Tech-Driven Trials: Revolutionizing Patient-Centric Design

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Abstract

Clinical trials are essential for advancing medical knowledge, developing new therapies, and enhancing healthcare outcomes. Despite this importance, a persistent challenge in trials is the significant underrepresentation of diverse populations[1]. This disparity hinders the development of universally effective treatments and leads to a lack of data on how new medical interventions perform across different demographic groups, potentially resulting in less effective treatments for marginalized populations[2].

Overview

The Association of Diversity in Clinical Trials (AOD) is an industry association that is dedicated to improving representation by developing and implementing comprehensive methodologies and policies that ensure historically underrepresented communities are meaningfully included in research. By fostering diversity in clinical studies, AOD empowers organizations to conduct equitable research, enhancing health outcomes and ensuring all populations benefit from scientific advancements. Through its working group platform, the AOD offers critical expertise and leadership.

At the core of this strategic endeavor is the Technology Enablement of Diverse Clinical Trials Working Group, a coalition of stakeholders from across the clinical trial spectrum, including sponsors, sites, diversity experts, technologists, medical professionals, and patient advocates. Led by CRIO, this working group convened with several organizations in the clinical trials sector, including uMotif, Alcanza, Accelerated Cure Project, and Worldwide Clinical Trials, ensuring a well-rounded perspective on the industry's needs and challenges.

CRIO is a leader in eSource technology, providing an enterprise grade eClinical solution that transforms clinical research whose mission is to design and deliver a modern, intuitive, and integrated software platform that reimagines clinical trials for quality, speed, and patient-centricity. CRIO recognizes the power of well-designed technology to drive diversity in

clinical research by expanding research opportunities to historically underrepresented communities.

The group's mission is to identify how technology can overcome barriers to diverse participation in clinical trials and to develop standards and best practices across the industry. This vision is operationalized through specific objectives, including identifying barriers that technology can impact, recommending technology standards and processes to promote diverse clinical trials, and developing public policy recommendations. The collaborative project not only meets high inclusivity standards but also incorporates innovative practices, setting new benchmarks for the field. The Technology Enablement of Diverse Clinical Trials Working Group aims to embed diversity considerations into each phase and component of technology development and implementation.

1. Introduction

Technology has emerged as a transformative force in numerous fields, and its potential impact on clinical trials is immense. Digital recruitment platforms, electronic health records, site-facing applications, mobile health applications, and remote monitoring present unprecedented opportunities for increasing diverse participation. The effective use of these tools, however, is contingent upon a well-conceived strategic framework that considers the intricacies of these populations and the interactions with technology. The framework discussed throughout this paper includes: digital recruitment platforms, direct interaction through fostering relationships and trust, mobile health applications, and shared dashboards. It is within this framework that this white paper is positioned to explore the ways in which technology can serve as a bridge to diversity in clinical trials.

For patients, technology can reduce geographical barriers, enabling sponsors and sites to recruit from broader areas, thus enhancing trial diversity. Patients gain more opportunities to learn about and participate in clinical trials, and technology can supplement or replace in-person

visits, allow investigational products to be shipped directly to them, and support hybrid remote approaches where feasible.

For Sites, technology can help minimize non-essential site visits to their clinics, allow for flexible scheduling, and automate workflows to manage their operations. Notwithstanding turnover and labor shortages, technology can become a critical backbone for ensuring the site study team members can focus on what's important - working with patients and ensuring proper levels of care are provided.

For Sponsors, technology enables a wider scale for clinical programs by enhancing their geographical reach, streamlining and accelerating their workflows, and leveraging prescriptive and predictive analytics to ensure high visibility across enrollment, patient safety, compliance, and overall health of the study.

2. Setting the Stage: Sponsor's Strategy and Goals

In alignment with FDA guidance, Sponsors are urged to define their diversity strategy and goals at the outset of a clinical trial design. This strategic approach is essential for ensuring that clinical trials reflect the diverse populations affected by the conditions being studied.This includes setting clear, measurable goals for recruiting participants from diverse backgrounds and developing targeted outreach programs to achieve these goals.

The FDA has emphasized the importance of diversity in clinical trials through various guidances, notably the FDA Reauthorization Act of 2017 (FDARA) and the subsequent FDORA (Food and Drug Omnibus Reform Act) of 2022. FDORA mandates that Sponsors submit a diversity action plan with each clinical trial application, detailing strategies to enroll participants from diverse populations. This includes considerations of race, ethnicity, age, sex, and other demographic factors. Sponsors must outline how they will recruit and retain diverse participants, describe potential barriers, and propose solutions.

