

Forum Conference - April 18, 2019
"Pioneers for Discovery: Reinventing the Research Enterprise"
Day 2 Schedule

Location: All Sessions are in Ballroom A and B unless otherwise specified.

7:00- 8:00	Registration/Breakfast **
8:00- 8:15	Welcome and Opening Remarks
8:15- 9:15	<p>Building Communication for Community-Based Research¹</p> <p><i>Keynote address will focus on the importance of communication between study teams and participants in community-based research – with a special focus on social determinants of health.</i></p> <p>Susmita Pati, M.D., MPH, Alan Alda Center for Communicating Science®</p>
9:15-10:00	<p>Viewing Consent to Clinical Trials Through the Lens of Clinical Consent¹</p> <p><i>Implementing the Common Rule revisions in relation to writing informed consent forms for research by looking at good consent practices that are used for making decisions about clinical care.</i></p> <p>Jerry Menikoff, M.D., J.D., OHRP</p>
10:00-10:15 Break**	
10:15-11:00	<p>FDA Real World Evidence Program - Opportunities and Challenges¹</p> <p>Participants will hear updates on the FDA’s Real-World Evidence (RWE) Program and Framework - opportunities and challenges associated with innovative technology, novel study designs, and demonstration projects to fill knowledge gaps.</p> <p>M. Khair ElZarrad, PhD, MPH, Office of Medical Policy, CDER, FDA</p>
11:00-11:45	<p>Making Mobile Clinical Trials a Reality¹</p> <p><i>Speakers will share recommendations from the Clinical Trials Transformation Initiative on incorporating mobile technologies into clinical trials, highlighting important scientific, practical, and ethical considerations for investigators, study staff, and IRB</i></p>

	<p><i>representatives.</i></p> <p>Michele Russell-Einhorn, J.D., Advarra Greg Licholai, M.D., MBA, Yale School of Management; PRA Health Sciences</p>
<p>11:45-12:45 Lunch and Networking ** Location: Ballroom C</p>	
<p>12:45-1:45</p>	<p>The Alda Method®: Making the Choice to Connect</p> <p><i>Alan Alda Center for Communicating Science® instructors will introduce the Alan Alda Method® principles on how to craft short, clear, information to non-scientific stakeholders.</i></p> <p>Elizabeth Bojsza, MFA, Alan Alda Center for Communicating Science® Brenda MacArthur, Ph.D., Alan Alda Center for Communicating Science®</p>
<p>1:45-2:00 Break**</p>	
<p>2:00-3:30</p>	<p>Breakout Sessions</p>
<p>Track 1</p>	<p>Fostering a Community Based Approach to Successful Research Location: Courtyard 4 and 5</p> <p>Lessons Learned from Patient Engagement Initiatives</p> <p><i>National Center for Advancing Translational Science Clinical and Translational Research Award Consortium members will share their examples of their patient engagement initiatives Each will provide their unique perspective and identify challenges that must be addressed to work meaningfully together to conduct patient, family and community-centered research.</i></p> <p>Nia Indelicato, MNO, University of Arkansas for Medical Sciences Cheryl Jernigan, University of Kansas Medical Center Kimberly Johnson, University at Buffalo Kim Kimminau, Ph.D., MA, University of Kansas Medical Center Valentine Mukudente, University of Utah Louisa Stark, Ph.D., University of Utah Laurene Tumiel-Berhalter, Ph.D., University at Buffalo Ashley Young, University of Arkansas for Medical Sciences</p>
	<p>Stakeholder Engagement Through Training and Regulatory Collaboration Efforts</p>

Conference participants will engage in a table top exercise to discuss key information they consider essential to include in the concise summary. Additionally, the session will include a "Design Studio" demonstration where patient, family, caregiver and community members will offer feedback.

Karen Blackwell, MS, CIP, University of Kansas Medical Center
Wendy Cogan, University of Kansas Medical Center
Cheryl Jernigan, University of Kansas Medical Center
Kimberly Johnson, University at Buffalo
Kim Kimminau, Ph.D., MA, University of Kansas Medical Center
Lynn Miller, University of Kansas Medical Center
Valentine Mukudente, University of Utah
Doug Sparling, University of Kansas Medical Center
Ashley Young, University of Arkansas for Medical Sciences
Ruben Zaragoza, University of Kansas Medical Center

Track 2

Enabling Clinical Research through Electronic Health Records and Big Data Initiatives

Location: Courtyard 1 and 2

Leveraging the Electronic Health Record System to Support Research

Use of the electronic health record (EHR) has evolved beyond the EHR as just a source for secondary data use. This presentation will describe how the EHR is becoming instrumental in subject recruitment, research data capture, and study administration, and the implications of this evolution related to human subject protections.

Tamara Winden, Ph.D., FHIMSS, MBA, University of Kansas Health System, University of Kansas Medical Center

NIH and PCORnet Big Data Resources for Catalyzing Observational Studies and Trials

In this interactive session, participants will hear approaches for Electronic Health Records (EHR) and clinical research integration and its intersection with human subject's protection. Two national initiatives, PCORnet and the NIH Accrual to Clinical Trials Network, that leverage EHR data to improve study development, execution, and relevance for patients and communities, will be discussed.

Russ Waitman, Ph.D., University of Kansas Medical Center

Track 3	<p>The Alda Method® Building Some Basics</p> <p>Location: Courtyard 3</p> <p><i>Interactive session utilizing a sequence of improvisational theater techniques developed to help speak more vividly and expressively about research and foster a more genuine connection with stakeholders.</i></p> <p>Elizabeth Bojsza, MFA, Alan Alda Center for Communicating Science® Brenda MacArthur, Ph.D., Alan Alda Center for Communicating Science®</p>
3:30-3:45	Break**
3:45-4:30	<p>“Ask the Feds”¹</p> <p>Jerry Menikoff, M.D., J.D., OHRP; Yvonne Lau, MBBS, MBHL, Ph.D., OHRP; Jaime Hernandez, J.D., M.Be., OHRP</p>
4:30-4:45	Closing Remarks
4:45-6:00	<p>Networking Reception** Location: Outside Ballroom A</p>

** This portion of the event is independently sponsored. OHRP staff and resources will not be used to develop, promote or otherwise support this portion of the event.

¹ Eligible for CIP Credit