

T3: Trials, Tech and Transformation

May 30-31, 2018

Raleigh Convention Center, Raleigh, NC

LEVERAGE THE PARADIGM SHIFT TO TRANSFORM YOUR CLINICAL TRIALS

New Technology. Patient Engagement. Clinical Collaboration.



Navigating the Patient Journey: A Story of Hurdles to Health

T.J. Sharpe, Patient, Speaker, Writer
and Advocate, Starfish Harbor, LCC



Where Do We Stand and What Lies Ahead? Transforming the Clinical Trial Landscape

Greg Koski, PhD, MD, Co-Founder and
President/CEO, Alliance for Clinical Research
Excellence and Safety (ACRES)

CLOSING MODERATED GROUP DISCUSSION:

How do we segue from these insights, success stories,
new technologies and innovations into an implementation
phase in our own companies?

Christina Bodurow, PhD, former Senior Director,
External Sourcing, Eli Lilly

Greg Koski, PhD, MD, Co-Founder and President/CEO,
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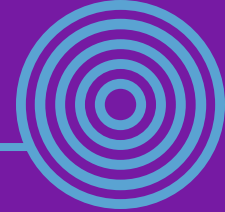
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7:15	<i>Registration & Coffee</i>	
	PLENARY SESSION	
8:10	Chairperson's Opening Remarks	
8:15	Where Do We Stand and What Lies Ahead? Transforming the Clinical Trial Landscape Greg Koski, PhD, MD, Co-Founder and President & CEO, Alliance for Clinical Research Excellence and Safety (ACRES)	
8:45	New Tech and Innovations in Digital Health for Clinical Research and Trials – FDA Perspective	
9:20	<i>Networking and Refreshment Break in Exhibit Hall</i>	
	TRACK A: PARADIGM SHIFTS IN CLINICAL TRIALS – PARTNERSHIPS AND COLLABORATION	TRACK B: PATIENTS AS PARTNERS – VOICE OF THE PATIENT
9:55	Chairperson's Remarks Christina Bodurow, PhD formerly Senior Director, External Sourcing, Eli Lilly	Chairperson's Remarks
10:00	PANEL DISCUSSION: Sponsor-CRO Collaborative Partnerships: adding Equity and Finding the Equilibrium Frank Leu, CEO, Novapeutics Nancy Meyerson-Hess, Associate Partner, admenicum Business of Patients	2018 UPDATE: Assessing and Quantifying the Use and Impact of Patient-Centric Initiatives on Drug Development Practices Stella Stergiopoulos, Senior Project Manager, Tufts Center for the Study of Drug Development
10:45	PANEL DISCUSSION: Are You Easy To Do Business With? Norman Goldfarb, Chairman, MAGI; Editor, The Journal of Clinical Research Best Practices ; Managing Director, First Clinical Research LLC	INTERACTIVE PANEL/AUDIENCE DISCUSSION: Voice of Patient Protocol. It's Essential, So How Do We Maximize It? Robin Farmanfarman, Investor and VP, Invicta Medical Jasmine Bengier, Research Services Project Manager, Center for Information & Study on Clinical Research Participation (CISCRP) Rob Metz, Senior Vice President, Global Business Operations, Horizon Pharma
11:30	Track Presentation Available for Sponsorship	Track Presentation Available for Sponsorship
12:00	<i>Networking Lunch in Exhibit Hall</i>	

	PLENARY SESSION	
1:10	Chairperson's Remarks	
1:15	Navigating the Patient Journey: A Story of Hurdles and Health T.J. Sharpe, Patient, Writer, Advocate, Starfish Harbor LLC	
1:45	Patients as Partners Case Study: What We've Learned and Where We're Going	
2:20	<i>One-to-one Appointments & Networking and Refreshment Break in Exhibit Hall</i>	
	TRACK A: PARADIGM SHIFTS IN CLINICAL TRIALS - DIGITAL TRANSFORMATION	TRACK B: PATIENTS AS PARTNERS – RECRUITMENT AND ENGAGEMENT
3:25	Chairperson's Remarks	Chairperson's Remarks
3:30	PANEL DISCUSSION: Moving from Paper to Digital. What's Working, What's Not? Kate Yawman, Product Line Manager, Bio-Optronics Gary Thompson, MS, Senior Director, Data Sciences and Solutions, Eli Lilly and Company Cassandra Smith, Associate Director, Investigator & Patient Engagement, Janssen Evan Yuen, Global Clinical Trial Leader, Genentech Melissa Menke, Founder and CEO, Access Afya	INTERACTIVE PANEL/AUDIENCE DISCUSSION: Voice of Patient Practical - Engagement, Recruitment and Research: Build a Fully Integrated Approach Lani Hashimoto, Clinical Program Benchmark Manager, Trial Operations Management, Novartis Daisy Daeschler, Research Partnerships Officer, The Michael J Fox Foundation Kay James, Executive Director, Cystic Fibrosis Foundation , Carolinas Raleigh Chapter
4:15	CASE STUDY: eConsent Lessons Learned Speaker TBA, Pfizer	How Lilly is Using Social Media to Attract More People to Research Elizabeth Mascherino, Advisor, Clinical Innovation, Eli Lilly
4:45	PANEL DISCUSSION: All This New Tech to Capture Data. How Can We Incorporate More Effectively and Efficiently? Jake LaPorte, Head of Digital Development, Novartis Amanda Goltz, Vice President, Digital Innovation, BTG Plc Jasmine Bengier, Research Service Project Manager, Center for Information & Study on Clinical Research Participation (CISCRP)	Real World Data, What is it and How Do We Use Biomarkers? Nancy Meyerson-Hess, Associate Partner, admenicum Business of Patients David Dworaczyk, PhD, formerly Head of Life and Health Sciences Strategic Development, Oracle & Member Board of Directors, Pistoia Alliance, Inc.
5:45	<i>Collaboration Bar and Drinks - Networking Reception</i>	

