REAL-WORLD EVIDENCE ALLIANCE

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RWE Alliance Submits Comments on FDA's RWE Draft Guidance, Highlights Recommendations for Agency's RWE Program and RWE Derived from EHR/Claims Data

Washington, D.C. (January 24, 2022) – Today, the RWE Alliance submitted a substantial comment letter in response to the U.S. Food and Drug Administration (FDA) draft guidance on using electronic health records (EHRs) and medical claims data to support regulatory decision making across therapeutic areas.

The RWE Alliance commends the Agency for providing this draft guidance. The RWE Alliance is committed to identifying methods that can enhance confidence in RWE study results and facilitate the integration of transparent, auditable, reproducible, and scientifically valid RWE in regulatory decision making. To this end, the RWE Alliance's comments include recommendations for FDA to incorporate in the final guidance and recommendations for further implementation of FDA's RWE Program. For example, we encourage the Agency to:

- State more clearly in the final guidance that different approaches to RWE studies can be appropriate in specific use cases, depending on the circumstances
- Provide recommendations for successful use of RWD curated from more than one source
- Address the distinctions between EHR and medical claims data and differentiate the recommendations for these two data sources
- Clarify that the appropriate approach to outcome validation in a specific use case will be study dependent
- Consider increased communication with external stakeholders about concrete RWE use cases

"FDA's draft guidance for using EHRs and medical claims data in regulatory decision making represents a key step on our journey toward standardized methods for evaluating and analyzing RWD," said Jeremy Rassen, Co-Founder and President at Aetion. "These methods are a necessary component of high-quality and credible RWE, and the level of detail in the guidance signals FDA's commitment to advancing the use of EHR and claims data in product submissions. We are pleased to share our experience and insights with the Agency as it works to finalize the guidance."

"As a pioneer in the use of EHR-derived RWD in oncology with a mission to learn from the experience of every cancer patient, Flatiron has helped expand the use of high-quality, reliable RWE to improve patient lives," said Michael Vasconcelles, MD, Chief Medical Officer at Flatiron Health. "We look forward to helping FDA promote shared learnings and consistent standards across applications of RWE."

"We continue to appreciate FDA's commitment to expanding the scope of data considered in regulatory decision making. With the recent draft guidance surrounding the use of EHRs and medical claims data, FDA is taking an additional important step in its use of RWE," said Rob Kotchie, President, Real World Solutions, IQVIA. "As a founding member of the RWE Alliance,

IQVIA is committed to advancing the FDA effort through responses to the draft guidance that promote the use of RWE for the benefit of patients."

"As a leader in real-world care, Syapse sees tremendous value in leveraging RWD and RWE for regulatory purposes to more acutely understand care provided in the community," said Dr. Thomas Brown, Chief Medical Officer at Syapse. "Syapse is enthusiastic in its support of the FDA's draft guidance and greatly appreciates the opportunity to share our experience in using RWE to further codify its use, ultimately helping to improve access to novel therapies for patients suffering from serious illness."

"The inclusion of multimodal RWE in regulatory decision making is essential to improving treatment options for patients and advancing medical product innovation," said Lauren Silvis, Senior Vice President for External Affairs at Tempus. "We look forward to ongoing engagement with FDA to help advance the use of high-quality data from diverse real-world sources."

About RWE Alliance

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 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.

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