Category: Community Outreach and Engagement, and Community Representation and Inclusion – Idea

Inclusion by Design: Protocol Development Strategies for Inclusion of Non-English-Speaking Participants in Investigator-Initiated Trials

M. Esplin, C. Moynier

Huntsman Cancer Institute at the University of Utah

1. Background

Recruitment and enrollment of a diverse study population, especially non-English-speaking participants, has been an ongoing challenge in clinical research. In addition to significantly limiting investigational treatment options in diverse populations, lack of diversity has negatively impacted the generalizability of results, as the sample populations often do not reflect the general demographics of the United States. Common hurdles in enrolling these participants include structural communication barriers, particularly the availability of translated documents (including short- and long-form Informed Consent Forms and validated study questionnaires), the cost of translation services, and limited availability of interpreters. If these barriers are not carefully considered and mitigated during the development of an Investigator-Initiated Trial (IIT), protocol design elements may inadvertently and unnecessarily exclude non-English-speaking participants.

2. Goals

To provide a streamlined workflow for increasing inclusion of non-English-speaking participants in IITs, starting with inclusion-centered protocol development.

3. Solutions and Methods

Protocol design emphasizing accessibility for non-English-speaking participants, including the following practices:

- Initial budgeting automatically includes funds for translation services. Additional institutional funds are set aside for mileage and hotel accommodation for patients traveling from far distances
- Preferential utilization of validated questionnaires that have pre-existing validated translations available
- Use of translators for the completion of unvalidated questionnaires and study documents
- Automatic inclusion of non-English-speaking participants unless it's been determined that inclusion is not feasible
- Inclusion of decentralized elements, including remote interpretation services, in the protocol to minimize participant burden
- Development of protocol-specific workflows to proactively address the unique logistical challenges of enrollment and retention of non-English-speaking participants
- Local Institutional Review Board (IRB) requirements for Spanish-speaking participants to be included in all prospective studies (unless determined to not be feasible)
- Site Initiation Visit (SIV) training including a section regarding whether inclusion of non-English-speaking participant is allowed and outlines initial steps for the Clinical Research Coordinator (CRC) when potential non-English-speaking participant is identified

- Required notification of planned consent of a non-English-speaking participant and close collaboration between the clinical research coordinator, protocol writer, and regulatory team to develop a participant-specific enrollment plan

4. Outcomes

Increasing our focus on inclusion of non-English-speaking patients from the initiation of protocol development has helped establish a functional framework for inclusion of these participants. We will continue to assess and refine our processes with involvement from our institutional research participant advocacy group.

5. Lessons Learned and Future Directions

Although using this plan has helped streamline enrollment of non-English-speaking participants, creating a participant-specific logistical plan still requires a significant amount of time and effort, resulting in delays in consent and enrollment. This is especially true if the participant speaks a logographic language or one that is uncommon in the catchment area, or if the study uses questionnaires with user or license agreements. Additional process improvements and resources will be needed to address these logistical barriers.