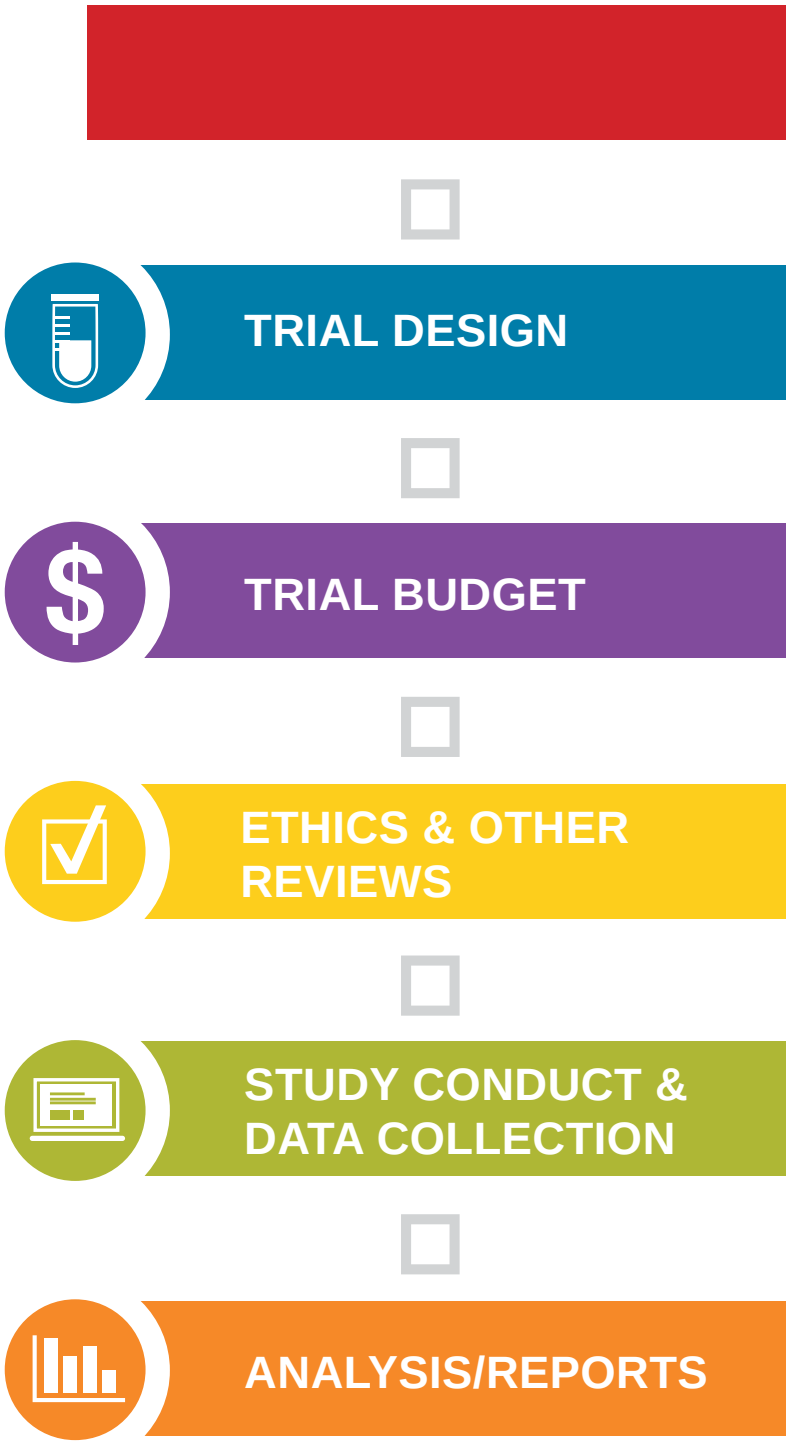
ASH DEI TOOLKIT FOR CLINICAL TRIAL SPONSORS

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



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 H[FOXVLRQ FULWHULD DYRLG QRQVSHFL¿F DQG SRWHQWLDOO DV ³XQDFFHSWDEOH´ RU ³XQFRQWUROOHG´ ZKHUH PRUH VSHFL
  - 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.

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. 7 K H O D W W H U W D N H V L Q W R F R Q V L G H U D W L R Q I D L U Q H V V L Q G L V W U 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 _____ _____

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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

NASEM Report to Congress: Improving Representation in Clinical Trials and Research

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, 6FLHQWL¿F $IIDLUV $OLFH .XDEDQ 06 DW akuaban@hematology.org