DEPARTMENT of BIOSTATISTICS EPIDEMIOLOGY & INFORMATICS | Perelman School of Medicine University of Pennsylvania

12th Annual Conference on Statistical Issues in Clinical Trials

Center for Clinical Epidemiology and Biostatistics
April 17, 2019
Arthur H. Rubenstein Auditorium
Smilow Center for Translational Research (SCTR)

Electronic Health Records (EHR) in Randomized Clinical Trials: Challenges and Opportunities

7:30 am– 8:30 a m	**REGISTRATION AND BREAKFAST**	
8:30 am –8:40 am	**WELCOME**	
8:40 am – 8:55 am	**Opening Remarks/Logistics: Susan S. Ellenberg, PhD -** University of Pennsylvania	
	AM MODERATOR: KRISTIN LINN, PhD - University of Pennsylvania	
	CASE STUDIES	
8:55 am - 10:15am	**DENISE ESSERMAN, PhD** Yale University	From Screening to Ascertainment of the Primary Outcome using EHR, Challenges in the STRIDE Trial
	STEVEN ZELIADT, PhD University of Washington	The APPROACH Trial: **A**ssessing **P**ain, **P**atient **R**eported **O**utcomes and **C**omplementary and Integrative **H**ealth
	RICHARD PLATT, MD, MSc Harvard Medical School and Harvard Pilgrim Health Care Institute	The IMPACT-AFib Trial: **IM**plementation of an RCT to im**P**rove Treatment with Oral **A**nti**C**oagulan**T**s in Patients with Atrial Fibrillation
	MATTHEW T. ROE, MD Duke University	Leveraging Electronic Health Record Data for Pragmatic Randomized Trials in Learning Health Care Systems in the United States – Lessons Learned from the ADAPTABLE Trial
10:15 am - 10:40am	**BREAK**	
10:40 am - 11:10 am	**AM OPEN FORUM**	
11:10 am – 11:35am	**BENJAMIN A. GOLDSTEIN, PhD -** Duke University. *Design Considerations for Running Health System Based Trials Through the Electronic Health Record*	
11:35 am - 12:00 pm	**MARK LEVENSON, PhD -** Food and Drug Administration**.** *Regulatory perspective to performing RCTs in an EHR environment*	
12:00 pm-1:00 pm	**LUNCH**	
	PM MODERATOR: PAMELA SHAW, PhD - University of Pennsylvania	
	STATISTICAL METHODS	
1:00 pm -1:30 pm	**PATRICK J. HEAGERTY, PhD -** University of Washington. *Addressing heterogeneity in the data, design, and analysis of pragmatic trials embedded in delivery systems*	
1:30 pm –2:00 pm	**SUSAN M. SHORTREED, PhD -** Kaiser Permanente Washington Health Research Institute. *Using real-world data to improve trial design*	
2:00 pm- 2:30 pm	**JINBO CHEN, PhD -** University of Pennsylvania**.** *Study design issues for exploiting EHRs to design clinical trials*	
2:30 pm – 3:00 pm	**BREAK**	
3:00 pm – 3:30 pm	**PM Panel Discussion** **REBECCA HUBBARD, PhD -** University of Pennsylvania **BILL CAPRA, PhD -** Genentech	
3:30 pm – 4:30 pm	**PM OPEN FORUM**	
4:30 pm - 4:40 pm	**CLOSING REMARKS:** Susan S. Ellenberg, PhD - University of Pennsylvania	