7:15	Coffee and Registration	
	TRACK A: PARADIGM SHIFTS IN CLINICAL TRIALS - NEW TECHNOLOGY AND INNOVATIONS	TRACK B: CLINICAL RESEARCH: REAL-TIME DATA AND ANALYTICS
7:55	Chairperson's Remarks	Chairperson's Remarks
8:00	CASE STUDY: Blockchain tech Bob Stewart, CTO & Board Member, Alliance for Clinical Research Excellence and Safety (ACRES) & CEO, Exochain	Digital Health: Merging Tech, Innovation and Analytics for Your Wellbeing Dr. Joseph Ronzio, DHSc, CPHIMS, Deputy Chief Health Technology Officer, Department of Veterans Affairs (requested)
8:30	CASE STUDY: Fox Insights: Leveraging Technology in an Online Study Daisy Daeschler, Research Partnerships Office, The Michael J. Fox Foundation	PANEL DISCUSSION: Voice Assistants and Conversational AI - Is it the Total Package?
9:00	QUICKFIRE CASE STUDIES (3): mHealth and apps Yvonne (Yu-Feng) Chan, MD, PhD, FACEP, Director, Center for Digital Health, Associate Professor, Genetics and Genomic Sciences & Associate Professor, Emergency Medicine, Icahn School of Medicine at Mount Sinai	PANEL DISCUSSION: Big Data and Big IT - Big Changes for Clinical Research Michael Hay, Head of Product Intelligence, Pharma Intelligence
10:15	One-to-one Appointments & Networking and Refreshment Break in Exhibit Hall	
	TRACK A: PARADIGM SHIFTS IN CLINICAL TRIALS - THE CHANGING LANDSCAPE	TRACK B: INSIGHTS AND INNOVATIONS FROM IMMUNO-ONCOLOGY AND RARE DISEASE
10:45	Chairperson's Remarks Gary Thompson, Senior Director, Eli Lilly and Company	Chairperson's Remarks
10:50	Automated Insulin Delivery Systems and the Regulatory Pathway: Interactive Strategies for Clinical Studies to Premarket Submission Andrea Bell-Vlasov, PhD, Scientific Reviewer, CDRH, Office of InVitro Diagnostics and Radiological Health (OIR), FDA	CASE STUDY: Successful Drug Development
11:20	Science 37 & AOBiome: Lessons Learned from an Industry-First Virtual Clinical Trial Dr. Belinda Tan, MD, PhD, Chief Medical Officer and Co-Founder, Science 37	PANEL DISCUSSION: What Can We Learn and Implement from Immuno-Oncology and Rare Disease Trial Design? Heather DiBenedetto, MS RAC, Head, Therapeutic Operations, Moderna Therapeutics
11:50	Track Presentation Available for Sponsorship	Track Presentation Available for Sponsorship
12:20	Networking Lunch in Exhibit Hall	
	PLENARY SESSION	
1:35	Chairperson's Remarks	
1:40	Radical Transformation of Clinical Research and the Clinical Trials Landscape: What is Really Possible? Where Could We be in 5 or 10 Years?	
2:10	MODERATED GROUP DISCUSSION: How Do We Segue from These Insights Learned and Implement in Our Own Companies? Christina Bodurow, PhD, formerly Senior Director, External Sourcing, Eli Lilly Greg Koski, PhD, MD, Co-Founder and President & CEO, Alliance for Clinical Research Excellence and Safety (ACRES)	
3:00	End of Conference	

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Conference Venue

Raleigh Convention Center
500 South Salisbury Street
Raleigh, NC 27601