Identifying and engaging key stakeholders is crucial for successful implementation of diversity strategies. This includes patients, sites, and the broader community. By mapping out

patient experiences at each trial phase, sponsors can tailor their strategies to address logistical, cultural, and socioeconomic barriers, meeting the needs and preferences of diverse populations. Clinical trial sites must be selected and equipped to support diverse participant recruitment, which includes choosing locations that serve diverse populations and training staff on cultural competency. Engaging with the broader community, including patient advocacy groups, local healthcare providers, and community leaders, can enhance outreach efforts and build trust within diverse communities.

Clinical trial design that integrates the complexities of the patient experience and patient expectations must occur at the initial contact through to trial completion. This holistic approach helps in aligning technology selection and process development with diversity objectives. Choosing accessible and user-friendly technologies, such as mobile health apps and telemedicine, can enhance participation by accommodating varying levels of tech-savviness. Developing patient-centric processes, like flexible visit schedules, transportation support, and culturally appropriate communication materials, can address barriers to participation.

In summary, a well-defined diversity strategy aligned with FDA guidance, coupled with a thorough consideration of the patient experience, is essential for designing inclusive clinical trials. By engaging stakeholders at every level, sponsors can ensure that their trials are representative of the populations they aim to serve, ultimately leading to more effective and equitable healthcare solutions.

3. Methodology

The Working Group used a top-down methodology featuring three-scenario stress-test exercises. These exercises aim to evaluate the effectiveness of technological solutions under various conditions and patient demographics to ensure they are resilient and adaptable.

Several virtual meetings occurred before the in-person Technology Enablement of Diverse Clinical Trials working group meeting to develop and hone recommendations. This collaborative effort involved an expert panel comprising diverse perspectives and specialties

from the aforementioned organizations. Through these sessions, a refined set of principles to guide the selection and implementation of technologies in clinical trials was established.

These principles were informed by a comprehensive review of the literature, the participants' own extensive experience working in and with clinical trials, and the development and application of hypothesized principles against several realistic case studies.

4. The Framework

To further the study's diversity objectives, the technology should be assessed along ten key dimensions. When making the assessment, the project buyer should be doing so from the perspective of the *target end users* - the specific individuals who will be interacting with the technology. The ten key dimensions are:

1. Easy installation and usability
2. User accessibility and configurability
3. Interoperability with existing systems
4. Reusability and value add
5. Self-service capabilities
6. Simplified workflows
7. Tool for collaboration and engagement
8. Ready availability of support
9. Trustworthiness
10. Rich information capture.

Identifying the correct target is critical. For most clinical trials, the users will be the site and/or the patient. Within the site side, however, there could be several different roles, each with their own perspective, skills and requirements - for instance, the Principal Investigator; clinical research coordinator; clinical rater; lab technician; traveling nurse; or patient navigator. On the patient side, the personas will be the patients who fulfill the eligibility criteria of the protocol - i.e., patients with a specific set of medical conditions and history - as well as each of the intersecting

dimensions of diversity the sponsor is seeking (be it race, ethnicity, gender, geography, socioeconomic status). Also, there may be additional roles to consider who will interact with the technology, such as parents, guardians or caregivers. With the target persona(s) in mind, the project buyer should assess the technology along each of these dimensions:

Easy Installation and Usability: The technology should be quick to install and easy to use, whether it's web-based software or hardware. For software, it should load quickly and have an intuitive interface with minimal clutter, resembling popular consumer apps. For hardware, it should require minimal assembly, include fresh batteries if needed, and be portable and discreet, with clear instructions for any required setup.

User Accessibility and Configurability: The technology should be accessible and configurable to meet diverse user needs, including those who are hearing impaired or speak different languages. Configurability should allow users to set and retain preferences for language, timezone, notifications, and other settings, enhancing the user experience and ensuring inclusivity.

Interoperability with Existing Systems: The technology should work seamlessly with other systems used by both patients and research sites. This includes integrating with personal calendars, payment systems like PayPal or Venmo, and allowing login with common accounts like Google or Facebook. For research sites, it should have an API to integrate with electronic health records and other industry-specific systems.

Reusability and Value Add: The technology should provide value beyond the study. For patients, it could offer clinical feedback or deliver study results post-trial. For researchers, it should allow multi-study use from one login and could add value by providing site performance benchmarks or downloadable patient data for future recruiting efforts.

Self-Service Capabilities: The technology should empower users to perform all necessary actions independently, without relying on customer support. It should accommodate different languages and reading levels and provide a user-friendly interface that does not require technical skills, with exceptions only for policy-based restrictions.

