From: Bayha, Ryan (NIH/OD) [E]
To: Agnes Balla
Subject: RE: Questions and Input on the FDA-NIH Resource on Terminology for Clinical Research
Date: Wednesday, July 10, 2024 7:46:20 AM

CAUTION: EXTERNAL EMAIL

Dear Agnes,

Thanks for your email. We will be happy to consider the comments you provided below.

Ryan Bayha
Director of Strategic Engagement
NIH Office of Science Policy

From: Agnes Balla <Agnes.Balla@ucop.edu>
Sent: Wednesday, July 3, 2024 4:40 PM
To: SciencePolicy <SciencePolicy@od.nih.gov>
Subject: [EXTERNAL] Questions and Input on the FDA-NIH Resource on Terminology for Clinical Research

Dear NIH Office of Science Policy,

I write on behalf of the research policy office at the University of California (UC) system. We understand that on May 6, 2024, the FDA and the NIH jointly issued a Request for Information (RFI) to solicit feedback on a glossary of terms related to clinical research and clinical study designs, including those utilizing real-world data (RWD) to generate real-world evidence (RWE). The deadline to comment on this RFI was June 23, 2024.

With sincere apologies for missing the deadline, we hope that NIH and FDA will consider our question and input, explained below, on the glossary of terms.

Question:
Would the FDA-NIH Clinical Research Working Group be able to clarify whether the glossary is applicable to only those FDA-approved studies that use RWD for medical device/therapeutics or would they also apply to those studies focused on other interventions or observations (e.g. fitness interventions for cancer survivors, retrospective observational studies for cancer risks, etc.)? If the glossary is intended to apply to all studies, then we suggest the following edits:

- **Non-interventional (observational) study**: Please consider the below change shown in red if the glossary is intended to apply to all studies.
    - A type of study in which individuals are not assigned to a medical product *or other intervention* according to a protocol.
- **Observational Study, Retrospective:** Please consider the below clarifications shown in red if the glossary is intended to apply to all studies.

- A study that identifies the population and determines the exposure/treatment *based on data collected during a time period prior to the start of the study*. The variables and outcomes of interest are determined *during the design of the study*.

Input:

Please include the terms real-world data (RWD) and real-world evidence (RWE) with their definitions in the glossary. We recognize that FDA provides definitions for these terms elsewhere (such as on this FDA site), but the UC community would welcome using the glossary as a one-stop shop for all terms associated with clinical research and clinical study designs. For ease of reference, we've provided the definition of each term below along with further rationales for why these terms would be important to include in the glossary.

- Real-World Data (RWD):
  - **Definition:** Data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources. Examples of RWD include data derived from electronic health records, medical claims data, data from product or disease registries, and data gathered from other sources (such as digital health technologies) that can inform on health status.
  - **Rationale:** RWD is increasingly utilized to inform clinical study designs and regulatory decisions. Including a definition of RWD in the glossary would provide clarity on its sources and applications.
- Real-World Evidence (RWE):
  - **Definition:** Clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD.
  - **Rationale:** As RWE is becoming a critical component in the evaluation of medical products, its inclusion in the glossary would help standardize the understanding of how RWE is generated and utilized.

We welcome any opportunity to further discuss. If you have any questions, please feel free to contact me.

Sincerely,

Agnes Balla

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