ExpandedAccessSummit

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The Third Annual Expanded Access Summit®
January 27-29, 2020
National Press Club | Washington DC

Conference Agenda v1

Monday, January 27

6:00 – 9:00pm	Session A: The Workshop Global Regulation and Industry Best Practices
6:00 – 6:30pm	**Evening Check-in and Networking** • Meet the event directors and speakers • Hors d'oeuvres, beverages
6:30 – 6:40pm	**Introduction:** Why do we have pre-market access? What are the legal, ethical, and practical underpinnings? • **Jonathan Darrow;** JD Faculty Member, Harvard Medical School
6:40 – 7:10pm	**US Regulation,** Project Facilitate and government initiatives to lower barriers • **Richard Klein;** Former Director, Patient Liaison Program, FDA • **Amy Barone, MD;** Medical Officer, Oncology Center of Excellence, FDA
7:10 – 7:40pm	**Global Regulatory Landscapes,** including reimbursement & data capture • **David Schwicker, PhD;** ORPHA Strategy Consulting
7:40 – 8:00pm	**Break**
8:00 – 8:20pm	**Named Patient EAPs and Cohort EAPs;** what they're each for • **David Farber;** Senior Partner, King & Spalding
8:20 – 8:40pm	**Utilizing the Range of EA Channels;** a strategy primer on where and when to undertake pre-market access programs • **Kevin Weatherwax;** Managing Director, Michigan Institute for Clinical and Health Research, University of Michigan Health System
8:40 – 9:00pm	**Business Agreements with Health Care Providers;** traditional and non-traditional trial sites • **Erika Segear, PhD, RAC;** Associate Director of Regulatory Affairs, Duke University School of Medicine • **Chris Beardmore;** CEO, Anova LLC
9:00pm	**Workshop Adjourned**

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Tuesday, January 28 (Morning)

8:00am – 5:00pm	**Session 1: The Global Stakeholder Forum** **Integrating Expanded Access into the Clinical Development Process**
	
7:30 – 8:15am	**Morning Check-in and Networking** • Meet the exhibitors • Hot breakfast
8:15 – 8:30am	**Opening Remarks** • **Jess Rabourn, CFA;** Executive Producer, Expanded Access Summit | CEO, WideTrial, Inc.
8:30 – 9:30am	**The Founders;** Are we meeting the original promise of Expanded Access? • **Frank Young, MD, PhD** EVP Clinical & Reg Affairs, TissueTech Inc.; Former FDA Commissioner, 1984-1989 • **Tony Fauci, MD** Director, National Institute of Allergy and Infectious Diseases (NIAID) 1984-Present • **Stuart Nightingale, MD** Consultant on Public Health and Regulatory Affairs, NIH Former FDA Associate Commissioner for Health Affairs • **Steve Usdin** Senior Editor, BioCentury
9:30 – 10:15am	**A Smarter, More Inclusive Drug Development Process;** FDA Outlook • **Janet Woodcock, MD;** Director, Center for Drug Evaluation and Research (CDER), FDA
10:15 – 10:30am	**Break**
10:30 – 11:30am	**Seeing Past the Narratives;** Stakeholder leaders examine the politics, misconceptions, and competitive interests that can hold back innovation in this space • **Mark Boutin;** Chief Executive Officer, National Health Council • **Jeff Leider;** President, X2, "Let Them Be Little" Foundation • **Marjorie Speers, PhD;** Executive Director, Clinical Research Pathways • **Anne Cropp, PharmD;** Chief Science Officer, Early Access Care LLC
11:30am – 12:30pm	**Strategies for Expanded Access Feasibility and Utility;** Operational and scientific considerations for meaningful engagement of the intended patient population(s) • **Paul Aliu, PharmD;** Global Head of Medical Governance, Novartis Oncology • **Marcel van Kuijck, PhD;** Vice President, Global Medical Affairs, Ultragenyx

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Tuesday, January 28 (Afternoon)

8:00am – 5:00pm	Session 1: The Global Stakeholder Forum Integrating Expanded Access into the Clinical Development Process
12:30 – 1:15pm	**Buffet Lunch**
1:15 – 1:45pm	**Lunch Keynote** • **Chris Austin, MD;** Director, National Center for Advancing Translational Sciences, NIH
1:45 – 3:00pm	**Designs for Integrating Treatment and Research;** Pragmatic trials and virtual clinical trials under Expanded Access pathways • **Sean Khozin, MD, MPH** [*Pending Confirmation]; Founding Director, Information Exchange and Data Transformation (INFORMED), FDA • **Suanna Bruinooge, MPH;** Director of Research Strategy, CENTRA, ASCO • **Stuart Bell, PhD;** Vice President, Real World Evidence, Inceptua Medicines Access • **Amy Barone, MD;** Medical Officer, Oncology Center of Excellence, FDA
	
