ACRO
ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

July 8, 2019

Dr. Lauren Milner
Health Science Policy Analyst
Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

RE: ACRO Comment—
Submitting Documents Using Real- World Data and Real-World Evidence to the Food and Drug Administration for Drugs and Biologics; Draft Guidance for Industry
Docket No. FDA–2019–D–1263

Dear Dr. Milner,

The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. In 2018, ACRO member companies managed or otherwise supported a majority of all FDA-regulated clinical investigations worldwide. With more than 130,000 employees engaged in research activities in 114 countries, the member companies of ACRO advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.

ACRO thanks the Agency for this Draft Guidance, which is an important step towards the use RWD/RWE to enhance clinical research and to support regulatory decisions regarding safety and/or effectiveness.

ACRO asks the Agency to consider two additional sections for inclusion in the Final Guidance.

Standardized Summary Assessments of the Quality of Data underlying RWD Submissions
In addition to the cover form presented in the Draft Guidance, we ask FDA to consider asking sponsors to provide standardized summary assessments of quality of data underlying real-world-data submissions. By providing standardized descriptions of elements such as data quality, data context, and protocol completeness, this would provide ready means of understanding and contextualizing findings by reviewers. We feel this will enhance the transparency, replicability, and evaluability of real-world evidence, especially when evaluating RWE in the context of multiple submissions.

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Insights and examples for elements that could be incorporated in such standardized summary assessments may be found in the below references:

- Joint ISPOR/ISPE taskforce on RWE available at: https://www.ispor.org/publications/newsletters/newsletter/newsletter-detail/ebulletin-october-2017/update-on-the-joint-ispor-ispe-special-task-force-on-real-world-evidence-in-health-care-decision-making
- Health Canada guidance available at: https://www.canada.ca/en/services/health/publications/drugs-health-products/real-world-data-evidence-drug-lifecycle-report.html#a4 (Elements of Protocol Development and Data Quality)
- Duke Margolis Center for Health Policy available at: https://healthpolicy.duke.edu/sites/default/files/atoms/files/characterizing_rwd.pdf

Glossary of Key Terms

The two-page glossary provided by the Agency in the "Framework for FDA'S Real-World Evidence Program" is useful. We believe it would be helpful to append that brief glossary again in the Final Guidance, with two additional terms included.

Line 96 of the Draft Guidance references *"Natural history studies for development of a clinical outcome assessment or biomarker."* It would be helpful to add a definition of "natural history studies" to the glossary.

Line 146 of the Draft Guidance references "Product and/or disease registry data." It would be helpful to add definitions of these terms to the glossary.

ACRO thanks the FDA for this Draft Guidance on Submitting Documents Using Real- World Data and Real-World Evidence to the Food and Drug Administration for Drugs and Biologics. Please do not hesitate to contact ACRO if we can answer any questions or provide additional details.

Respectfully submitted,

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