

Real-World Evidence: Challenges and Opportunities During COVID-19



The urgent needs of the COVID-19 pandemic have more squarely brought into focus the role real-world evidence (RWE) can play in analyzing and informing product development and clinical and public health decisions. Specifically, the U.S. Food and Drug Administration (FDA) is participating in the COVID-19 [Evidence Accelerator](#), in partnership with Friends of Cancer Research and the Reagan-Udall Foundation, to bring leading experts together to share insights and use RWE to help answer the most pressing research questions raised by the pandemic.

The FDA believes that RWE can play an informative role in analyzing potential therapies, vaccines, and diagnostics for COVID-19. At the recent “Establishing a High-Quality Real-World Data Ecosystem” [workshop](#) hosted by the Duke Margolis Center for Health Policy, Amy Abernethy, the Principal Deputy Commissioner of Food and Drugs and Acting Chief Information Officer at the FDA, highlighted the work of the Evidence Accelerator initiative, noting that RWE allows the FDA to constantly update its understanding of COVID-19 and recurrently analyze data to address changing needs. Amongst the other presenters, the general discussion focused on the many hurdles industry needs to address to establish a robust and more accurate RWE data ecosystem, including efficient capture of reliable data at the source. While internet access, smartphones, and wearable technology enable consumers and patients to keep meticulous records of their biometric data, the vast amount of collected data does not necessarily lead to efficient or fruitful analysis currently. FDA noted during the workshop that, to be more insightful, RWE stakeholders must narrowly tailor their collection to what is actually useful and relevant to clinical endpoints, fit for purpose, rather than merely what is easily accessible. Eric Perakslis, a Rubenstein Fellow at Duke University, noted that stakeholders must balance the usefulness of RWE collection against the risk of over-surveillance for each data point collected. While not discussed during the workshop, collecting massive data sets must also be weighed against the ever-present risk of data breach. Finally, speakers also discussed patient-generated health data (PGHD) and the need for aligned stakeholders who are motivated to collect this data and understand the process for doing so, including a plan for handling outlier data which is unavoidable with PGHD.

In the context of the COVID-19 pandemic, RWE presents an opportunity for real-time learnings toward quicker identification and development of treatments and vaccines. As a result, the pandemic has only strengthened the importance of RWE in product development and, if deployed well, could help support more efficient and expedited product development plans.

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