Bridging Clinical Research & Clinical Health Care
a clinical research collaborative

DAY ONE AGENDA

TUESDAY, APRIL 3	
6-8 PM	Exhibitor Access to Set Up
WEDNESDAY, APRIL 4	
7-7:45 AM	Registration, Continental Breakfast and Exhibits
7:45-8:15 AM	Welcome to the Bridging Clinical Research & Clinical Health Care Collaborative **Badhri Srinivasan, ABD, MS, Head, Global Development Operations, Novartis**
8:15-8:45 AM	Collaborative Keynote Presentation **Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research, FDA**
BRIDGING REGULATORY (SPONSORED BY ADVARRA)	
Bridging Regulations to Real-World Health Care Session Moderator: Jeff Wendel, President, Advarra	
8:45-9 AM	Use of Electronic Health Records in Clinical Investigations **Leonard Sacks, MD, Acting Deputy Director, Office of Medical Policy, CDER, FDA**
9-9:15 AM	New Laws and Regulations Affecting Expanded Access, Research, Consent and IRB Oversight **David Vulcano, MBA, MSW, Assistant Vice President and Responsible Executive for Clinical Research, HCA Healthcare**
9:15-9:30 AM	Using eConsent to Improve Patient Understanding and Regulatory Compliance **Michele Russell-Einhorn, JD, Chief Compliance Officer and Institutional Official, Advarra**
9:30-9:45 AM	**Discussion**
Harmonization of Common Data Models to Facilitate the Generation of Real-World Evidence Session Moderator: Mitra Rocca, Associate Director, Medical Informatics, FDA	
9:45-10 AM	Harmonization of Various Common Data Models and Open Standards for Evidence Generation **Mitra Rocca, Associate Director, Medical Informatics, FDA**
10-10:15 AM	Oncology Use Case for the PCORTF Model Harmonization Project **Sean Khozin, MD, MPH, Associate Director (Acting), Oncology Center of Excellence, FDA**
10:15-10:30 AM	Panel Discussion **Michael Ibara, PharmD, Elligo Pharmacovigilance Expert for the PCORTF Model Harmonization Use Case Project**
10:30-11 AM	**Networking Break and Exhibits**
Regulatory Implications and Opportunities With New Technology in Clinical Research	
11-11:15 AM	Case Study: Use of Wearables and Sensors in Clinical Trials by University of Chicago and Litmus Health **Sam Volchenboum, MD, PhD, Director, Center for Research Informatics, The University of Chicago**
11:15-11:30 AM	Case Study: Biometric Monitoring Devices for Assessing Endpoints in Clinical Trials: Developing an Ecosystem **Stephen Arnerić, PhD, Executive Director, Coalition Against Major Diseases, and Professor of Research, University of Arizona College of Medicine**

11:30-11:45 AM	Case Study: FDA's Perspective on the Use of Mobile Devices in Clinical Trials **Ken Skodacek, MS, Policy Analyst, Clinical Trials Program, Center for Devices and Radiological Health, FDA**
11:45 AM-12 PM	**Discussion**
12-1 PM	**Networking Lunch and Exhibits**
BRIDGING TECHNOLOGY (SPONSORED BY SAAMA TECHNOLOGIES, INC)	
Creating Synergies Between Health Care and Clinical Trial Data Through Technology Session Moderator: Karim Damji, Senior Vice President, Product Management and Marketing, Saama	
1-1:30 PM	A Framework to Implement Trial Management Analytics **Karim Damji, Senior Vice President, Product Management and Marketing, Saama Technologies, Inc.**
1:30-1:45 PM	How AI is Transforming Patient Recruitment for Clinical Trials **Wout Brusselaers, MBA, Co-Founder and Chief Executive Officer, Deep 6 AI**
1:45-2 PM	**Discussion**
Role of Electronic Health Records in Bridging Research With Health Care Session Moderator: Rebecca Kush, PhD, Scientific Innovation Officer, Elligo Health Research	
2-2:15 PM	Current Uses of Electronic Health Records for Clinical Research, Moving Toward a Learning Health System **Rebecca Kush, PhD, Scientific Innovation Officer, Elligo Health Research**
2:15-3 PM	**Panel Discussion:** • **Lauren Becnel,** PhD, Vice President of Strategy and Innovation, CDISC • **Jose Galvez,** MD, NIH Clinical Center • **Hugh Levaux,** PhD, Founder and CEO, Protocol First • **Amy Nordo,** MMCi, BSN, CPHQ, Product Manager, Duke University Office of Research Informatics • **Era Prakash,** MHSA, Director, Product Management, Allscripts • **Prasanna Rao,** IBM Watson Health • **Komathi Stem,** MSE, Founder and CEO, monARC Bionetworks
3-3:30 PM	**Networking Break and Exhibits**
Bridging Clinical Research and Clinical Care in Precision Oncology Oncology Keynote Speaker: Laura Esserman, MD, MBA, Director, UCSF Carol Franc Buck Breast Care Center	
3:30-4 PM	Checklists: Integrating Care and Research to Re-engineer Health Care **Laura Esserman, MD, MBA, Director, UCSF Carol Franc Buck Breast Care Center**
4-4:15 PM	**Marty Tenenbaum, PhD, Founder and Chairman, Cancer Commons**
4:15-4:30 PM	Ideal Organized Clinical Trials **George Lundberg, MD, Chief Medical Officer, Self Care Catalysts**
4:30-4:45 PM	Clinical Trial Accrual: Can We Use Technology To Drive Enrollment? **B.J. Rimel, MD, OB/GYN, Gynecologic Oncologist, Cedars-Sinai Medical Center**
4:45-5 PM	Video Presentation: *Changing the Culture, Changing the Establishment* **Sponsored by BlueCloud**
5:30-7 PM	**Networking Reception, Sponsored by Frenova Renal Research (Location: Annapolis 1-4)**

