

# ConnectedHealthInitiative

January 27, 2023

Ms. Grail Sipes  
Assistant Director for Biomedical Regulatory Policy  
Office of Science and Technology Policy  
Executive Office of the President  
1650 Pennsylvania Avenue NW  
Washington, D.C. 20504

**RE: *Connected Health Initiative Comments to the White House Office of Science and Technology Policy on Clinical Research Infrastructure and Emergency Clinical Trials [87 FR 71368]***

Dear Assistant Director Sipes:

The Connected Health Initiative (CHI) writes to provide input to the White House Office of Science and Technology Policy (OSTP) in response to its request for input on clinical research infrastructure and emergency clinical trials.<sup>1</sup> CHI appreciates OSTP and National Security Council's partnered efforts to ensure that coordinated and large-scale clinical trials can be efficiently carried out across a range of institutions and sites to address outbreaks of disease and other emergencies.

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. CHI is a longtime active advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease, specifically regarding clinical trials and investigations. For more information, see [www.connectedhi.com](http://www.connectedhi.com).

Digital health technologies (DHTs) are radically improving the American healthcare system and will continue to do so. For example, mobile app-enabled telehealth and remote monitoring of patient-generated health data continues to represent the most promising avenue for improved care quality, reduced hospitalizations, avoidance of complications, and improved satisfaction, particularly for the chronically ill. CHI is a longtime supporter of modernizing and streamlining today's regulatory system to enable leveraging the full potential of device software functions controlling, or part of, a

---

<sup>1</sup> 87 FR 71368.

hardware device (i.e., Software in a Medical Device, or SiMD) and for devices that are not part of a hardware device (i.e., Software as a Medical Device, or SaMD). A governance infrastructure that empowers providers to choose the best technology and cloud services to innovate within the health sector is critical to advance DHTs.

Digital health technological advances in software applications can vastly improve many facets of clinical trials, strengthening the infrastructure necessary to address disease outbreaks like COVID-19 and other public health emergencies. 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 from the underrepresented groups that intend to use the medical device. These advances also help bridge the racial divide in representation by aiding in participant recruitment and continued engagement, collecting data, and supervising clinical trial sites and investigators. CHI recognizes that people of color are historically excluded from various facets of the healthcare system and appreciates the OSTP's examination of the changing and increasingly intricate clinical trial enterprise and its crucial role in medical product development.

Broadly, CHI encourages OSTP to partner with trusted organizations committed to equity and diversity, and private sector clinical trial sponsors to improve community outreach. Distrust in the healthcare system is prevalent among many underrepresented communities due to structural barriers to accessing healthcare and deep-rooted perceptions of physician bias. Providing a platform for widely recognized and respected community advocacy groups to provide their views, review educational materials, and eventually promote studies they deem helpful should be a priority.

DHTs are critical for supporting coordinated and large-scale clinical trials conducted across a range of institutions and sites to address outbreaks of disease and other emergencies. Traditionally, in the context of clinical trials, there has been a limited use of DHTs 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, 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 diversity of types of data and use cases. The benefits of the full range of DHTs available today include:

- 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);
- 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;

- Reduced training costs, as smartphones are widely adopted and typical subjects will already be trained on how to use their own devices;
- Use of any device, whether a phone at work or a tablet at home, to access the data in a continuous manner, with data interoperability based on open and consensus-based standards (these standards include: the Continua Alliance's Design Guidelines,<sup>2</sup> Health Level 7 [HL7],<sup>3</sup> ISO 12052 [Health informatics -- Digital imaging and communication in medicine including workflow and data management],<sup>4</sup> and the Integrating the Healthcare Enterprise [IHE] initiative<sup>5</sup>);
- 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.<sup>6</sup> However, in the context of clinical investigations, a lack of clarity from the FDA regarding the use of DHTs has reduced uptake. Given the rapid development of DHTs, FDA guidance that will facilitate the use of DHTs in a clinical investigation as appropriate for the evaluation of medical products is necessary and timely and will greatly assist Independent Review Boards (IRBs) conduct investigations of non-significant risk under 21 CFR Part 812. Not only is this modernization of FDA guidance good public policy, but it would also be consistent with Congress' goals in the Food and Drug Administration Safety and Innovation Act of 2012 to promote innovation, protect patient safety, and avoid regulatory duplication.<sup>7</sup> FDA's efforts to enable the responsible use of DHTs will also assist in bridging the digital divide and providing needed disease prevention and treatment to America's most vulnerable citizens, in alignment with the Administration's priorities for eliminating disparities in healthcare.

To support its goals improving the U.S. clinical trials infrastructure and improving the ability to carry out emergency clinical trials, we strongly urge OSTP and the NEC to:

- Advance Guidance on the Use of Digital Health Technologies in Clinical Trials: Support the FDA's rapid finalization of its guidance on the use of DHTs in clinical investigations.
- Explore and Support Bring Your Own Device (BYOD) Capabilities: We urge OSTP and NEC to further explore the BYOD model. The BYOD model, whether using mobile apps and/or accessories to a mobile device, holds great potential to

---

<sup>2</sup> <http://www.continuaalliance.org/products/design-guidelines>.

