



Eastern Maine Medical Center Clinical Research Center

Creating a Research Consortium between Northern Light Health and Massachusetts General Hospital's Alzheimer's Disease Research Programs.

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Background

- Nationally, Maine is underrepresented in aging research and has been recognized as one of the Institutional Development Awards (IDeA) eligible states by NIH.
- Northern Light's Alzheimer's disease research program has had great success in growing Maine's largest clinical trials program for Alzheimer's disease and related disorders (ADRD).
- We sought partners from other higher profile institutions to help us diversify and expand our research into investigator-initiated studies.
- Fortuitously, the Alzheimer's Clinical and Translational Research Unit at Mass General Hospital (MGH) asked if we'd be interested in partnering with them to help recruitment into an innovative trial, they were starting with donor funding.
- Recruitment into research trials can be challenging in rural states like Maine and the ACTRU recognized our strength in recruitment

Objectives and Methods

- The aim for the current study was to demonstrate the ability to form an effective collaboration across institutions.
- A secondary aim was to demonstrate successful recruitment of underrepresented, underserved patients into an investigator-initiated pilot study led by principal investigators (PI) from Massachusetts General Hospital (MGH) and local site PI from Northern Light Health (NLH) clinical research center.
- About 10 virtual stakeholder sessions were arranged over a year to facilitate the study start up and development of best practices for offering recruitment as a service for investigator-initiated trials.
- Topics covered during the stakeholder planning sessions included: protocol reviews, assessing local site feasibility, submitting local context review for institutional IRB, facilitating study specific data use and sub award agreements.
- Additional training sessions were organized by the principal site research team, to facilitate the screening process and train Northern Light research staff on study protocols including remote cognitive assessment over Zoom.

Results

- The NLH team met the enrollment goal of 10 subjects within two months.
- Innovative component: Administering online/zoom version of the cognitive screen.
- The two teams continue biweekly conference calls over Zoom between Boston and Bangor and study monitor visits every 3 months by the coordinating team at MGH.

The following were important factors in study initiation and achieving recruitment goals

- 1) Close institutional ties due to clinical affiliations
- 2) alignment of research interests among the principal investigators
- 3) highly skilled and experienced research teams
- 4) standardized processes for initiating legal and IRB reviews and engaged aging study populations.

Results

Table 1: This effort led to the co-development and sharing of the following products

Resource	Purpose
Trainings <ul style="list-style-type: none">• Protocol specific• Coordinator specific• Rater specific	To facilitate shared understanding and implementation of the research protocol.
Regulatory files <ul style="list-style-type: none">• Informed consents• Local context IRB review• Adverse event reporting system• Data monitoring tools	To facilitate IRB review and approval processes
File and data sharing system <ul style="list-style-type: none">• Adopted Dropbox for study documents• REDCap for data collection and management	To facilitate document sharing and data sharing between the institutions
Contract and budget <ul style="list-style-type: none">• Site specific legal and financial agreements	To facilitate the legal contracting and study specific agreements

Discussion

- Rural elderly patients are often underrepresented in investigator-initiated trials. Covid 19 pandemic further exacerbated rural populations' recruitment related barriers.
- This study intends to share the experience of startup and recruitment as a model for NLH investigators working with investigators at large academic centers.
- The subsequent goal is to develop a strategic approach and framework for clinician scientists to engage in multi-site investigator-initiated research at other sites in Maine and northern New England.

References

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