PRE-APPROVAL Access Programs

Sheraton Philadelphia University City Hotel | Philadelphia, PA

Main Conference Agenda

Tuesday, September 26th

7:30AM	**Registration & Coffee**			
8:45AM	**Chairperson's Welcome and Opening Session**			
9:00AM	**KEYNOTE: Defining PAP's with the Future in Mind: Gene Therapy and What's to Come** **Pat Furlong,** President and CEO, **Parent Project Muscular Dystrophy**			
10:00AM	**Weighing your Options: Considering, Selecting and Managing a PAP Effectively** **Catherine Blansfield,** Vice President and Access and Outcome Services, **National Organization for Rare Diseases**			
10:45AM	**Networking Break**			
11:30AM	**The Moral Dilemma: Providing Potentially Life-Saving Drugs in an Ethical Manner** **Andrew McFadyen,** Executive Director, **The Isaac Foundation**			
12:15PM	**Roundtable Discussions**			
	Table 1: EU Tom Watson, Pre-Approval Access Expert, TW Consulting Group Ltd.	**Table 2:** US Brian J. Malkin, Former FDA Counsel	**Table 3:** Canada Andrew McFadyen, Executive Director, The Isaac Foundation	**Table 4: Brazil** Luiz Andre Magno, Global Medical Affairs Leader – Neuroscience, Janssen Pharmaceutical
1:00PM	**Networking Lunch Break**			
1:45PM	**The Expanded Access (EA) Navigator Program for Single Patient or Compassionate Use: A one Stop Shop** **June Wasser,** Executive Director and CEO, **Reagan-Udall Foundation for the FDA**			
2:30PM	**Explore How the New Trump Administration Affects the Future of Pre-Approval** **Naomi Lopez Bauman,** Director of Healthcare Policy, **Goldwater Institute** **Brian J. Malkin,** FDA Counsel, **Arent Fox LLP** **Alison Bateman-House,** Research Assistant Professor, Division of Medical Ethics, **NYU** **Paul Melmeyer,** Director of Federal Policy , **National Organization for Rare Disorders**			
3:15PM	**Afternoon Coffee Break—Network Over Refreshments**			
3:45PM	**The Considerations Taken Into Account to Build a Successful PAP** **Karen Bartels,** Director, Global Medical Affairs, Early Clinical Development and External Research, **AstraZeneca**			
4:30PM	**Examining the Hold-Up in Drugs Approvals to Identify Area of Reform: The FDA, Big Pharma or Cost?** **Naomi Lopez Bauman,** Director of Healthcare Policy, **Goldwater Institute** **Frank Burroughs,** CEO, **Abigail Alliance for Better Access to Development Drugs** **Kevin Weatherwax**, Administrative Program Director, Co-Chair—Expanded Access Oversight Committee, **University of Michigan Health Systems** **Karen Bartels,** Director, Global Medical Affairs, Early Clinical Development and External Research, **AstraZeneca**			
5:15PM	**End of Day One**			

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Main Conference Agenda

Wednesday, September 27th

7:30AM	**Registration & Coffee**
8:45AM	**Chairperson's Welcome and Opening Session**
9:00AM	**KEYNOTE: Get an Insider's Look into J&J's Compassionate Use Advisory Committee (CompAC): 17 Months of Data Provides Groundbreaking Insight into the Patient Perspective** **Beverly Harrison,** Head of Patient Support, **Janssen Pharmaceutical Companies of Johnson & Johnson**
10:00AM	**Explore Manufacturers' Challenges to Facilitate Understanding and Potential Approaches Within Gene Therapy** **Jessica Imrie,** Rare Diseases, Gene Therapy Head of Strategy and Operations, **GSK**
10:45AM	**Networking Break**
11:30AM	**Strategies for Interpreting Regulations within your Access Programs** **Paul Aliu,** Global Head Medical Governance, **Novartis**
12:15PM	**Anticipate and Understand the Unforeseen Roadblocks of PAPs and their Repercussions** **Ramana Sonty,** Director, Global Medical Organization, **Johnson & Johnson** **Paul Aliu,** Global Head Medical Governance, **Novartis** **Tom Watson,** Pre Approval Access Expert, **TW Consulting Group Ltd.**
1:00PM	**Networking Lunch Break**
1:45PM	**Adapting Big Pharma Logistics Strategies to Ensure Success within Biotech Organizations** **Arun Kumar,** President & CEO, **Neuracon Biotech Inc**
2:30PM	**Converting PAP data into Real World Lessons Learned to Advance the Cure** **Romina Oxborough,** Director Clinigen Consulting, **Clinigen Group**
3:15PM	**Afternoon Coffee Break—Network Over Refreshments**
3:45PM	**Understanding Recent Legislative and Regulatory Developments, Including 21st Century Cures and the Final Rule** **Jane Reese-Coulbourne,** Senior Consultant, **MK&A**
4:30PM	**Collecting Adverse Event Data and their Impact on Drug Development** **Richard Klein**, Former Director, FDA Patient Liaison Program at Food and Drug Administration, **FDA**
5:15PM	**End of Day Two**

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PLEASE NOTE THE PRESENTATIONS WILL BE AVAILABLE BEGINNING Wednesday, October 4th, 2017.

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