<sup>3</sup> <http://www.hl7.org/implement/standards/index.cfm>.

<sup>4</sup> [http://www.iso.org/iso/catalogue/catalogue\\_tc/catalogue\\_detail.htm?csnumber=43218](http://www.iso.org/iso/catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43218).

<sup>5</sup> [http://www.ihe.net/About\\_IHE/](http://www.ihe.net/About_IHE/).

<sup>6</sup> 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/UCM263366.pdf>.

<sup>7</sup> See P.L. 112-144 (Sec. 618).

increase efficiency, improve data accuracy, provide real-time access to data, result in greater study participant investment, and break down geographic barriers to participant pools. BYOD devices that utilize proper risk management techniques (including building security into a mobile app from its inception and the use of encryption) along with participant training will greatly improve the integrity of the trial, and can easily provide novel clinical endpoints sponsors and investigators need in standardized formats through the use of application programming interfaces (APIs), software programs that allow for the automated exchange of data between systems, and positioning the sponsor to nimbly address challenges (e.g., a mid-trial device switch by a particular participant for any reason).

Relatedly, CHI continues to support FDA updates to its definition and scoping of DHTs in clinical trial guidance currently under development to address when a DHT is a medical device that has a software function that is not subject to Part 812 per Section 520(o)(1) of the Food, Drug & Cosmetic Act.

- Flexibility in Use of DHTs: OSTP and NEC are encouraged to take an outcome-based approach that is as agnostic to specific technologies and processes as possible. CHI urges OSTP and NEC to provide the flexibility sponsors may need to evolve their use of DHTs as this area of technology continues to rapidly develop. For example, OSTP and NEC can encourage this flexibility by prioritizing a technology neutral policy to sponsor use of DHTs, and by reinforcing that DHTs may be upgraded mid-investigation if its capabilities and performance initially authorized for the investigation are possible. In other words, sponsors should not be discouraged from leveraging improved features and enhancements to DHTs they are already using in an investigation.
- Development and Use of Novel Clinical Endpoints: DHTs can and should unlock novel clinical endpoints that will provide opportunities for additional insights into participant function or performance that were previously not easily measurable, including and/or in combination with Clinical Outcome Assessments (COAs) and biomarkers, outside of a clinic setting and over time, and that such insights will be crucial to improved clinical investigations. Sponsors should develop and utilize novel clinical endpoints based on input from stakeholders (i.e., patients, disease experts, caregivers, clinicians, engineers, and regulators) to ensure that the novel endpoint is both clinically relevant and the data is adequately captured by the DHT. To augment existing guidance on this topic, CHI has proposed that FDA provide further insights into validation of novel clinical endpoints in the event that such a novel clinical endpoint combines COAs and biomarkers, including whether a sponsor needs to address each component of the combined novel clinical endpoint, or if the entire novel clinical endpoint can be used as a justification.
- Address Adverse Events: With respect to the need to plan and train for handling known adverse events associated with a DHT, CHI has supported the FDA in recommending that sponsors develop best practices to address adverse events using the continual data flows that DHTs provide over time. Such best practices

should account for differentiating between true adverse events and false indications of adverse events, consistent with other FDA guidance and industry standards, and enable maximum flexibility for sponsors to appropriately address adverse events (consistent with our recommended approach to the use of DHTs that may enjoy upgraded functionalities after an investigation launches). We urge OSTP and NEC to align its efforts with this important body of work.

- Address Equity: With respect to the design and operation of clinical trials using DHTs, we urge OSTP and NEC to encourage the consideration of health equity goals through the identification, disclosure, and mitigation of biases while encouraging access to databases and promoting inclusion and diversity. Moreover, decentralized clinical trials increase the opportunity for underrepresented communities to participate.
- Hold Further Consultations with Impacted Stakeholders: Hold publicly-accessible workshops, and make publicly available technical resources and educational materials, on how to embrace the use of new technologies and innovations (including mobile apps and the BYOD model) in clinical trials and investigations, which will help address the reluctance of review boards, clinical sponsors, and investigators to embrace advanced technologies into their processes.

It is crucial that the governance models that lie at the foundation of clinical infrastructure operate in a way that supports sharing relevant data to accelerate digital health technology research and encourages engagement of underrepresented communities. CHI appreciates the opportunity to submit its comments to the FDA and urges its thoughtful consideration of the above input.

Sincerely,



Brian Scarpelli  
Senior Global Policy Counsel

Leanna Wade  
Policy Associate

**Connected Health Initiative**  
1401 K St NW (Ste 501)  
Washington, DC 20005