



May 29, 2026

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2026-N-2476 — Advancing the Use of Digital Health Technologies in Clinical Investigations for Drugs and Biological Products

Dear Sir or Madam:

ATA Action appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) request for information regarding the advancement of digital health technologies (DHTs) in clinical investigations. We commend the Agency for its continued leadership in this space, particularly given the close alignment with ongoing efforts related to Patient-Focused Drug Development, PDURS, digitally derived endpoints, and broader patient-centered digital innovation.

ATA supports FDA's commitment to modernizing clinical research through the thoughtful integration of DHTs. At a high level, we encourage the Agency to focus on the following cross-cutting priorities to help ensure scalable, consistent, and patient-centered adoption of these technologies:

1. Predictability and Consistency Across FDA Centers

ATA Action emphasizes the importance of consistent and predictable expectations across FDA Centers, including the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and, where relevant, the Center for Devices and Radiological Health (CDRH), for the use of DHT-derived data in clinical investigations.

Clear alignment on evidentiary standards for digitally derived endpoints, as well as consistent treatment of similar DHT use cases across review divisions, is critical. Variability in expectations can introduce uncertainty for sponsors, potentially limiting investment and slowing the adoption of innovative, patient-centered tools. Greater harmonization across Centers would serve as a key enabler of efficient development and broader utilization of DHTs.

ATA Action encourages FDA to clarify which engagement pathways are most appropriate for different categories of DHT-related questions, including early concept discussions, fit-for-purpose considerations, endpoint development, and cross-center issues. Greater transparency regarding available forums,

expectations for submitted background information, and how coordinated feedback will be provided across Centers would help reduce uncertainty and support more efficient development planning

2. Fit-for-Purpose, Risk-Based Approaches to DHT Evidence

ATA Action encourages FDA to continue advancing fit-for-purpose and risk-based frameworks for evaluating DHTs, particularly for wearable-derived measures and software-enabled endpoints.

Given the diversity of DHTs and their varying risk profiles, regulatory expectations should remain flexible and proportionate. Many DHTs, especially those that are low burden and present minimal safety risk, may not align with traditional evidentiary paradigms. Accordingly, FDA should support flexible approaches to evidence generation and allow sponsors to tailor validation strategies based on the specific context of use, risk profile, and intended role of the DHT within a clinical investigation. In addition to narrative guidance, ATA Action encourages FDA to provide practical implementation tools, such as case studies, templates, checklists, and decision trees, to help sponsors apply regulatory expectations more consistently across different DHT categories and contexts of use.

3. Clear FDA Guidance on Digitally Derived Endpoints

ATA Action believes additional FDA guidance on digitally derived endpoints would significantly support broader and more consistent adoption.

Specifically, we encourage the Agency to clarify expectations related to:

- Validation and verification of digitally derived measures
- Interpretability and clinical meaningfulness
- Use across therapeutic areas and study designs
- Endpoint positioning (e.g., primary, secondary, exploratory)
- Approaches to managing and accounting for real-world variability in DHT data
- Clinical meaningfulness and interpretability of digitally derived endpoints
- Approaches to missing data, adherence challenges, and real-world variability in decentralized or hybrid settings

Flexible evidentiary approaches for rare diseases and other settings with limited precedent or constrained data availability ATA Action also encourages FDA to provide practical implementation tools—such as case studies, templates, checklists, and decision trees—and to further clarify expectations for digitally derived endpoints, including novel, composite, and exploratory endpoints, as well as approaches to missing data and real-world variability in decentralized or hybrid clinical investigations. Greater clarity in these areas would reduce uncertainty, support more efficient trial design, and enhance confidence among sponsors and investigators.

4. Structured Opportunities for Public Dialogue and Workshops


ATA supports the convening of additional FDA-led public workshops and collaborative forums focused on DHT use in clinical investigations.

These forums would provide valuable opportunities to advance shared understanding of key issues, including validation principles, data integrity, and practical examples of successful regulatory applications of digitally derived endpoints. Continued engagement with stakeholders including sponsors, clinicians, patients, and technology developers will be essential to building consensus and accelerating progress in this rapidly evolving field.

Conclusion

ATA Action appreciates FDA's leadership in advancing the integration of digital health technologies into clinical research. By prioritizing consistency, flexibility, clarity, and ongoing stakeholder engagement, the Agency can help unlock the full potential of DHTs to improve trial efficiency, enhance patient participation, and generate more meaningful, real-world evidence.

We welcome continued collaboration with FDA on these important issues.

A handwritten signature in blue ink that reads "Lani Reilly". The signature is fluid and cursive, with the first name "Lani" and last name "Reilly" clearly distinguishable.

Lani Reilly
Vice President, Industry Affairs
ATA Action