Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

November 25, 2025 | 11:00 am–12:00 pm

Virtual Format

MEETING PURPOSE

To negotiate FDA's Complex Innovative Designs (CID) and Advancing Real-World Evidence (RWE) Pilot Program proposals for PDUFA VIII.

PARTICIPANTS

FDA		INDUSTRY	
Mary Thanh Hai	CDER	Mark Taisey	BIO (Amgen)
Nana Adjeiwaa-Manu	CDER	Donna Boyce	PhRMA (Pfizer)
Marie Bradley	CDER	Annetta Beauregard	BIO
Meghana Chalasani	CDER	Rob Berlin	BIO (Vertex)
Irene Chan	CDER	Steve Berman	BIO
Emily Ewing	CDER	Carl Garner	PhRMA (Eli Lilly)
Andrew Kish	CDER	Kristy Lupejkis	PhRMA
Mark Levenson	CDER	Alison Maloney	PhRMA (Bayer)
Rajanikanth Madabushi	CDER	Adora Ndu	BIO (Bridge Bio)
Janet Maynard	CDER	Katrin Rupalla	PhRMA (J&J)
Amy Comstock Rick	CDER	Drew Sansone	BIO (Alkermes)
		Derek Scholes	BIO
		Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry finalized their approach to FDA's CID proposal and began negotiating FDA's Advancing RWE Pilot Program proposal.

Approach to FDA's CID Proposal

FDA reviewed the CID proposal, noting that it will be incorporated into standard review practice and that FDA will ensure there are appropriate subject matter experts (SMEs) and oversight for CID. Additionally, FDA noted that the Agency is not requesting additional resources for the CID program. FDA and Industry agreed on the approach to the CID proposal and will begin drafting

language for inclusion in the PDUFA VIII commitment letter to reflect the CID program being incorporated into standard review practice.

Approach to FDA's Advancing RWE Pilot Program Proposal

FDA reviewed the Advancing RWE Pilot Program proposal, noting that the pilot launched in early 2023 and that RWE continues to evolve and mature. Additionally, FDA presented the Agency's RWE efforts since PDUFA VI, including public meetings to connect with stakeholders, demonstration research projects, guidances, presentations, publications, and workshops. Lastly, FDA presented on approvals that in part used RWE and reasons for RWE-related denials in response to previous Industry questions on this topic area.

FDA presented the position that the Advancing RWE Pilot Program has shown value and proposed that it be continued under PDUFA VIII given Industry demand for the program, opportunities to continue refining the Agency's approach to RWE, and the Agency's focus on externally sharing how RWE can be used during the drug development process.

FDA-Industry Discussion on Advancing Real-World Evidence Pilot Program Proposal

FDA and Industry agreed that the Agency has made an effort to advance RWE but are not aligned on FDA's proposed approach to the pilot program for PDUFA VIII. Industry presented the position that they have not seen the expected uptake of RWE under the RWE Pilot Program. Industry expressed concerns that continuing the pilot under another PDUFA cycle may not result in broader use of RWE. Additionally, Industry expressed an interest in seeing broader acceptance of RWE-focused studies at the Agency.

FDA asked Industry to clarify what 'expected uptake' means and Industry responded that they had expected more review divisions utilizing RWE for regulatory decision making. FDA explained that uptake of an RWE proposal depends on the Real-World Data (RWD) and whether limitations preclude its use. FDA also expressed that maintaining the Advancing RWE program will help develop consistency in the Agency's RWE-related decision-making. FDA and Industry agreed to continue negotiating the Advancing RWE Pilot Program proposal to align on next steps for PDUFA VIII.

Next Steps

The goals for the next meeting on December 2nd will be to continue discussing Industry's Facilitate First Cycle Reviews proposal, FDA's Model-Informed Drug Development proposal, and FDA's Rare Disease proposal.