DAY ONE - MONDAY, MAY 8, 2018

8:30 am
Registration

8:30 am
Co-Chair's Opening Remarks
Jim Roach, MD
CMO, **Pulmatrix**

9:15 am
Bloomberg Intelligence on Biotech Landscape
- How the current pricing structure will impact the biotech industry
- What can CMOs do to help inform the discussion of the future?
- How is this affected by the evolving relationship between industry and academia?
- We're seeing many more companies focused on rare diseases and immuno-oncology than common diseases now. How is the shift in therapeutic areas affecting the industry?

Asthika Goonewardene, MBA
Senior Biotech Analyst, **Bloomberg Intelligence**

9:45 am
How is the Shifting Biotech Life Cycle Changing Clinical Partnerships with Big Pharma and the Role of the CMO?
- Why are many biotechs staying in tact as opposed to looking for an exit strategy?
- What is the CMO's role with big pharma in the partnership? What is big pharma's role in the partnership? Do they have a say in trial design and operations?

Luba Greenwood
Vice President, Global Mergers & Acquisitions and Business Development, **Roche**

Christopher Heery, MD
CMO, **Bavarian Nordic**

Marc Schwabish, PhD
SVP, Business Development and US Operations, **Fusion Pharmaceuticals**

Beth Trehu, MD
CMO, **Jounce Therapeutics**

10:15 am
Finding the Common Ground between CMOs and VCs
- CMOs are looking for VCs who take a long term view at their science as an investment
- Is it always important to be the quickest, cheapest, option?
- Are you looking for an exit strategy or a long-term strategy?

Vikas Goyal, MBA
Associate, **SR One**

Santosh Vetticaden, MD, PhD, MBA
Chief Medical & Scientific Officer, **Depomed Inc**

10:45 am
Networking Break

11:15 am
Annual Keynote Address: Anticipating the Migration of Clinical Research Into Clinical Care and the Impact on Biotech
Identifying, initiating and conducting clinical trials among traditional investigative sites remains highly inefficient and unpredictable. Several major trends are moving industry-funded clinical trials into large health systems. This session:
- Reviews major trends and conditions driving this migration
- Explores new clinical trial models and processes emerging in clinical care settings
- Anticipates new and modified capabilities to best leverage health system advantages

Ken Getz
Director of Sponsored Research/Founder, **Tufts CSDD/CISCRP**

11:45 am
Opportunities for CMOs to Engage More Directly with Patients
- What do patients, patient advocacy, regulators, and industry view as the benefit-risk of clinical research?
- How do we get patient and patient advocacy input while maintaining control of clinical development?
- How patient engagement can drive greater efficiencies in clinical trials

Nerissa Kreher, MD
CMO, **AVROBIO**

Jodie Sherman Gillon
Global Medical Lead, Patient Engagement Rare Diseases, **Pfizer**

Jeff Sherman, MD, FACP
CMO, EVP R&D, **Horizon Pharmaceuticals**

12:15 pm
Lunch and Therapeutic Specific Round Tables
Take the first 20 minutes to get lunch and take a break. At 12:35 you have the option of joining a Therapeutic Specific Round Table where a leader is assigned to help facilitate discussion in your specific therapeutic area of interest.

Breakout Sessions Addressing Therapeutic Areas
Join a discussion with other researchers in your therapeutic area for a collaborative session exchanging creative solutions, lessons learned, and creating new pathways.

Table 1
Addressing CNS Disorders

Table 2
Addressing Rare Disease

Table 3
Addressing Oncology

Table 4
Addressing Gene Therapy

1:15 pm
Working With FDA and Regulatory Agencies to Advance Drug Development

- 2007 introduction of Risk Evaluation and Mitigation Strategy (REMS)
- FDA Initiative: Health Education Labor and Pensions (HELP)
- 21st Century Cures Act accelerating approval
- Releasing clinical data from NDAs for public use
- What is the FDA looking for when it comes to approving a new drug?
- How would they respond to certain early stage results?
- What is required to get orphan drug status?
- Can regulators approve my innovation?

Speaker TBA

1:45 pm
Taking a Strategic Approach to Regulatory Challenges
Thomas Lonngren
Strategic Advisor, **NDA Group**

2:15 pm
How to Find the Right People and Build the A-Team?
The model of the recruiter has stayed the same, but the ability to successfully recruit the right people for your team has drastically changed.

- How do you recruit for specific skill sets within your therapeutic area?
- What is the best way to fill difficult positions?
- If you're based in an area full of talent, like Boston, how do you retain that talent?
- If you're based in an area without high recruiting potential, how do you attract talent?

Brandon Atkinson
Chief People Officer, **Roivant Sciences**

2:45 pm
Best Practices in Communication and PR Strategy

- How can CMOs more effectively communicate with CEOs, CSOs, and Clinical Operations executives in order to provide a comprehensive summary of the science and business aspects of the company?
- Learning to communicate to investors, analysts, board members, professional groups, investigators, patient advocacy using language they respond to
- How can you help your CEO sell the accelerated clinical development path?
- How can we better educate the public on expectations for clinical trial outcomes?
- What can we be doing better to address negative press coverage?
- How do you manage a crisis, like a death in your clinical trial, to the public?
- How can we prepare for negative outcomes before they happen in real-time?

