ACRO Innovate Advocate Collaborate

April 6, 2026

Ethan Gabbour, Center for Drug Evaluation and Research
Phillip Kurs, Center for Biologics Evaluation and Research
Lowell M. Zeta, Acting Deputy Commissioner for Policy, Legislation, and International Affairs
Food and Drug Administration
10903 New Hampshire Ave, Bldg. 51
Silver Spring, MD 20993-0002,

RE: ACRO Comment Submission on:
E22 General Considerations for Patient Preference Studies; International Council for Harmonisation
Docket No. FDA-2026-D-0207

Dear Mr. Gabbour, Mr. Kurs, and Mr. Zeta

Founded in 2001, the Association of Clinical Research Organizations (ACRO) is 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 specialized services across the entire spectrum of development - from preclinical, 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.

ACRO supports the development of this harmonized approach on the use, design, conduct, analysis and submission of patient preference studies (PPS). ACRO agrees with the importance of generating qualitative and quantitative insights about the relative importance of characteristics that are considered by patients when making decisions about drugs.

Digital Study Infrastructure:
Patient preference studies are increasingly conducted using electronic data capture systems, decentralized trial platforms, and digital patient engagement tools. While the draft guideline appropriately focuses on methodological considerations, we ask FDA to consider incorporating into the final guideline acknowledgement of the growing role of interoperable digital infrastructure in supporting PPS conduct, improving data quality, and facilitating regulatory transparency. Recognizing the role of modern digital research platforms would help ensure that the final guideline remains applicable and appropriately nimble as clinical research continues to evolve.

Data Standards and Interoperability:
The draft guideline discusses the submission of PPS results within the Common Technical Document but does not address the role of interoperable data standards in enabling integration between PPS data and clinical trial datasets. Encouraging the use of common data standards and structured data formats could facilitate reuse of PPS data across studies, improve transparency of regulatory submissions, and support more efficient integration of patient preference evidence within benefit-risk assessments.

Integration with Clinical Trial Design:
The draft guideline notes that PPS can inform clinical trial design, endpoint development, and benefit-risk assessment. Additional clarification regarding how PPS evidence may be integrated into these processes would be valuable for both sponsors and regulators. Providing further, illustrative case examples or considerations for how PPS findings should be used to inform endpoint prioritization, trial design decisions, or regulatory submissions could improve consistency in the application of PPS across development programs.

Section 1.3 – Lines 29 to 48:
ACRO welcomes the clarity on the scope of the guideline. This section is helpful in stating what is included (patient stated-preference studies) and what is not included (carer preferences or healthcare professional preferences, patients reported outcome measures).

Section 4.4 – Lines 239 to 250:
ACRO welcomes the recognition, in lines 207-208, that some methodologies may not be feasible in very rare diseases. ACRO recommends including reference to these situations within "Section 4.4, Sample Size."
In addition, we recommend adding new text as follows: "The feasibility of the sample size should be considered, for example, in studies regarding rare diseases. While most quantitative PPS research has been conducted using discrete choice experiments, methods such as thresholding may be more appropriate where there are smaller numbers of potential participants."

Thank you for the opportunity to provide comment on ICH E22. Please do not hesitate to contact ACRO (knoonan@acrohealth.org) if we can provide additional information.

Respectfully submitted,

Karen Noonan
Senior Vice President, Global Regulatory Policy