ConnectedHealthInitiative

September 26, 2024

Commissioner Robert Califf
U.S. Food & Drug Administration
10903 New Hampshire Ave
Silver Spring, Maryland 20993-0002

RE: ***Connected Health Initiative Comments on the Food and Drug Administration's Draft Guidance for Industry on "Diversity Action Plans To improve Enrollment of Participants From Underrepresented Populations in Clinical Studies"*** [***Docket No. FDA-2021-D-0789]***

Dear Commissioner Califf:

The Connected Health Initiative (CHI) writes to provide input on the Food and Drug Administration's (FDA) draft guidance on the much-needed diversity plans to improve enrollment of participants from underrepresented populations in clinical trials.[1] CHI recognizes that people of color are historically excluded from various facets of the healthcare system and appreciates the FDA's examination of the changing and increasingly intricate clinical trial enterprise and its crucial role in medical product development. Technological advances in software applications can vastly improve many facets of clinical trials, especially bridging the racial divide in representation by assisting in participant recruitment and continued engagement, improving the collection of data, and supervising clinical trial sites and investigators. While mobile apps hold the potential to revolutionize the effectiveness of clinical trials, these solutions are ineffective without sufficient racial and ethnic representation in the data generated by those that intend to use the medical device.

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

[1] 89 FR 54010.

As a longtime active advocate for the increased use of innovative technology in the delivery of healthcare, CHI engages with a broad and diverse cross-section of industry stakeholders focused on advancing clinically validated digital medicine solutions to address healthcare inequities. In 2020, CHI and the Consumer Technology Association released the Advancing Health Equity Through Technology whitepaper to address longstanding health disparities in the United States that were amplified by the COVID-19 pandemic. The whitepaper explored ways in which the increasing use of health technology such as mobile health, wearables, remote monitoring, telehealth, and use of artificial intelligence (AI) in clinical decision support can improve the country's response to health disparities in underrepresented communities and demographics.

Distrust in the healthcare system is prevalent among many of these communities due to structural barriers to access to healthcare and deep-rooted perceptions of physician bias. Broadly, CHI suggests the guidance (once finalized) be distributed to private sector clinical trial sponsors, to better equip them to improve outreach to racially diverse communities. Empowering widely recognized community advocacy groups and trial advisory boards to provide their views, review educational materials, and eventually promote studies they deem helpful is integral to restoring trust in the healthcare system and increasing willingness to participate in potentially life-saving clinical trials. Additionally, we encourage the FDA to promote the inclusion of new, non-traditional locations for clinical trials, while also incorporating an easily accessible tool for stakeholder feedback and engagement in multiple languages.

Traditionally in the context of clinical trials, there has been a limited use of digital health technologies that leverage patient-generated health data (PGHD) due to the costs associated with distributing, connecting, tracking, and maintaining mobile devices during an investigation. With the revolution of smartphone adoption and connected devices' increased familiarity and reach into the diversity of communities and populations in the United States, clinical investigations can now largely discard these concerns, particularly when embracing the "bring your own device" (BYOD) model. Such models may utilize specialized instruments as accessories to smartphones/tablets/etc., enabling a much more complete evaluation of a patient's condition across a myriad of types of data and use cases. The benefits of the full range of digital health technologies available today in clinical trials include:

- Reduction of barriers to the inclusion of underrepresented communities and populations (and enhanced subject retention and subject involvement in the clinical trial) due to the ease of reporting PGHD through smartphones or tablets as well as the ability to access this data;
- The ability to attain PGHD for data management in real time;
- Increased authenticity of patient-reported outcome data, particularly when such data is aggregated directly from sensors collecting PGHD (i.e., the trial participant is bypassed in the reporting process);
- Reduced training costs, as smartphones are widely adopted, and typical subjects will already be trained on how to use their own devices;

- The removal of geographic restrictions from trials and investigations allowing access to a more diverse set of trial subjects than would otherwise be possible; and
- Reduced maintenance and support costs for sponsors.

The FDA has consistently demonstrated its willingness to embrace advanced technology and connectivity in the healthcare continuum.[2] We appreciate the focus on reaching racially and ethnically diverse groups to better streamline a pathway to the market for medical devices with software functions that can radically improve the American healthcare system, and strongly support FDA ensuring that all clinical trials and federally funded studies comply with National Institutes of Health policies that mandate population diversity. Connected device and mobile app-enabled telehealth and remote monitoring of patient-generated health data continues to represent the most promising avenue for a more inclusive clinical trial process that will result in improved care quality, reduced hospitalizations, avoidance of complications, and improved satisfaction.

Greater diversity in clinical trials to mitigate disparities in healthcare is certainly facilitated using today's connected health technology but is also significant in the context of emerging technologies. For example, this guidance can and should be directly linked to the shared priority of mitigating biases in datasets used for developing AI tools.[3] We applaud the FDA for drafting a proposed guidance that details specific strategies that sponsor metrics linked to diverse enrollment goals.

[2] *E.g.*, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, MOBILE MEDICAL APPLICATIONS (2015), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM26 3366.pdf.

[3] We urge FDA to consider the CHI's recommendations for policymakers regarding healthcare AI policy in its development of the guidance at issue. *See*, *e.g.*, https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf.

CHI appreciates the opportunity to submit its comments to the FDA and urges its thoughtful consideration of the above input.

Sincerely,

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