Translating Real-World Data into Real-World Evidence Project
Webinar 1: US and European Stakeholder Perspectives

Draft Agenda
Tuesday, July 20, 2021
10:00am – 12:00pm EST

Meeting Open		
Moderators: *Veronica Miller, Forum for Collaborative Research & Sandra Lehrman, Lehrman Family Research Fund*		
10:00am EST	Welcoming Remarks & Program Introductions	*Veronica Miller, Forum for Collaborative Research*
10:10am EST	Discussion with Leadership Representatives from US and Europe a. Overarching Principles for Fit-for-Purpose Data b. Data Quality and Effective Standards for Regulatory Process c. Practical Application of Real-World Evidence	*John Concato, FDA* *Gianmario Candore, EMA/COMP*
10:40am EST	Lessons Learned from Use of Real-World Data as External Controls	*Bettina Hansen, University of Toronto*
10:55am EST	Fit-for-Purpose Data	*Jerry Vockley, University of Pittsburgh* *Satrajit Roychoudhury, Pfizer*
11:15am EST	Multi-Stakeholder Panel a. The Role of Data at Different Stages of Drug Development: From Proof of Concept to Confirmatory b. Translation of Real-World Data from Various Sources to Fit-for-Purpose Evidence	*Jerry Vockley, University of Pittsburgh* *Satrajit Roychoudhury, Pfizer* *John Concato, FDA* *Ruby Mehta, FDA* *Violeta Stoyanova, EMA/COMP* *Bettina Hansen, University of Toronto* *Ruth-Anne Pai, PSC Partners Seeking a Cure*
11:45am EST	Preview Webinar 2: Statistical Analysis and Data Quality	*Rima Izem, Novartis*
11:50am EST	Conclusions/ Next Steps	*Veronica Miller, Forum for Collaborative Research*
Adjourn Webinar		