REAL-WORLD EVIDENCE ALLIANCE

info@rwealliance.org
rwealliance.org

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

Re: Submitting Documents Using Real-World Data and Real-World Evidence to the Food and Drug Administration for Drugs and Biologics; Draft Guidance for Industry; Availability (Docket No. FDA-2019-D-1263)

Dear Sir or Madam:

The RWE Alliance appreciates the opportunity to comment on the draft guidance entitled "Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics" (the "Draft Guidance").[1] We are a recently formed coalition of real-world data and analytics organizations with a common interest in harnessing the power of real-world evidence ("RWE") to inform regulatory decision making to improve patients' lives. 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.

The RWE Alliance envisions a future in which data generated in everyday clinical practice and everyday life through electronic health records, administrative claims and billing data, product and disease registries, personal devices, wearables, and health applications will be used to generate evidence that complements clinical trial data to inform regulatory decisions. To achieve this goal, the RWE Alliance advocates for policies that will advance FDA's RWE Framework, encourage the use of RWE to better understand treatment effects in underrepresented populations, enhance opportunities for RWE organizations to consult with FDA, and increase communication on the generation and use of RWE.[2]

With respect to this final principle in particular, we strongly believe that communication about FDA's review of RWE in marketing applications is crucial to advancing best practices in the use of RWE for regulatory purposes and to ensuring a widespread understanding of the benefits that RWE ultimately delivers to patients. To increase this communication, we support FDA raising broader awareness about current and potential

[1] 84 Fed. Reg. 20368 (May 9, 2019).
[2] Additional information about what we believe is available on our website, which is available at https://rwealliance.org/what-we-believe/.

uses for RWE. We also support FDA providing more detailed guidance on how RWE should be presented in submission packages and product labeling, as well as FDA making public a summary of the Agency's review of RWE when included in original or supplemental applications.

I. Comments on the Draft Guidance

The RWE Alliance applauds FDA's publication of the Draft Guidance and, in particular, the Agency's intention to track submissions that include RWE. We agree this tracking can help enhance FDA's understanding of the scope and use of RWE in submissions, and our hope is that insights from this effort will enrich the information that the Agency shares with the public about how RWE can most effectively be used and incorporated in development programs. To this end, we have suggested some minor modifications to the proposed table to further clarify the role of RWE in the communications and submissions with the Agency.

Proposed Table in Cover Letter for Submissions with RWE

Original draft table with proposed changes embedded	Rationale for Change
Product under review [Proprietary name (generic name)]	New row proposed. While this information will be captured in the cover letter, it may be useful to include in the table for easy tracking purposes.
SNOMED CT **Disease / medical condition**	New row proposed. Capturing medical condition in the table will allow the FDA and its stakeholders to more easily track the use of RWE by disease/condition area.
Purpose(s) of Using RWE as Part of the Submission (Select all that apply) ▢ To provide evidence in support of effectiveness or safety for a new product approval	No changes (except minor editorial change to delete and move "of") in the second sentence.

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Original draft table with proposed changes embedded	Rationale for Change
☐ To provide evidence in ~~of~~ support of labeling changes for an approved drug, including: ☐ Add or modify an indication ☐ Change in dose, dose regimen, or route of administration ☐ Use in a new population ☐ Add comparative effectiveness information ☐ Add safety information ☐ Other labeling change. Specify: ☐ To be used as part of a postmarketing requirement to support a regulatory decision	
Study Designs(s) Using RWE (Select all that apply) ☐ Randomized pragmatic clinical trial ☐ Single arm trial with external control arm ☐ Observational study ☐ Other study design. Specify:	The changes proposed in this section are intended to specify further the designs using RWE.
RWD Source(s) Used To Generate RWE (Select all that apply) ☐ Data derived from electronic health records ☐ Medical claims and/or billing data ☐ Product, disease, and/or pregnancy registry data ☐ Patient-generated data ☐ Other data source ~~that can inform on health status~~, Specify:	Consistent capture of RWD sources can inform a regulatory framework for emerging clinical data generation/use. We suggest adding pregnancy registry data as well as patient-generated data to track the use of these RWD sources as well.

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II. Conclusion

Thank you for considering these comments and for FDA's continued work to implement the Agency's RWE program. Please let us know if you have any questions regarding these comments, and we would welcome the opportunity to discuss further.

Best,

The RWE Alliance