



ASH DEI TOOLKIT FOR CLINICAL TRIAL SPONSORS

*Incorporating DEI Principles Throughout
the Clinical Trial Life Cycle*

This guide is designed to help trial sponsors incorporate DEI principles throughout the trial life cycle. It includes actionable recommendations, reference articles, and additional resources from both national and international regulatory bodies and research organizations.



ACTIONABLE STEPS TO INCORPORATE DEI IN THE CLINICAL TRIAL PROCESS





FORMULATING YOUR RESEARCH QUESTION

- Understand the patient population/epidemiology of the disease and set goals that capture disease epidemiology.
- Based on the disease epidemiology and demographics of the site catchment area, select clinical trial sites (and site leads) with the goal of achieving a representative patient population.
- Review [existing resources](#) aimed at improving enrollment of underrepresented participants (e.g., [FDA diversity plan](#), [ICH guidelines](#), [MRCT diversity clinical research tool kit](#), [Just Ask](#), [NIH All of Us Research Program](#), etc.).
- Engage with relevant patient advocacy groups and lived experience experts (LEEs)* early and often as:
 - You craft your research question.
 - Outline your diversity goals; and
 - Strive to build trust with the patient community participating in the study.
- Seek meaningful contribution from health care providers (HCPs) on study concept/design.

**Lived Experience Experts (LEEs) are individuals, their caregivers, and family members directly impacted by hematologic diseases. Their diverse and personal knowledge gives them the unique ability to translate lived experiences into meaningful system change. Collaborating with patient advocacy groups may be a good source for identifying appropriate LEEs.*

TRIAL DESIGN

- Carefully consider and assess [your inclusion and exclusion criteria](#).
 - Examine how each criterion impacts the target patient population's ability to participate. For example, in eligibility criteria, avoid unnecessarily strict organ function, or eligibility tests. For exclusion criteria, avoid nonspecific and potentially biased terms such as "unacceptable" or "uncontrolled" where more specific definitions can be used.
 - Government agencies like the FDA, NIH, Health Canada, MHRA, and EMA are supportive of broadening inclusion criteria, so develop a protocol that represents patients in the real world.
- Solicit the guidance of a statistician to help select an appropriate and diverse sample size.
- Consider opportunities for de-centralizing the trial with study activities closer to home (e.g., mobile nursing or phlebotomy for safety monitoring).
- Consult with LEEs to understand how much effort may be required for the enrollment objectives.



TRIAL DESIGN (continued)

- Leverage the expertise of LEEs, patient advocacy groups, and/or community advisory boards (CABs) to review your protocol, collect patient-centric feedback, and work collaboratively to:
 - Create a plain language version of the protocol. It should describe the purpose of the study, key inclusion and exclusion criteria, major efficacy outcomes, potential adverse events, and why the study will benefit the patient population. Translate into different languages as appropriate.
 - Generate culturally and linguistically appropriate educational resources for HCPs and patients to build an understanding of the trial design e.g., a 1-page information guide that complements a more in-depth informed consent form (ICF).
- Incorporate strategies to engage HCPs or community physicians who will likely be offering your trial to their patients. In doing so, consider:
 - Return of the patient to the HCP after the trial is complete.
 - Communication of trial results with the HCP during and at the end of the trial.
 - Acknowledgement of the HCPs participation in the study.
- Clearly articulate diversity recruitment goals to the trial site(s).
- Design consent forms that are easy to read and, translated into different languages especially for trial sites with large populations of non-English speaking patients.
- Eliminate unnecessary study visits in the trial design (e.g., excessive PK/PD visits).
- Ensure that patients understand they can stop participating at any time without risk or repercussions.

TRIAL BUDGET

- Include funding for patient assistance in your budget for community engagement efforts, appropriate participant compensation (e.g., travel, housing or childcare assistance, or a discretionary debit card for trial related activities like gas, food, etc.), and unique geographic or societal challenges to address barriers for trial participants.
- Consider adding LEEs as key personnel in your research grant and compensate them for their time.

THE CLINICAL TRIAL PROCESS



ETHICS & OTHER REVIEWS

- Develop a protocol that ensures the institutional review board (IRB) or research ethics committee (REC) is reviewing the trial not just for safety and ethics principles, but also for justice principles. The latter takes into consideration fairness in distribution of benefits realized from the research study as well as its burdens.
- Include information on how the drug, device, or other therapy being studied could work in different subgroups and any prior data on heterogeneity of treatment effect. This will further justify your rationale for the selected inclusion and exclusion criteria and will facilitate the review of your protocol.
- Initiate early and regular conversations with regulators to establish changes to the protocol, including eligibility criteria, that will broaden enrollment. See the [FDA Support for Clinical Trials Advancing Rare Disease Therapeutics \(START\) Pilot Program](#) for more information.

STUDY CONDUCT & DATA COLLECTION

- Leverage telemedicine and other decentralized approaches for data collection to meet patients where they are.
- Engage a diverse workforce (including trial leaders) for the execution of the trial and ensure cultural competency and inclusive clinical research training for all research staff.
- Discuss with the trial site(s) the importance of representative enrollment and make sure the site(s) are aware of your diversity goals as the sponsor.
- Recruit participants/sites from regions that are historically under-represented in trials.
- Engage patient advocacy groups and HCPs in the recruitment of patients. Enable availability of trial participation in community practices that resemble the desired trial population.
- Use social media to promote awareness, education, and to build trust with patients, caregivers, and advocates.
- Ensure a robust informed consent discussion and process, and allow time for patients, caregivers, and allies to ask questions. Avoid same day consent if possible (especially if the provider hasn't established a relationship and/or trust with the patient).
- Use clear language and definitions around what compensation is available. Intentionally and proactively discuss opportunities for compensation and respect the time and effort the patients are committing.