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DAY TWO AGENDA

THURSDAY, APRIL 5	
7-8 AM	**Patient Advocacy Matching Breakfast:** Opportunity for attendees to meet with various patient advocacy groups **Moderator: John Lewis, MA, Consultant, Intersect Strategies** **Participants:** • **Sarah Berk,** MPH, Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson's Research • **Keith Fargo**, PhD, Director of Scientific Programs and Outreach, Alzheimer's Association • **Amy Miller**, PhD, President and CEO, Society for Women's Health Research • **Andrew Spiegel,** JD, Executive Director, Global Colon Cancer Association and Global Pneumonia Prevention Coalition • **Hrant Jamgochian,** JD, CEO, Dialysis Patient Citizens
BRIDGING PEOPLE AND PROCESSES	
8-8:15 AM	Welcome and Introduction to Bridging People and Processes Session **Ivor Clarke, CEO, SubjectWell**
8:15-8:45 AM	Bridging People and Processes Keynote Presentation **Greg Simon, JD, President, Biden Cancer Initiative**
8:45-9:15 AM	Patient Keynote Presentation **T.J. Sharpe, Cancer Survivor and Patient Advocate**
Patient Perspective on Research and Health Care Session Moderator: Joshua C. Rubin, JD, MBA, MPH, MPP Program Officer for Learning Health System Initiatives, University of Michigan Learning Health Sciences	
9:15-9:30 AM	Patient Empowerment and the Learning Health System **Joshua C. Rubin, JD, MBA, MPH, MPP, Program Officer for Learning Health System Initiatives, University of Michigan Learning Health Sciences**
9:30-9:45 AM	Principles of Advocate Involvement in Access Decisions **Andrew Spiegel, JD, Executive Director, Global Colon Cancer Association and Global Pneumonia Prevention Coalition**
9:45-10 AM	Enhancing Clinical Trial Design Through the Patient Journey **Sarah Berk, MPH, Associate Director, Research Partnerships, The Michael J. Fox Foundation for Parkinson's Research**
10-10:15 AM	**Discussion**
10:15-10:30 AM	**Networking Break and Exhibits**
CRO Perspective: Bridging Clinical Trial Processes to Real-World Health Care Session Moderator: David Windley, MBA, Managing Director, Jefferies LLC	
10:30-10:45 AM	**David Windley, MBA, Managing Director, Jefferies LLC**

10:45-11 AM	The Use of Real-World Diagnostic Data to Inform Clinical Trial Design Optimization **Bill Hanlon, PhD, Chief Development Officer, Regulatory Affairs, Strategic Product Development, Market Access Solutions, Covance**
11-11:15 AM	**Clare Grace, PhD, Vice President of Site and Patient Access, Syneos Health**
11:15-11:30 AM	**Kent Thoelke, Executive Vice President, Scientific, Medical Affairs and Safety, Commercialization Services, PRA Health Sciences**
11:30-11:45 AM	**Discussion**
11:45 AM - 12:45 PM	**Lunch With Media Partners and Exhibits**
Established Bridges: Health Care Integrations With Clinical Research Session Moderator: Kurt Mussina, MBA, General Manager, Frenova Renal Research	
12:45-1 PM	**Kurt Mussina, MBA, General Manager, Frenova Renal Research**
1-1:15 PM	The Practicality of Big Data in a Community-Based Setting **Dee Anna Smith, Chief Executive Officer, Sarah Cannon**
1:15-1:30 PM	**Jennifer Weis, Business Analyst, Mayo Clinic**
1:30-1:45 PM	**Discussion**
New and Returning Investigators: Why Clinicians Choose to Add Clinical Trials to Their Practice (Or Not) Session Moderator: Deirdre BeVard, Chief Operating Officer, Elligo Health Research	
1:45-2 PM	Born Again Investigators: Why Health Care Investigators Are Adding Clinical Trials to Their Practices Now **Ken Getz, MBA, Director of Sponsored Research, Associate Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine**
2-2:30 PM	**Panel Discussion:** • **Peter Glass**, MB, ChB, FFA, Chief Medical Officer, Advantia Health • **Christian Burns**, President of Clinical Operations and Marketing, ClinEdge • **Raymond Nomizu**, JD, Co-Founder, Clinical Research IO
Pharma's Role in Bridging Clinical Research and Health Care Session Moderator: Joseph Kim, Senior Advisor, Clinical Innovation, Eli Lilly and Company, TransCelerate	
2:30-3 PM	A Case for Pharma Playing an Integral Role in Bridging Clinical Research & Health Care **Ken Getz, MBA, Director of Sponsored Research, Associate Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine**
3-3:15 PM	How Can We Influence Clinical Trial Awareness, Access and Information Exchange? **Joseph Kim, Senior Advisor, Clinical Innovation, Eli Lilly and Company, TransCelerate**
3:15-3:30 PM	**Craig Lipset, Head of Clinical Innovation, Pfizer**
3:30-3:45 PM	**Discussion**
3:45-4 PM	**Wrap-Up**