Simplified Workflows: Technology should simplify workflows by minimizing clicks and avoiding redundant data entry. It should present users with only the necessary screens at the right time, reducing the risk of errors and ensuring efficient processes.

Tool for Collaboration and Engagement: The technology should facilitate human interaction and collaboration among patients, site staff, and caregivers. It should enable direct communication, support ecosystem interactions, and ensure urgent safety reviews are promptly addressed.

Ready Availability of Support: Despite intuitive design, users may encounter issues requiring support. The technology should offer readily available customer support within the app, such as intelligent help searches, chatbots, or live chat. Hardware should include easy access to support, like a phone number or barcode for callbacks.

Trustworthiness: Given the sensitive nature of clinical trials, the technology must inspire trust. This involves thorough vendor due diligence, ensuring security and privacy standards, and presenting a professional image with accredited credentials and a transparent privacy policy.

Rich Information Capture: Sponsors need full transparency into patient engagement and diversity throughout the trial. The technology should capture detailed information on patient interactions from initial contact to trial completion, helping sponsors identify drop-off points and opportunities to improve representation in future trials.

5. Case studies

The following three case studies represent hypothetical clinical trials, and the types of technology that would be used. The AoD working group used these and other case studies to apply the framework against the target technologies.

Scenario #1: Alzheimer's prevention trial - Digital End to End Recruiting

Indication: Prevention of Alzheimer's

Goal: 2000 participants in the United States

Population: Aged 50 and older

Generally healthy, do not have Alzheimer's

Possess a specific biomarker predictive of the disease

Protocol: A central recruiting firm will perform digital marketing and telephone screenings, then refer patients to a local laboratory for a blood test. If the biomarker is confirmed, the patient will be directed to a designated nearby research facility to participate in a four-year observational study to monitor Alzheimer's onset involving regular exams, blood tests, medical evaluations, and rating scales.

Diversity: Historically, Alzheimer's trials have involved primarily white participants, despite black patients being twice as likely to be affected but 35% less likely to be diagnosed[1], with only 2% of trial participants being black[2]. To increase diversity, the sponsor is targeting African American and Latinx communities by selecting community practices in areas with many patients of color.

Technology: A central recruiting firm employs web-based advertising and phone screenings to educate and pre-screen prospective patients. The website provides a phone number for initial pre-screening, and if the individual qualifies, they receive a

[1]https://www.nia.nih.gov/news/data-shows-racial-disparities-alzheimers-disease-diagnosis-between-black-and-white-research
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10318422/

consent form to sign over the phone. Qualified individuals are referred to a local lab for a blood test and, if confirmed for the biomarker, are directed to the nearest research site, with the technology designed to enable diverse enrollment through targeted advertising for minority populations.

Applying the framework

Easy installation and usability: The recruitment website should be easy to read and navigate, with a clear call to action, such as a simple form or click-to-call link. Users should be able to dial directly from their phones by clicking the website link.

User accessibility and configurability:The technology platform should allow patients to choose their preferred communication methods, such as receiving notifications in English or Spanish via email or text. These preferences should be shared with the research site to ensure a consistent and respectful experience.

Interoperability with existing systems: The technology should seamlessly integrate with modern smartphones, providing features like text notifications with barcodes for lab visits and links to Google Maps. This minimizes the burden on patients and fits into their regular phone usage.

Reusability and value add: The technology should deliver blood sample results to patients with explanations and steps for health management, allowing patients to easily share results via a clickable link with their primary care providers, enhancing knowledge transfer and trust.

Self-service capabilities: Self-service capabilities should include Spanish-language consent and communication, independent self-screening, and access to real-time support. Patients should be able to self-screen to ensure honest responses and save time, with real-time support available for questions or in-person completion. These features enhance accessibility and efficiency for diverse populations.

Simplified workflows: The system should offer options like at-home visits from a traveling nurse

or easy walk-in lab visits with barcodes. It should allow for self-scheduling and appointment reminders, catering to busy patients' needs.

Tool for collaboration and engagement: The technology should facilitate communication among stakeholders, enabling video calls, one-click calling, and automated system follow-up to the patient. It should send necessary information between patients, labs, and research sites, and follow up with patients to ensure site contact.

Ready availability of support: The system should include readily available support, such as a phone number for live interaction and notifications. This ensures patients can get help throughout the process, improving their experience.

Trustworthiness: A recruitment tool built around these themes will naturally increase patient trust. Addressing language barriers, providing tools and support, and incorporating engaging content enhances the patient experience and connection to the research process.

Rich information capture: A well-developed recruitment platform captures comprehensive data on enrollment and diversity metrics throughout the process. It tracks demographics at each stage, from initial contact to trial completion, including self-screening, lab visits, and site participation. This data helps sponsors identify recruitment successes and challenges, especially regarding diverse populations. Sponsors can then adjust strategies to improve representation and overall trial effectiveness.