DATA ANALYSIS AND RESULTS REPORTING

Both to the Scientific & Patient Communities

- Disseminate the results to patients in language that they can read and understand (e.g., plain language/multilingual summaries, photovoices). Use relevant patient-centric organizations, and/or cultural and linguistic community experts.
- Leverage any existing patient-facing technology used during the trial to deliver key findings to participants.
- Ensure standardization of diversity data reporting for studies, such as required by [clinicaltrials.gov](https://www.fda.gov/oc/ohrt).
- Collaborate with experienced/expert patient groups to develop patient friendly graphics and social media posts that can help translate the results of the study for the patient population in an engaging way.
- Seek post-study feedback and overall takeaways/impressions from the study population and their supporting communities. This will help guide future and follow up studies relating to the same topic.
- Recognize HCPs who participated in the study through acknowledgement (with permission) in publications and seek their input on the interpretation of findings, review, and revisions of manuscripts thereby giving them an opportunity to meet [ICMJE criteria](#) for authorship.
- Acknowledge the contributions patients, their families, and supporting communities.

RELEVANT DEI RESOURCES

RELEVANT DEI IN CLINICAL TRIALS RESOURCES

[FDA Guidance: Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials; Draft Guidance for Industry; Availability](#)

Provides recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan (referred to as the “Plan”) to enroll adequate numbers of participants in clinical trials from underrepresented racial and ethnic populations in the United States.

[FDA Guidance: Enhancing the Diversity of Clinical Trial Populations-Eligibility Criteria, Enrollment Practices, and Trials Designs, DRAFT Guidance for Industry](#)

Recommends approaches that sponsors of clinical trials intended to support a new drug application or a biologics license application can take to increase enrollment of underrepresented populations in their clinical trials.

[FDA Guidance: Collection of Race and Ethnicity Data in Clinical Trials, Guidance for Industry and Food and Drug Administration Staff](#)

Lays out FDA expectations for and recommendations on the use of a standardized approach for collecting and reporting race and ethnicity data in submissions for clinical trials for FDA regulated medical products conducted in the United States and abroad.

[FDA Guidance: Evaluation and Reporting of Age, Race and Ethnicity-Specific Data in Medical Device Clinical Studies, Guidance for Industry and Food and Drug Administration Staff](#)

Provides guidance to improve the quality, consistency, and transparency of data regarding the performance of medical devices within specific age, racial, and ethnic groups.

[FDA Webinars and Presentations on Health Equity and Diversity in Clinical Trials](#)

A series of FDA webinars and presentations on health equity and enhancing DEI in clinical trials.

[FDA Support for Clinical Trials Advancing Rare Disease Therapeutics Pilot Program](#)

Announces the opportunity for a limited number of sponsors to participate in a pilot program allowing for more frequent communication with FDA staff to provide a mechanism for addressing clinical development issues.

[FDA Project Equity](#)

Provides information about a program to ensure that the data submitted to the FDA for approval of oncology medical products adequately reflects the demographic representation of patients for whom the medical products are intended.

RELEVANT DEI RESOURCES

[NASEM Report to Congress: Improving Representation in Clinical Trials and Research](#)

Models the potential economic benefits of full inclusion of men, women, and racial and ethnic groups in clinical research and highlights new programs and interventions in medical centers and other clinical settings designed to increase participation.

[NIH All of Us Research Program](#)

Provides a database - All of Us - that can inform thousands of studies. It creates opportunities to: a) know the risk factors for certain diseases; b) figure out which treatments work best for people of different backgrounds; c) connect people with the right clinical studies for their needs; d) learn how technologies can help us take steps to be healthier.

[National Institute of Minority Health & Disparities \(NIMHD\)– Diversity In Clinical Trials](#)

Outlines the institute’s strategic goals with a focus on diversity in clinical trials

[NHLBI Innovative Clinical Trials Resource](#)

Provides infrastructure and expertise to support awardees of the NHLBI “Catalyzing Innovation in Late Phase Clinical Trial Design and Statistical Analysis Plans Initiative” (U34/X01).

[MRCT Guidance Document on Achieving Diversity, Inclusion, and Equity in Clinical Research](#)

Aims to clarify the importance of, advance the goals of, and provide practical and actionable ways to improve diverse representation of participants in clinical research.

[Just Ask – Equity and Diversity in Clinical Research](#)

Provides support to research teams and clinical staff to improve minority enrollment in research.

[PCORI: Guide for Researchers: How to Assist Community Partners to Use Digital Technology](#)

Provides guidance for research teams wanting to engage community members and patients who are not familiar with digital technology.

[ICH - Guideline on General Considerations for Clinical Trials](#)

Includes guidance that is both appropriate and flexible enough to address the increasing diversity of clinical trial designs and data sources being employed to support regulatory and other health policy decisions, while retaining the underlying principles of human subject protection and data quality.

[ICMJE – Authorship Guidelines](#)

The International Committee of Medical Journal Editors (ICMJE) recommendations are a set of guidelines produced by the International Committee of Medical Journal Editors for standardizing the ethics, preparation and formatting of manuscripts submitted to biomedical journals for publication. Authorship Guidelines outline specific criteria to be met to qualify for authorship of a medical journal manuscript.

ACKNOWLEDGEMENTS

The ASH DEI Toolkit for Clinical Trials was developed by participants in the Society's Roadmap to Improve DEI in Hematology Clinical Trials with extensive input from ASH's Subcommittee on Clinical Trials and Health Equity Task Force. ASH thanks all members who contributed to this effort.

QUESTIONS?

For more information about the ASH DEI Toolkit for Clinical Trials, contact the ASH Deputy Director, Scientific Affairs, Alice Kuaban, MS, at akuaban@hematology.org

