Dual Coordination Centers in ALL ALS Consortium: Not Too Many Cooks in the Kitchen

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BACKGROUND

- The Access for All in ALS (ALL ALS Consortium) was funded by the National Institutes of Health (NIH) as an Other Transaction Agreement (OTA) led by two Clinical Coordination Centers (CCC):
  - The Neurological Clinical Research Institute (NCRI) at Massachusetts General Brigham (MGB)
  - Barrow Neurological Institute (BNI)

- Each CCC received separate funding awards for the ALL ALS Consortium and were tasked with coordinating and collaborating to achieve the primary project goal: to establish a consortium, lead natural history studies, and establish a repository of clinical data and corresponding bio-samples to support open ALS research.

AIMS & OBJECTIVES

- Utilize resources from both CCCs to maximize efficiency in the following shared responsibilities;
  - Budgeting and Contracting
  - Clinical study site start up and activation
  - Clinical site management
  - Participant enrollment and retention
  - Outreach and Community Engagement

METHODS

- The consortium is overseen and guided by Accelerating Medicines Partnerships for ALS (AMP ALS) and the NIH

- Two CCCs use shared resources to manage sites, data, and samples

- Data and samples sent to NIH repositories for open-source sharing with research community

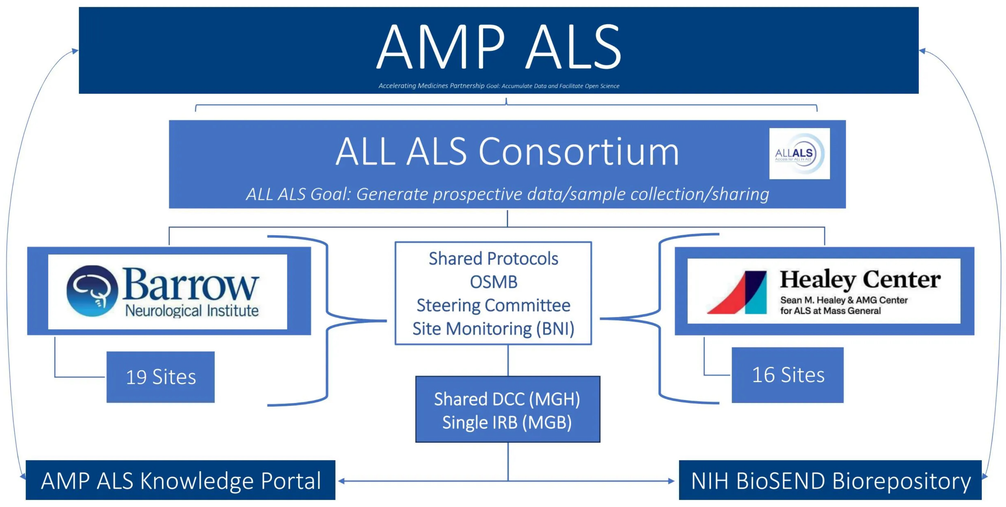

Figure 1: ALL ALS Consortium Organization

Figure 2: ALL ALS Consortium CCCs

- 36 Clinical Research Sites selected to participate in Consortium
  - Sites split between WCCC and ECCC to share oversight and management responsibilities

- MGB IRB used as single IRB (sIRB) serves all sites
  - All sites signed Reliance Agreement for MGB sIRB to serve as IRB of record

- Shared resources to reduce burden and maximize resources
  - Vendor contracting based on institutional history and IDC
  - Data Coordination Center (DCC) hosts and manages study data
  - Shared monitoring for all CCCs
  - Shared tools for Project Management
  - Shared framework for Policies and Procedures

OUTCOMES

- Within the first year, the CCCs developed and launched two separate study protocols (ASSESS and PREVENT)

- Within 24 months of initiation, the CCC's activated a total of 32 sites and enrolled more than 900 participants into the consortium

- By leveraging existing contracting services, agreement execution time for site and vendor contracts was minimized, resulting in quicker implementation.

- ALL NIH Milestones met at the time of this abstract

DISCUSSION

- The dual-CCC model has enabled the teams to explore innovative ways to utilize shared resources to strategize and streamline clinical operations for successful study start-up and management of the ALL ALS Consortium
- Leveraging already existing infrastructure and developing an open culture between two different organizations had an impact on successful implementation of the consortium
- Aligning two different organizations' unique institutional requirements and workflows presented some challenges

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