Scenario #2: eCOA/EDC (same study as above but different technology):

Technology: Sites will use electronic Clinical Outcome Assessment (eCOA) tablets for clinical scales and Electronic Data Capture (EDC) systems for data capture. eCOA is a digital tool that captures patient-reported, clinician-reported, and observer-reported outcomes using devices like tablets and smartphones. It ensures consistent data collection, improves accuracy, and enhances patient

engagement through an intuitive interface. These technologies, whether procured from a single vendor or separately, must be user-friendly to encourage new research sites and promote diversity in clinical trials.

Applying the framework

Easy installation and usability: The eCOA tablet should be pre-configured, easy to ship, and require minimal setup, with features like a beeping mechanism to locate misplaced tablets. The EDC system should be web-based, accessible via common browsers, and intuitive, with embedded training modules.

User accessibility and configurability: Systems should allow configuration settings for time zones and user notification preferences, such as when to receive alerts, and what type of alerts to receive. This ensures that the site's and individual users' preferences are respected and maintained.

Interoperability with existing systems: The eCOA and EDC systems should interoperate with common data elements like subject IDs or visit number. The EDC should integrate with site data collection systems and allow for seamless data transfers.

Reusability and value add: The eCOA tablet should be reusable across studies, with remote loading of new settings. The EDC should offer permanent log-ins, training certificates, and configurable dashboards for site personnel to manage multiple studies efficiently.

Self-service capabilities:Self-service features in eCOA and EDC technologies allow site staff to manage data collection and quality control processes. Site staff should be able to provision users, complete built-in training requirements, and complete data forms without needing specialized IT support.

Simplified workflows: Both systems should be designed to reflect the chronological data collection process and include branching logic to avoid redundant data entry. For example, if a subject is not a person of childbearing potential, they should not complete questions related to urine pregnancy tests. Instructions and alerts should be clear, intuitive, and free of jargon.

Tool for collaboration and engagement: The eCOA system is for single raters, while the EDC system facilitates data collection from multiple stakeholders and supports internal communication and query redirection among site staff and sponsors. An EDC system could facilitate workflow by allowing site staff to redirect queries to colleagues, such as from a site coordinator to a Principal Investigator, and enabling CRAs to "tag" medical monitors for input.

Ready availability of support: Support for eCOA and EDC technologies should be accessible within the application, with an in-app helpline connecting users to live support agents familiar with the study and system. This ensures efficient problem resolution and a better user experience.

Trustworthiness: Strong vendor reputations improve sponsor-site relationships, as trust is built over time through positive experiences. Sites prefer vendors with a history of being site-friendly.

Rich information capture: Sponsors should capture demographic data and reasons for screen failures and drop-outs to gain actionable insights into trial diversity and identify failure points related to diverse populations.

Scenario #3: Rare Disease Study with Open Label Extension – Concierge and ePRO data capture

Indication:	Adult Rare Disease, causing pain and discomfort
Goal:	500 participants in the United States
Population:	Adults aged 30 and older
	Suffering from rare disease which causes pain and discomfort
	Both urban and rural
Protocol:	The 12-month study for a new drug requires clinic visits, followed by a 3-year Open Label Extension that can be done at home. Patients must provide daily and

weekly symptom information, with only 20 centers of excellence having the appropriate investigator expertise across the USA, mostly at urban academic medical centers (AMCs).

Diversity: Urban AMCs have struggled to recruit diverse populations, especially from rural areas due to logistical challenges. The sponsor aims to increase rural participation by using new patient concierge services to reduce participant burden and expand the AMC's existing patient pool.

Technology: The sponsor will offer full-service travel and stipends through a patient concierge service, combining human and technology support for travel arrangements. An electronic Patient Reported Outcome (ePRO) solution will capture daily and weekly symptom data between visits

Applying the framework

Easy installation and usability: The patient concierge service should be easy to use and accessible via multiple channels (e.g., human assist via phone, AI-enabled chat, self-service), integrating with common apps like Lyft and Uber. The ePRO platform should support Bring-Your-Own Device (BYOD), offer simple registration, and provide tutorials and reminders for an intuitive user experience that is on par with applications that the patient may use in their daily life.

User accessibility and configurability: The concierge and ePRO services should support multiple languages and be available beyond traditional business hours across various time zones. ePRO should offer text enlargement, screen contrast options, and timezone-based reminders for accessibility.

