to integrate the heterogeneous but complementary data sources.

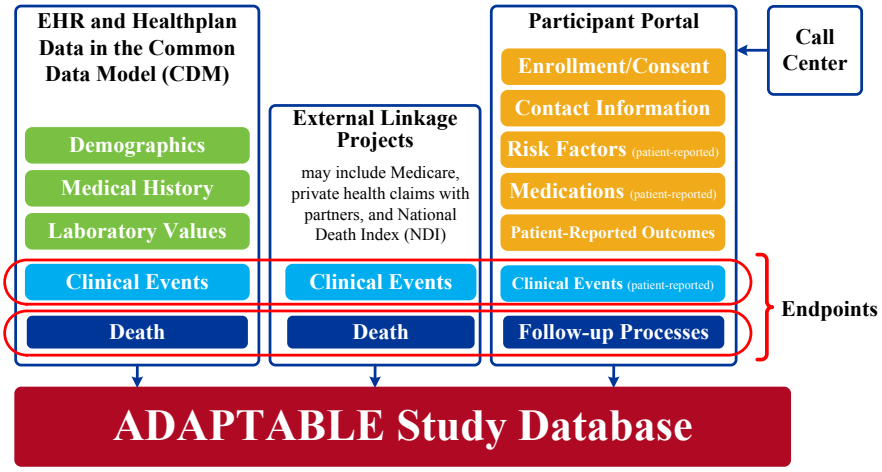

Figure 1. The ADAPTABLE study database will amalgamate multiple data sources in an integrated ecosystem.

A key component of the PCORnet DRN is the use of data generated in the delivery of healthcare, both from electronic health records (EHRs) and health plan claims. The PCORnet Common Data Model (CDM) specifies a standardized representation of these data optimized for distributed analysis and deployed to form a foundation of the "network of networks." Use of the CDM, in conjunction with PCORnet's established network typology and governance processes, is an innovative feature of the ADAPTABLE study database. ADAPTABLE will also incorporate prospective data through a participant portal, designed for direct interaction with study participants, electronic consent, randomization processes, and collection of self-reported and call center-mediated data.

Results

The ADAPTABLE architecture will encompass multiple data stores and associated processes. Each source will be incorporated within the characteristics of its provenance, including processing, latency, and consistency. Endpoints will be ascertained by applying algorithms for comprehensive surveillance across multiple sources.

Features of the trial data flow will include the integral role of the site-specific identification of potentially eligible patients via computable phenotypes, determination of eligibility, and approach for potential participants.

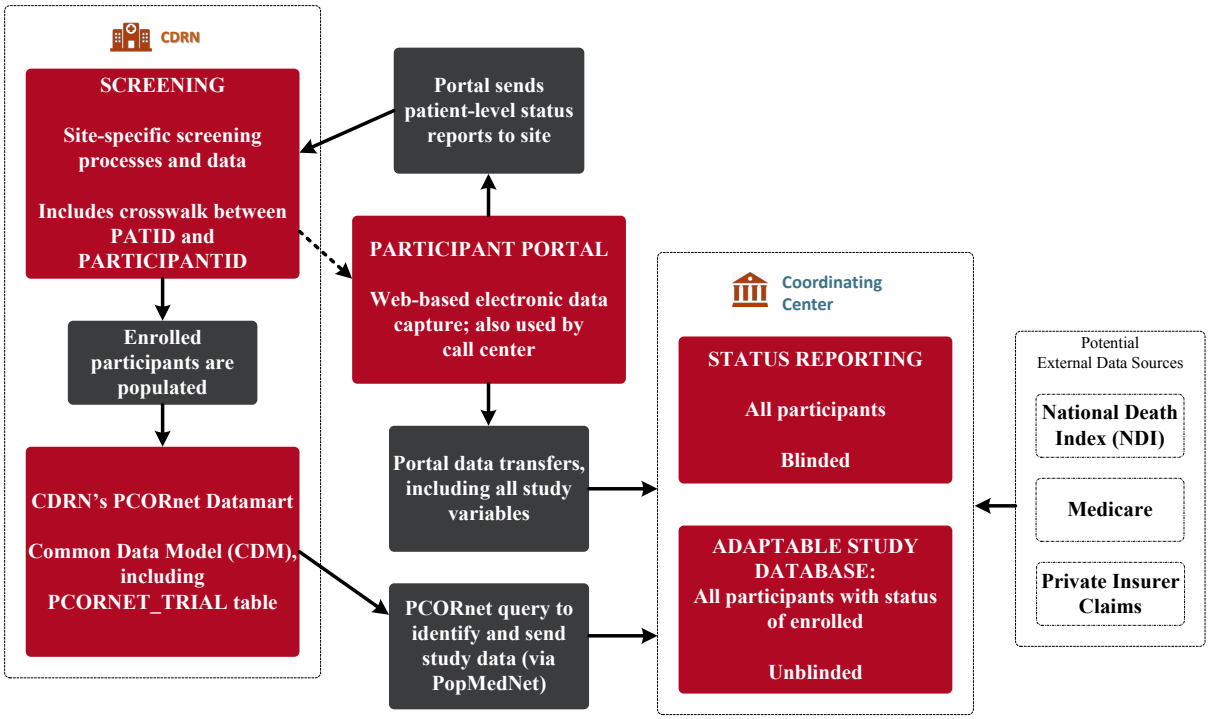

Figure 2. Data flows for the ADAPTABLE trial. Data stores are indicated in red, and data exchange processes are indicated in gray.

Discussion

ADAPTABLE presents a new opportunity to develop and field-test a robust and scalable infrastructure to support execution of distributed network pragmatic clinical trials.

References

1. PCORnet. ADAPTABLE Aspirin Study [cited 2015 September 21]. Available from: http://www.pcornet.org/aspirin/.
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3. Fleurence RL, Curtis LH, Califf RM, Platt R, Selby JV, Brown JS. Launching PCORnet, a national patient-centered clinical research network. Journal of the American Medical Informatics Association : JAMIA. 2014;21(4):578-82.