REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Frequently Asked Questions:
COVID-19 Real-World PIVD (Performance of In Vitro Diagnostics)

Is there a particular need to focus on EUA (or renewal of EUA) vs a PMA? Or is the focus on both?	We are looking to identify how RWD/RWE can be utilized to improve and support regulatory review, including authorization and approval pathways. Focus on EUA or full market approval (FMA) would depend on the current status of the IVDs being used (e.g., new technologies may be looking to obtain EUAs, while tests with EUAs may be seeking FMA). Identifying how any of these processes can be improved would be of interest. The evidence demonstration is greater for PMA than EUA. But one could also imagine an EUA pathway that is more robust given the current caseload and significantly more knowledge than from the start of the pandemic.
In addressing the secondary question of developing a framework for regulatory submission—is it safe to assume that applicants could include in a proposal that part of the approach will be to have some engagement with FDA and other stakeholders to identify the data elements, study design domains, and related questions that should be addressed to provide confidence in the regulatory submission?	Applicants can propose engaging FDA and other stakeholders as part of their approach. However, considerations will be needed regarding the level and amount of required participation. The feasibility of what is being proposed within the study time period should be taken into account.

Eligible applicants must have the ability to assess the real-world performance of diagnostic tests.	
What are the minimum required data elements?	Ideally, all required core COVID-19 diagnostic data elements at the federal and state levels per the HHS guidance would be captured. However, submissions can be eligible if not all data elements are available (e.g., patient residence county would not be critical to assess test performance). For reference, interested applicants can be directed to the HHS COVID-19 data reporting technical implementation guides for lab and non-lab testing.
How can core diagnostic data sets along with RWD/RWE collected across the TPLC be used to improve the quality and performance of IVDs over time?	This is about establishing a framework for data collection that addresses potential biases and ensures the essential elements needed to review regulatory submissions.