ACRO Innovate Advocate Collaborate

December 22, 2025

Tami Belouin, Center for Biologics Evaluation and Research
Grace R. Graham, Deputy Commissioner for Policy, Legislation, and International Affairs
Food and Drug Administration

RE: ACRO comment submission on *Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products* [FDA-2025-D-3049-0002]

Dear Ms. Belouin and Ms. Graham,

Founded in 2001, the Association of Clinical Research Organizations (ACRO) is a non-profit trade association representing the world's leading clinical research and technology organizations, which provide specialized services that are integral to the development of drugs, biologics and medical devices that enable patients to live longer, healthier, and more productive lives. ACRO members provide a wide range of services and digital technologies across the entire spectrum of development – from pre-clinical, proof of concept, and first in human studies through post-approval, pharmacovigilance, and health data research. ACRO member companies employ nearly 400,000 people worldwide and conduct research in every global region.

General Comments

ACRO welcomes the draft guidance on *Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products.* ACRO members conduct and support clinical research across a wide range of different therapies and conditions, including rare diseases and cell and gene therapy (CGT) products. We appreciate the discussion of methods and approaches for capturing postapproval safety and efficacy data for CGT products. In particular, ACRO welcomes the Agency's introductory statements on the importance of postapproval monitoring, given the potential for CGT products to have long-lasting effects.

Specific Comments

Lines 21-22
ACRO notes that this guidance does not address data collected for the purpose of expanding clinical indications. It would be helpful to include a reference to the relevant guidance at this point, such as the current draft guidance on *Innovative Designs for Clinical Trials of Cellular and Gene Therapy Products in Small Populations for industry.*

Line 54
There appears to be a misspelling of an abbreviation: "LFTU" instead of "LTFU."

Line 65
ACRO notes that four postapproval methods and approaches have been included in this draft guidance: (1) Real-World Data (RWD) and Real-World Evidence (RWE); (2) Electronic Health Records (EHRs), Medical Claims, and Vital Statistics Data; (3) Registries; and (4) Decentralized Data Collection. As noted within the

subsequent text, EHRs and Registries are forms of RWD and RWE, not separate methods or approaches. ACRO suggests adding a clarifying sentence to explain that these approaches are not mutually exclusive.

Lines 204-241
ACRO members are committed to removing barriers to the adoption of decentralized elements in clinical trials, as detailed in the DCT Toolkit resources available on the ACRO website (https://www.acrohealth.org/initiatives-hub/decentralized-trials/). Therefore, ACRO welcomes the recognition of decentralized data collection as a potential method to support capture of postapproval efficacy and safety data. The need to reduce burdens for patients as much as possible is particularly important when collecting data over a longer time period.

Thank you for the opportunity to comment on this draft guidance. Please contact ACRO (knoonan@acrohealth.org) if we can answer any questions at all.

Respectfully submitted,

Karen Noonan

Karen Noonan
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