Interoperability with existing systems: The patient concierge should integrate with services like Uber and Lyft, while ePRO should work with concierge and reimbursement services for seamless patient experiences. Workflow integration with other patient-facing technologies should be enabled.

Reusability and value add: The concierge service should include all aspects of the patient's experience and be reusable across multiple studies. ePRO should deliver study updates, video conferencing, and feedback options, supporting future studies and reducing device management complexity and reclaiming devices at the end of the study.

Self-service capabilities: The patient concierge service should enable self-service for travel preferences and bookings, with options for reimbursement uploads. ePRO should offer account management, study information, reminders, and help features for self-sufficiency.

Simplified workflows: The concierge services should integrate with ePRO for a seamless patient experience, offering easy access to itineraries and support. ePRO should provide all study information in one place, with intuitive, visually appealing questionnaires.

Tool for collaboration and engagement: The concierge service should provide sufficient human contact and adaptability for travel changes, with well-briefed providers. ePRO should map the study journey, alert sites to important data, and capture real-time compliance and feedback.

Ready availability of support: The concierge service should offer 24/7 technology-enabled and human-assist support in multiple languages. ePRO helpdesk support should also be available 24/7 across preferred channels, ensuring efficient, appropriate, and empathetic issue resolution.

Trustworthiness: The concierge service should use trusted brands and ensure secure handling (e.g., data protection policies and technologies) of patient data and financial information. ePRO should build trust by clearly explaining data use, security measures, and providing transparent information about the study.

Rich information capture: The concierge service should capture satisfaction data while respecting patient privacy preferences (e.g., opt-in for sharing data). ePRO should tie data to patient demographics for analysis, helping sponsors understand and improve enrollment and completion rates across diverse populations.

6. Conclusion and Recommendations

Technology offers unparalleled opportunities to bridge gaps in clinical trial diversity by reducing geographical barriers, streamlining recruitment processes, and enhancing participant engagement. By leveraging digital tools, sponsors, CROs, and other research organizations can reach broader and more diverse populations, ultimately leading to more inclusive and representative clinical research.

Sponsors, CROs, and the broader clinical trial industry must commit to prioritizing diversity in clinical trial design and implementation, investing in technology solutions that enhance accessibility and engagement, and collaborating with community partners to build trust and foster participation among underrepresented populations. By taking these steps, the industry can ensure that clinical trials are more inclusive and that the resulting medical interventions are effective for all populations.

Appendix A: Summary of Key Recommendations

1. Integrate Technology into Recruitment and Retention:
    - Use digital recruitment platforms and mobile health applications to engage diverse populations.
    - Facilitate direct interaction through features like messaging, video calls, and shared dashboards to maintain engagement and support.
2. Enhance Participant Support and Configurability:
    - Provide multi-language support, culturally sensitive materials, and user-friendly technology interfaces.
    - Design technologies that are accessible to all users, accommodating different languages, abilities, and preferences.
    - Provide accessible and responsive support options to address any issues participants or site staff may encounter.
3. Tool for collaboration and engagement
    - Develop tools that enhance communication and collaboration among all stakeholders, including participants, site staff, and sponsors.
4. Foster Trust through Inclusive Staffing and Transparent Practices
    - Recruit site staff who represent underserved populations and provide ongoing cultural competency training to ensure comfort and trust for participants.
    - Implement robust data security measures, prioritize participant privacy, and use reputable, accredited technology vendors to ensure reliability.
    - Clearly explain data usage, provide information about technology vendors, and maintain communication with participants about the trial's progress and findings.

5. Apply the principle scorecard outlined in this white paper to select the technologies employed

Appendix B: Implementation Approach

1. Establish a Cross-Functional Implementation Team:
    - Form a dedicated team comprising representatives from sponsors, clinical research organizations (CROs), sites, patient advocacy groups, and technology vendors.
2. Develop Detailed Implementation Plans:
    - Create comprehensive plans outlining specific actions, timelines, and responsibilities. This should include the integration of technology solutions and the establishment of metrics for success.
3. Pilot Programs:
    - Initiate pilot projects in diverse geographic locations to test the feasibility and effectiveness of proposed solutions. Gather data on recruitment, retention, and participant diversity.
4. Training and Capacity Building:
    - Provide extensive training for all stakeholders, focusing on cultural competency, technology usage, and patient engagement strategies.
5. Technology Integration:
    - Ensure the seamless integration of digital recruitment platforms, electronic health records, site-facing applications, mobile health applications, and remote monitoring tools into existing workflows.
6. Monitoring and Evaluation:

- Implement robust monitoring systems to track progress, identify challenges, and make data-driven adjustments. Regularly evaluate the impact on participant diversity and study outcomes.

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