3:00 – 4:00pm	**HealthCare Delivery Systems as Partners for Access;** The symbiosis of stakeholders • **Michael Kurilla, MD, PhD;** Director, Clinical and Translational Science Awards (CTSA) Program, NCATS, NIH • **Andrew Shuman, MD, FACS;** Chief of Clinical Ethics Services, University of Michigan Medical School • **Erika Segear, PhD, RACS;** Associate Director of Regulatory Affairs, Duke University School of Medicine • **Jonathan Darrow, JD;** Faculty Member, Harvard Medical School
4:00 – 5:00pm	**Frameworks for Cost Recovery;** Sustainability at scale; stakeholder economics • **Jess Rabourn, Chartered Financial Analyst;** CEO, WideTrial Inc. • **Peter Pitts;** President, Center for Medicine in the Public Interest (CMPI) • **Alexander Natz;** Secretary General, European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) • **National Director of U.S. HealthCare Delivery System,** [*TBA, pending confirmation]
5:00pm	**Session Adjourned**

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Tuesday, January 28 (Evening)

5:15 – 8:00pm	Grand Reception
	
	Gourmet Food and Beverage
	Exhibitor Galleries Open
	Music, Ping Pong Tournament, Additional Activities

6:00 – 8:00pm	Session B: The Innovators Showcase Real Solutions and Service Offerings Presented by Leaders in the Field
6:00 – 6:30pm	**Set 1** • Four presenters, schedule TBA 6 minutes each, 1-minute turnaround
6:30 – 6:45pm	Break
6:45 – 7:15pm	**Set 2** • Four presenters, schedule TBA 6 minutes each, 1-minute turnaround
7:15 – 7:30pm	Break
7:30 –8:00pm	**Set 3** • Four presenters, schedule TBA 6 minutes each, 1-minute turnaround
8:00pm	Showcase Adjourned

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Wednesday, January 29 (Morning)

8:00am – 5:00pm	Session 2: The Interactive Forum Charting the Course for Modern Clinical Development
7:45 – 8:15am	**Morning Check-in and Networking** • Exhibitor galleries open • Continental breakfast
8:15 – 8:30am	**Recap of Day 1** • **Jess Rabourn, CFA;** Executive Producer, Expanded Access Summit | CEO, WideTrial, Inc.
8:30 – 9:30am	**Empowering Patients Who Seek Treatment Options** • **Behtash Bahador;** Director, Center for Information and Study on Clinical Research Participation (CISCRP) • **Kelly Ranallo;** President, Turner Syndrome Global Alliance; Associate, Rare Diseases, Sanofi • **Naomi Lopez Bauman;** Director of Healthcare Policy, Goldwater Institute • **Andrew Shuman, MD, FACS;** Chief of Clinical Ethics Services, University of Michigan Medical School
9:30 – 10:00am	**Adding "Big Data" Technology to EA Clinical Outcomes,** Computational advancements for getting the most from large sets of secondary outcomes data • **Nationally Recognized "Precision Medicine" Expert, to be announced**
10:00 – 10:30am	**Break**
	
10:30am – 12:00pm	**Who Should Pay for Exploratory Treatment Access?** • **Mark Boutin;** Chief Executive Officer, National Health Council • **Jeff Leider;** President, X2, "Let Them Be Little" Foundation • **National Director of Integrated Health Delivery System, to be announced** • **David Farber, JD;** Senior Partner, King & Spalding
12:00 – 12:15pm	**Introduction to the Interactive Strategy Challenge** • **Behtash Bahador;** Director, Center for Information and Study on Clinical Research Participation (CISCRP)

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Wednesday, January 29 (Afternoon)

8:00am – 5:00pm	**Session 2: The Interactive Forum** **Charting the Course for Modern Clinical Development**
12:15 – 1:15pm	**Box Lunch**
1:15 – 2:30pm	**Interactive Strategy Challenge:** Breakout groups respond to challenge scenario(s) • **Behtash Bahador;** Director, Center for Information and Study on Clinical Research Participation (CISCRP) • **Conference Attendees Representing Breakout Groups On-Stage**
2:30 – 3:00pm	**Policy Recommendations / Resolutions:** Moderated round-table forum for publishable outcomes of the Summit • **Steve Usdin;** Senior Editor, BioCentury • **Peter Pitts;** President, Ceter for Medicine in the Public Interest • **Marjorie Speers;** Executive Director, Clinical Research Pathways • **Open Floor for Round-table Input**
3:00pm	**Expanded Access Summit Adjourned**