

# Pre-Meeting Workshop on Data Sources for RWE

Chair: Danica Marinac-Dabic (FDA/CDRH)

Co-Chair: Michael Matheny (Vanderbilt University Medical Center)

## Objectives:

- To highlight a portfolio of Real-World Data Sources available for medical device research and surveillance globally
- To review the strengths and weaknesses of data sources in the domains of relevance, reliability, UDI adoption, access, transparency, and interoperability that can augment TPLC evaluation of health technology
- To discuss case examples in an interactive format to give participants an opportunity to share their experiences, express their needs, and promote conversations among multi-stakeholder partners

PRE-  
MEETING  
WORKSHOP  
October 21

TIME	TOPIC	PRESENTER
	<b>Registration</b>	
12:00pm-12:30pm	Attendee Introductions	
12:30pm-12:50pm	Overview of Data Sources: Strengths and Limitations	Eric Barrette (Medtronic)
12:50pm-1:10pm	Registries, CRNs and CRN-COP: The Role of MDEpiNet	Danica Marinac-Dabic (FDA/CDRH)
1:10pm-1:30pm	Claims Data: Examples from US	Jialin Mao (WCM)
1:30pm-2:00pm	EHR: Focus on NEST Test Cases	Michael Matheny (Vanderbilt)
	<b>2:00pm-2:15pm Break</b>	
2:15pm-2:45pm	Spotlight on Attendees- Your Case Examples and Challenges	All; Facilitated by Chairs
2:45pm-3:30pm	UDI/BUILD/AUDI/GUDID: Benefits and Challenges	Joe Drozda (Mercy) Daniel Bertges (VQI) Patrick Lupinetti (FDB)
3:30pm-3:55pm	Interoperability Needs and Successes	Jimmy Tcheng (Duke)
3:55pm-4:20pm	FHIR/App Demo: A Focus on Women's Health	Stephanie Garcia (ONC) Michael Flanigan (ONC) Bilal Chughtai (WCM)
4:20pm-4:35pm	Data Sources for In Silico Studies	Lisa Torosyan (FDA) Vahan Simonyan (WHISE/Emblema)
4:35pm-5:00pm	Discussion/Input on Future Topics of Interest	All; Facilitated by Chairs