DIGITAL HEALTH TRIALS

Clearing a Path for Broad Implementation of DCTs

Continued multi-stakeholder collaboration will be required to fully realize the benefits, and address any challenges, of Decentralized Clinical Trials (DCTs). This document outlines the steps needed to clear a path forward.

- **Harmonize laws and regulations at all levels**—including state- and country-specific laws regulating factors such as telemedicine and medical licensing, informed consent, privacy, and electronic signatures.

- **Help all stakeholders embrace change**—including for example:
  - Emphasizing the improvements that DCTs make possible (e.g., less burden for participants and caregivers, faster enrollment, greater access and diversity), building understanding of how trials are different when DCT elements are incorporated, and working towards a future in which regularly incorporating these elements in trial design is the norm.
  - Encouraging an approach to study design and execution that emphasizes scenario planning and operational flexibility and allows enough time for proactive, effective engagement with the broad range of stakeholders.
  - Developing in-depth trainings for current clinical research professionals, as well as working to understand and address workforce preparedness needs for the future.
  - Identifying incentives for all stakeholders that could drive broader implementation of DCT elements and reduce barriers.

- **Facilitate detailed, nuts-and-bolts knowledge sharing**—through activities such as:
  - Collecting and disseminating case studies that highlight emerging best practices as well as challenges and successful solutions. Topics for case studies include the following:
    - The impact of participant optionality (e.g., offering a choice of remote or in-person assessments) and other visit/assessment variations (e.g., at the country level to accommodate different laws and regulations) on data quality and acceptable approaches to controlling for data heterogeneity, accuracy (bias), error, and missing data.

- Acceptable monitoring options—including best practices for leveraging central statistical monitoring and quality tolerance limits in DCTs, recognizing that standards for safety and efficacy should be neither more nor less stringent than current clinical trials.
- The impact of home visits and assessments on participant and caregiver burden, the willingness of different patient populations to participate, and the associated needs and opportunities for mitigating increased non-compliance and dropout risk.
- How the flow of data can be designed to ensure that all sponsor and operational partner roles can conduct appropriate data queries, how Protected Health Information can be safeguarded when multiple parties may be accessing the same platform, and how data can be delivered to regulators in an acceptable, consolidated format.

- Creating example or concept protocols and informed consent materials that have been developed with input from, and satisfy the needs of, all stakeholders.
- Hosting ongoing, multi-stakeholder forums that facilitate open dialog and the sharing and documenting of experiences related to DCT elements—with the ultimate goal of supporting a cycle of continuous improvement in DCT design and execution.

- **Collect data to inform decision-making**—including the following:
  - Collecting and analyzing data comparing DCTs to traditional trials, particularly addressing issues of missing data, safety surveillance, and patient recruitment and retention.
  - Systematically evaluating, and regularly updating, data on patient preferences with respect to DCT features, as well as how these preferences may vary (e.g., based on participants' disease/condition, location, sociodemographic factors).
  - Holistically evaluating the costs (e.g., impact on total study budget) and financial 'return on investment' (e.g., the expected net present value of any reductions in time to enroll or dropout rates) of implementing DCT elements.
  - Evaluating non-financial forms of value provided by DCT elements, such as reduced patient burden and increased participant diversity.

- Assessing the ability of remote (non-site based) data collection to support greater research insights while maintaining data integrity, security, and privacy

- **Work to understand the opportunities and address the challenges that DCTs present for enhancing participant diversity and access**—including better use of home health services; integrating community health centers and other providers (e.g., pharmacists) into the research process; and more generally driving towards the integration of clinical research and clinical care in medical practices and institutions both large and small.

- **Shift away from the use of study-specific technologies and tools**—define quality and interoperability standards that allow sites the flexibility to invest in technologies and tools that best fit their needs and workflows while still ensuring that sponsor oversight requirements are met.

- **Collaboratively invest in novel endpoints and approaches for remote data capture that can support decentralization**; and utilize this opportunity to strive for trials that are more efficient, better meet the needs of clinical trial participants, and support researchers in obtaining better, more reliable information.