

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

Michelle Esplin¹; Colin Moynier¹

¹Huntsman Cancer Institute at the University of Utah

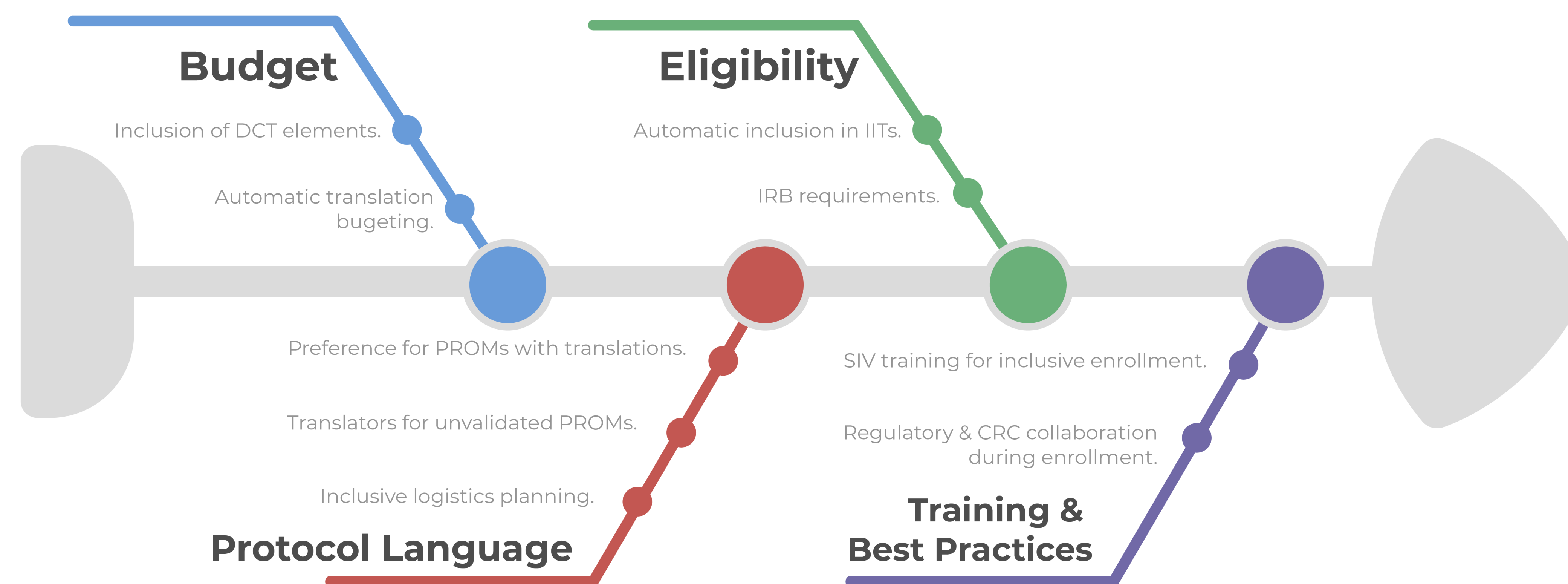
BACKGROUND

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 including cost and availability of translated documents, the cost of translation services, and limited availability of interpreters.

GOALS

To provide a streamlined workflow for increasing inclusion of non-English-speaking participants in Investigator-Initiated Trials (IIT), starting with inclusion-centered protocol development.

METHODS



OUTCOMES

A functional framework for inclusion of these participants has been established. We will continue to assess and refine our processes with involvement from our institutional research participant advocacy group.

LESSONS LEARNED AND FUTURE DIRECTION

Participant-specific logistical plans, while streamlined, still require significant effort and can result in delays, especially true if the participant speaks an uncommon or logographic language, or questionnaires have license agreements. Additional process improvements and resources will be needed to address these logistical barriers.