

May 23, 2023

Lauren K. Roth
Associate Commissioner for Policy
Food and Drug Administration, Dockets Management Staff
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: ACRO comment submission:
Framework for the Use of Digital Health Technologies in Drug and Biological Product Development

Dear Ms. Roth:

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-human studies through post-approval, pharmacovigilance and health data research. ACRO member companies manage or otherwise support the majority of all biopharmaceutical sponsored clinical investigations worldwide and advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

ACRO thanks the Agency for releasing this *Framework for the Use of Digital Health Technologies in Drug and Biological Product Development*. ACRO is pleased to provide the following feedback. ACRO would like to provide general comments, before moving on to specific pages within the Framework.

General comments:

ACRO supports the development of the Framework to implement the DHT programs for drugs, and ACRO welcomes the range of activities that are included.

ACRO notes and understands the scope and purpose of this Framework, with the Agency's reminder that *"This document is not a guidance document and does not propose or establish policies."* Therefore, ACRO does not discuss any specific digital health technology policies in this comment. Instead, we focus on the structure and proposed activities within the Framework.

Page-Specific Comments:

Pages 8-9, "DHT Steering Committee"

ACRO welcomes the establishment of the DHT Steering Committee and notes that the committee will engage with external stakeholders on DHT-related issues in human drug development. The Framework notes the composition of the steering committee as follows, *"The DHT Steering Committee consists of senior staff from CDER, CBER, and CDRH, including the DHCoE, as well as OCE and the Office of Clinical Policy and Programs."* We noted with interest two key roles of the steering committee:

- Gather information about the present state of DHTs, including specific challenges in their use
- Engage with external stakeholders on DHT-related issues in human drug development

As the trade association representing global CROs and global technology companies who are spearheading many of the digital technology innovations for clinical research, ACRO's membership includes digital technology experts who are at the frontlines of clinical trial modernization. ACRO members possess deep expertise in the ways in which DHTs can safeguard data quality and data integrity (including data flow, data controls, accountability, traceability, and lineage) – in addition to the data protection/privacy and cybersecurity considerations for DHTs. We would like to make ACRO member expertise available to the steering group. Indeed, we ask the Agency to consider establishing an external Advisory Group to act as a key resource group for the steering committee and would recommend that the Advisory Group include representation from:

- Digital technology *developers* – including sponsors, CROs, and technology companies
- Digital technology *end users* – including both sites and patients

Pages 9-11, “Technical Expertise and Training”

ACRO believes that this is a topic for which an external Advisory Group – consisting of digital technology developers such as sponsors, CROs, and technology companies – could be particularly valuable to the Agency. ACRO members have deep expertise across many of the training aspects listed in the Framework document and would be able to provide the Agency with insights on both currently existing technologies and emerging, cutting-edge technology.

Page 13, “Guidance”

The ongoing work on guidance is appreciated, together with the commitment to further guidance as informed by stakeholder engagement. ACRO is committed to enabling this process by gathering feedback from members on areas where further guidance would be helpful and sharing this with FDA.

Page 16, “External Organizations”

ACRO welcomes the continued engagement with industry stakeholders and looks forward to working with the FDA to advance the policy goals relating to the use of digital health technologies (DHTs) to support drug development and review.

Thank you for this opportunity to provide feedback. Please do not hesitate to contact ACRO (knoonan@acrohealth.org) if we can provide additional details or answer any questions.

Respectfully submitted,

Karen Noonan, Senior Vice President, Global Regulatory Policy