

3:50 pm - 4:05 pm

## 13<sup>th</sup> Annual Conference on Statistical Issues in Clinical Trials Center for Clinical Epidemiology and Biostatistics April 12, 2021 (Virtual)

## Cluster Randomized Clinical Trials (CRTs): Challenges and Opportunities

## Morning Moderator: Jesse Yenchih Hsu (University of Pennsylvania)

8:30 am – 8:35 am	Welcome: Jeff Morris, PhD (University of Pennsylvania)
8:35 am – 8:45 am	Opening Remarks/Logistics: Susan S. Ellenberg, PhD (University of Pennsylvania)
8:45 am – 9:00 am	<b>David M. Murray, PhD</b> (National Institute of Health): <i>Overview: Innovations in the Design and Analysis of Group-or Cluster-Randomized</i>
9:00 am – 9:25 am	<b>Victor De Gruttola, ScD</b> (Harvard University): Using network-level (and individual level) Information in design and analysis
9:25 am – 9:50 am	<b>Luke J. Keele, PhD</b> (University of Pennsylvania): <i>Complexities Caused by Noncompliance in Cluster Randomized Trials</i>
9:50 am – 10:15 am	<b>James P. Hughes, PhD</b> (University of Washington): <i>Current issues in the design and analysis of stepped wedge trials</i>
10:15 am – 10:30 am	BREAK
10:30 am – 11:10 am	<b>Morning Panel Discussion</b> : Alisa J. Stephens-Shields, PhD (University of Pennsylvania), Karla Hemming, PhD (Birmingham), and Michael A. Proschan, PhD (National Institute of Health)
11:10 am – 11:50 am	MORNING OPEN FORUM
11:50 am – 12:35 pm	LUNCH BREAK
Afternoon Moderator: James D. Lewis, MD, MSCE (University of Pennsylvania)	
12:35 pm – 1:00 pm	Lawrence H. Moulton, PhD (Johns Hopkins University): Randomization: Beyond the
	Closurization Principle
1:00 pm – 1:25 pm	Closurization Principle  Natalie E. Dean, PhD (University of Florida): The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness during Infectious Disease Outbreaks
1:00 pm – 1:25 pm 1:25 pm – 1:50 pm	Natalie E. Dean, PhD (University of Florida): The Ring Trial Design for the Estimation of Vaccine
	Natalie E. Dean, PhD (University of Florida): The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness during Infectious Disease Outbreaks  Deborah J. Donnell, PhD (University of Washington): Challenges in Implementing CRTs: from
1:25 pm – 1:50 pm	Natalie E. Dean, PhD (University of Florida): The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness during Infectious Disease Outbreaks  Deborah J. Donnell, PhD (University of Washington): Challenges in Implementing CRTs: from Hawthorne Effect to Measurement Bias  Weili He, PhD (AbbVie): Practical Considerations in Utilizing Cluster Randomization Trials in
1:25 pm – 1:50 pm 1:50 pm – 2:15 pm	Natalie E. Dean, PhD (University of Florida): The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness during Infectious Disease Outbreaks  Deborah J. Donnell, PhD (University of Washington): Challenges in Implementing CRTs: from Hawthorne Effect to Measurement Bias  Weili He, PhD (AbbVie): Practical Considerations in Utilizing Cluster Randomization Trials in Medical Research
1:25 pm – 1:50 pm 1:50 pm – 2:15 pm 2:15 pm – 2:30 pm	Natalie E. Dean, PhD (University of Florida): The Ring Trial Design for the Estimation of Vaccine Efficacy and Effectiveness during Infectious Disease Outbreaks  Deborah J. Donnell, PhD (University of Washington): Challenges in Implementing CRTs: from Hawthorne Effect to Measurement Bias  Weili He, PhD (AbbVie): Practical Considerations in Utilizing Cluster Randomization Trials in Medical Research  BREAK  Afternoon Panel Discussion: David M. Murray PhD (National Institutes of Health), Jeffrey N.

Closing Remarks: Mary E. Putt, PhD, ScD (University of Pennsylvania)