

# CCOS: Rigor and Reproducibility of Real-World Data Platforms Collaborative Workshop Agenda

The National Cancer Institute (NCI) Shady Grove Campus

9609 Medical Center Drive, Rockville, MD 20850

May 12, 2026

Time	Subject	Presenters
8:30 am	<b>Welcome and Opening Remarks (NCATS &amp; Co-Sponsor)</b>	M. Kurilla, MD, PhD, NCATS M. Desai, MD, PhD, Stanford University CTSA
8:40 am	<b>Session 1: Foundations and Applications of Real-World Data (RWD) &amp; Real-World Evidence (RWE) &amp; Rigor and Reproducibility Principles</b> <ol style="list-style-type: none"> <li><b>Defining RWD, RWE, and principles of rigor, reproducibility, and replicability: Scope and Governance:</b> This subtopic will cover the definitions and scope of Real-World Data (RWD) and Real-World Evidence (RWE) in healthcare, principles of rigor and reproducibility, along with governance frameworks to ensure rigor and to building trust RWE.</li> <li><b>Exploring Key RWD Platforms and Applications:</b> This subtopic will provide an overview of key healthcare-related RWD platforms, such as TriNetX, Epic Cosmos, Enact, N3C, and NIH registries, and discuss their applications in research, clinical practice, and population health, emphasizing the role of reproducibility in ensuring reliable outcomes.</li> <li><b>The Transformative Potential of RWE in Healthcare Innovation:</b> This subtopic will highlight how RWE involves different levels of evidentiary standards and drives advancements in personalized medicine and healthcare delivery, showcasing examples of successful applications that improve outcomes, while addressing the implications for healthcare, policy, and research, including the cost of poor reproducibility.</li> </ol>	M. Desai, MD, PhD, Stanford University CTSA
9:10 am	<b>Panel Session 2: Study Design and Methodologic Challenges in Generating Rigorous and Reproducible Real-world Evidence</b> <ol style="list-style-type: none"> <li><b>Techniques for Evidence Generation:</b> Methods for collecting, integrating, and analyzing healthcare-related RWD, ensuring data quality and scalability.</li> <li><b>Challenges with reproducibility in RWE generation:</b> Overcoming barriers to reliable evidence generation.</li> <li><b>Team Science and Collaboration:</b> Importance of interdisciplinary collaboration in generating RWE, strategies for fostering team science to tackle complex healthcare challenges.</li> </ol>	<b>Moderator:</b> N. Carlson, PhD, University of Colorado Anschutz <b>Speakers/Panelist</b> J. Brown, PhD TriNetX M. Bradley, PhD, FDA L. Barnes, MD, Stanford University
10:10 am	<b>Networking Break (30 mins)</b>	
10:40 am	<b>Panel Session 3: Governance models for sustainable and trustworthy RWD</b> <ol style="list-style-type: none"> <li><b>Governance models:</b> Models that treat RWD as infrastructure rather than data assets alone. How governance choices shape trust, accountability, auditing, and sustainability of RWD platforms across public, private, and hybrid contexts, taking a cue from public utility models.</li> <li><b>Balancing privacy, access, and public benefit:</b> Governance tradeoffs in large-scale RWD ecosystems, including protection versus stewardship, individual control versus population benefit, and inclusion versus regulation. Governance regulation such as access controls, transparency, and accountability to enable ethical reuse of RWD while maintaining public trust, minimizing risk, and ensuring benefits accrue to patients, health systems, and the public.</li> <li><b>Aligning incentives and realizing sustainability:</b> Aligning economic incentives, ownership models, and regulatory expectations. Public-private arrangements, compensation, and value-return models. Strategies for sustainability, while supporting reproducibility, broad community access and innovation.</li> </ol>	<b>Moderator:</b> M. Haendel, MD, University of North Carolina Chapel Hill <b>Speakers/Panelist</b> T. Matose, MBe, PhD, Cincinnati Children’s Hospital M. Banks, PEDSnet Family Advisory Council R. O’Hara, PhD, Stanford University CTSA
11:40 am	<b>Networking Lunch (75 minutes)</b>	
12:55 pm	<b>Topic Identification for Breakout Sessions</b>	R. O’Hara, PhD, Stanford University CTSA M. Desai, MD, PhD, Stanford University CTSA
1:25 pm	<b>Breakout Sessions: 5 Concurrent Topics</b>	NA
3:10 pm	<b>Networking Break (30 mins)</b>	
3:40 pm	<b>Actions to Barriers:</b> Presentations from breakouts with Q&A panel	R. O’Hara, PhD, Stanford University CTSA
4:25 pm	<b>Closing Remarks</b>	R. O’Hara, PhD, Stanford University CTSA
4:30 pm	<b>Adjourn</b>	

**\*Note: This agenda is tentative and can change at any time! (All times are ET!)**