



Real World Evidence in support of Regulatory Science for In Vitro Diagnostics



OIR Round Table Briefing - November 2017
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IVD RWE Working Group Member



Working Group Members

Industry

- Abbott
- BD
- Hologic
- IBM Watson
- ICON plc
- Janssen Diagnostics
- Roche
- Sysmex

Government

- FDA | CDRH | OIR
- CDC

MDIC



Real World Evidence (RWE) for IVDs

OBJECTIVE – Build a framework that may be used for applying RWE as a source of evidence used in support of regulatory decision making for IVDs

Following lead of National Evaluation System for Health Technology (NEST) that focuses on access to RWE



RWE IVD Framework Scope

- Current IVD RWE landscape
 - Identify current sources of RWE
 - How it is being applied now
 - Challenges
- Potential applications
- Data Quality and Criteria



Deliverables – current status

- Glossary - provide standardized vocabulary based on currently used terms, input from national and international agencies, standards bodies
- Analysis of current and historical experience to clearly identify and document current RWE usage for IVDs
 - Sources
 - Industry survey
 - Publication survey
 - Challenges and Barriers



Deliverables – future pathways

- Framework describing when RWE may be used to support regulatory decision making
 - Based on current landscape
 - Addresses data bias and quality
 - Includes benefit-risk considerations
- Framework may then be leveraged to apply RWE
 - Retrospective case study
 - Demonstration Project

Timeline & Progress

	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019
General Project Dates	Approve SOW	Value Proposition	Annual Public Forum			Annual Public Forum			
	Team Meetings 5/19, 6/20	Team Meetings 7/5, 7/19, 8/9, 8/23, 9/15	Team Meetings 10/11, 10/25						
Glossary	Initiate Glossary						Final Glossary		
Survey	Plan and Conduct		Conduct Follow up Interviews	Analyze and Begin report	Present Survey Results - AMDM?				
Landscape Analysis	Plan and Conduct			Analyze	Report Survey and Analysis MDICx w/NEST				
Framework			Plan Framework	Finalize Application Scope	ID Data Qualification / Criteria	Draft Framework - September	Public Comment - October Nov/Dec Release Framework		
Retrospective					Begin to Scope	Initiate Retrospective Case Study			
Demonstration Project						Scope Prospective Study	Begin Pilot / Demonstration Project		

- Industry survey – complete
- Follow-up interviews – in progress
- Glossary/Landscape Analysis – in progress
- Framework - initiated