Pavan Cheruvu, MD
CEO, **Axovant**

Zain Kassam, MD, MPH
CSO, **Finch Therapeutics**

Ian Walters, MD
VP, CMO, **Intensity Therapeutics**

3:15 pm
Networking Break

4:00 pm
Best Practices in Clinical Development and Outsourcing

- How do you go about establishing clinically relevant endpoints
- When is it best to involve KOLs of your field? Expert researchers?
- How do you involve KOLs in your communications with FDA/regulatory agencies?
- Do you have a good measure on what the endpoints are? Including patient forward outcome measures?
- How do you design a clinical trial where you get an early stage read out?
- What is an example of accelerated clinical development pathways?
- How can you create value as quickly as possible?

David Clark, MD
CMO, **Aldeyra Therapeutics**

Adrian Senderowicz, MD
SVP, CMO, **Constellation Pharmaceuticals**

4:30 pm
New Methods of Handling the Challenges of Patient Safety and Pharmacovigilance

- How have patient safety measures evolved?
- How do you prepare for the challenges of pharmacovigilance once your drug is approved?
- How is the digitization of health data creating new pathways in pharmacovigilance?

Anupam Agarwal
Global Drug Safety and Pharmacovigilance, **Zogenix, Inc**

Paul Beninger
Director, **Tufts University**

5:00 pm
Networking Reception

DAY TWO - TUESDAY, MAY 9, 2018

8:00 am
Registration

8:30 am
Chair's Opening Remarks

8:45 am
Keynote Fireside Discussion
Speaker TBA

9:15 am
Going from Big Pharma to Small Biotech Leadership: Challenges and Opportunities

- Handling the false assumption that small pharma is less secure
- Big pharma provides structured learning opportunities, but small pharma provides opportunities for exploration and collaboration
- Dealing with potential lack of resources when looking for answers

Manu Chakravarthy, MD, PhD
CMO, SVP Clinical Development, **Axcella Health, Inc**

Keith Gottesdiener, MD
CEO, **Rhythm Pharmaceuticals**

Azmi Nabulsi, MD
Deputy Chief Medical & Scientific Officer, Head of R&D Strategic & Professional Affairs, **Takeda**

10:00 am
CMO Exchange Between Small and Large Pharma: Addressing Mutual Challenges

- What experiences can be translated across the industry divide
- What can large pharma learn from small pharma to increase efficiency?
- What are the advantages of large pharma?
- Lessons learned

Steven Zelenkofske, DO
CMO, **UniQure**

10:30 am
Networking Break

11:15 am
Case Study: Preparing for the Challenges of Late Stage Trials
Case study from one company who lived to tell the tale.

Mark Currie, PhD
SVP, CSO, President of R&D, **Ironwood Pharmaceuticals**

11:45 am
CMO Leadership Case Study: A Unique Approach to Registration in a Large Indication
Hear from global and multicultural pharmaceutical executive, Christophe Arbet-Engels, about how Poxel decided in a very crowded market to go to a smaller country first, Japan, to start a Phase 3 registration program and find a commercial partner.

Christophe Arbet-Engels, MD, PhD
CMO, **Poxel Pharmaceuticals**

12:15 pm
Luncheon

1:15 pm
Should Patients Have the Right to Try?
The debate of compassionate use and right to try has created a lot of controversy in the industry. In this discussion, we unpack the implications, both positive and negative, of opening up that door.

Alison Bateman-House, MD
Assistant Professor Division of Medical Ethics, **NYU Langone Health**

1:45 pm
De-Risking a Failed Development Program
In this session, we explore how expanding phase 2 programs, balancing development for both regulatory and marketing purposes, and de-risking a failed development program can further advance your clinical trial in the long term.

Led by:
Jim Roach, MD
CMO, **Pulmatrix**

2:15 pm
Networking Break

3:00 pm
What Could Be a CMO's Career Trajectory?

- How Does Your Career Path Affect Your Success as a CMO?
- What could make a CMO more valuable once they're settled into their role?
- What can we be doing to grow and be more effective?
- When is it appropriate for a CMO to serve on the board of other companies?
- Navigating the healthy tension between R&D and Medical Affairs
- Early vs Late stage development programs
- How can medical professionals help bridge these gaps?

Moderated by:
Jim Roach, MD
CMO, **Pulmatrix**

Panelists:
Mark Corrigan, MD
Co-Founder, President R&D, **Tremeau Pharmaceuticals**

Steven Zelenkofske, DO
CMO, **UniQure**

3:30 pm

Pricing Trends and the Impact on R&D

- How has pricing structure evolved for better or for worse?
- How do we determine pricing of new drugs going to market?
- Is the current pricing structure sustainable?
- What are we doing to make drugs more affordable?

4:00 pm

Town Hall Meeting

- Managing geographic barriers
- How do you build and maintain and organization when you're not always present in the office?
- How can you best mentor, lead, and communicate across distances?
- How is technology changing how we run clinical trials?
- How are we adopting artificial intelligence into clinical development?
- What is the future of using algorithms to determine diagnoses?
- What technologies are helping us identify side effects early on?
- What is the CMOs Role in Shaping Society's View on the Value of Medicine?
- How can we educate the public on the value of clinical development?

Led by:
Jim Roach, MD
CMO, **Pulmatrix**

4:30 pm

Wrap-Up

5:00 pm

Conference Concludes