


Medical Devices (Includes IVDs)

## Step Inside the Real World™: Real-world Evidence Strategies in FDA Device Applications

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 Monday, September 13, 2021  12:00 PM – 1:15 PM EDT

### Speaker(s)



#### Stephen C. Weber, MD

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MSquared Associates and The Johns Hopkins School of Medicine



#### Sandra Siami, MPH

Senior Vice President, NESTcc  
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**Description:** Real-world evidence (RWE) has been used with increasing success for device applications. Understanding what constitutes valid scientific evidence remains a challenge to the use of this approach. Relevant guidance and case reports of successful device applications using RWE in constructing 510(k), De Novo, and PMA applications will be reviewed. Among this key guidance, the session will explore the principles and role of the NESTcc Research Methods Framework in ensuring rigorous methodologies and high-quality evidence in the design and execution of device evaluation studies. Participants will learn how the Methods Framework can help ecosystem stakeholders in the use of real-world data (RWD), including electronic health records and other sources. RWE, used correctly, can substantially decrease the time to device approval, and the cost of bringing devices to market.

### Learning Objectives:

- Explore the value of using a structured, methodological approach to medical device evaluations.
- Discover the benefit of following guiding principles in developing RWE research studies for regulatory submission.
- Understand the clinical and regulatory aspects of the use of RWE to gain regulatory approval of medical devices.