ge²p² global
governance, ethics, evidence, policy, practice

June 18, 2024

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Public Comment on FDA Docket No. FDA-2023-D-5470: Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products; Draft Guidance for Industry

To Whom It May Concern:
For your reference, the GE2P2 Global Foundation is a U.S.-headquartered, global NGO founded in 2016 with a mission to advance scientific rigor and ethical resilience in research and evidence generation across health, human rights, humanitarian action, education and sustainable development. Our key programmatic areas include biomedical research integrity, and we take a keen interest in human subject protections and informed consent.

More broadly, we are focused on governance processes and stewardship through our engagement of calls for input, comment and public consultation on laws, regulations, policies, guidance and other deliberative processes undertaken by regulatory bodies, multilateral agencies and the UN system, and more broadly by NGOs, civil society organizations, private organizations and non-state actors. This public consultation activity is undertaken by the Foundation's community of practice – operating in 30+ countries – includes researchers, scientists, ethicists, multilateral agency leaders, government and ministry officials, INGO leaders, and field practitioners across disciplines.

On behalf of the GE2P2 Global Foundation, I am pleased to submit these comments on FDA's draft guidance referenced above.

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The GE2P2 Global Foundation appreciates the thoughtful and comprehensive FDA draft guidance: Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products

We appreciate that the guidance – at *B. Summary of Proposed Approach [Lines 141-42]* – notes that sponsors should provide a "Description of how ethical considerations (e.g., issues related to human subject protection) are addressed."

However, we assess that it is important to specify informed consent in this context. We recognize the variety of possible sources and conditions under which real world evidence is collected, and argue that it is imperative that patients whose data is collected and used in regulatory submissions know that their data may be/will be used, and that they understand and consent to its use.

Further, we assess that it would be beneficial to specifically emphasize that requirements for effective informed consent must be met, especially in light of the fact that data in non-interventional study designs are, as noted in the guidance, often generated for purposes other than research.

We urge FDA to give consideration to adding language to this guidance to explicitly highlight the requirement for informed consent, with appropriate references and citations in footnotes to relevant FDA regulations and guidance.

Such an extension to the current draft language would fit well beginning at Line 142.

Another point in the text where such language might be considered is *D. Data Sources [Line 181-82]* which speaks to a “Description of the proposed data source(s), including how the data were originally 181 collected.” This description could well include information about the consent processes that addressed the collection and potential and/or specific research uses of such date.

In either instance, the footnote style of the draft overall provides adequate opportunity to include citations to relevant FDA guidance and other content.

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