REAL-WORLD EVIDENCE ALLIANCE

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

Re: E6(R3) Good Clinical Practice: Annex 2; International Council for Harmonisation; Draft Guidance for Industry; Availability (Docket No. FDA-2024-D-5601)

To the Food and Drug Administration:

The RWE Alliance appreciates the opportunity to comment on the draft guidance titled "E6(R3) Good Clinical Practice: Annex 2" ("Draft Guidance").[1] We are a coalition of real-world data ("RWD") and analytics organizations with a common interest in harnessing the power of real-world evidence ("RWE") to inform regulatory decision making to improve the lives of patients. Our members have deep knowledge and experience working with healthcare data across disease areas and patient populations, and we aim to bring these collective insights to bear in support of RWE policies.[2]

The RWE Alliance envisions a future in which data from electronic health records, administrative claims and billing records, product and disease registries, personal devices, wearables, and health applications will be used to generate evidence to support regulatory decision making related to medical product safety and effectiveness. To achieve these goals, the RWE Alliance advocates for policies that will (1) advance FDA's RWE Framework, (2) encourage the use of RWE to better understand treatment effects in underrepresented populations, (3) enhance opportunities for RWE organizations to consult with FDA, (4) increase communication on the generation and use of RWE, and (5) recognize the unique aspects of and opportunities for RWD/E.[3]

We appreciate FDA (the "Agency") and the International Council for Harmonisation ("ICH") for creating a series of Good Clinical Practice ("GCP") considerations tailored to evolving clinical trial designs and data sources used to generate evidence. We are

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[1] 89 Fed. Reg. 106519 (Dec. 30, 2024).

[2] For information about our members, please see our website, https://rwealliance.org/who-we-are/.

[3] Additional information about what we believe is available on our website, https://rwealliance.org/what-we-believe/.

encouraged by the Draft Guidance's focus on GCP considerations that may apply to a variety of RWD sources used in clinical trials. We agree with FDA that sponsors should apply special GCP considerations depending on the data sources used in a trial—e.g., based on whether RWD are used as primary or secondary data and on the data collection and acquisition process. We appreciate the Draft Guidance discussing a wide range of RWD-specific considerations in clinical trials, including those relating to the protection of data privacy and the reliability of trial results.

As use of RWD/E and other pragmatic or decentralized elements in clinical trials continues to expand, flexibility in how FDA applies policies that were developed in an earlier era will be important. The RWE Alliance believes that E6(R3) Good Clinical Practice: Annex 2 is a significant step, especially given the importance of harmonized guidelines for clinical trials, which are often conducted in multiple geographic regions.

We share the Agency's goal for advancing GCP considerations specific to RWD sources and innovative trial designs, and we welcome continued engagement with FDA and ICH on these topics. RWD organizations offer a unique perspective on best practices for evidence generation from RWD sources that is distinct from other ICH members and that can accelerate ICH's policy goals.

The RWE Alliance appreciates FDA's efforts to enhance global regulatory harmonization and convergence for RWD/E and to establish a dialogue with stakeholders on this topic. Thank you for considering these comments, and please let us know if you have any questions.

Best regards,

The RWE Alliance