DAY ONE - THURSDAY, APRIL 4, 2019

8:00 am
Registration and Morning Coffee/Tea

8:30 am
Co-Chairs' Opening Remarks
Zain Kassam, MD, MPH
Co-Founder, EVP, Clinical Development and Translational Medicine, **Finch Therapeutics**

Julie Krop, MD
CMO, EVP, Clinical Development & Regulatory Affairs, **AMAG Pharmaceuticals, Inc**

Steven Zelenkofske, DO
EVP, CMO, **Achillion Pharmaceuticals**

8:50 am
Keynote: How the CMO of Sage Therapeutics Positioned a New Indication for FDA Approval
In this session, hear from Dr Steve Kanes, CMO, Sage Therapeutics on how a company considered as an "up and comer" in the Cambridge biotech sector navigated the development and approval of the first treatment specifically designed for postpartum depression.
Steve Kanes, MD, PhD
CMO, **Sage Therapeutics**

9:25 am
Case Study: Life of a CMO Pre and Post IPO
Dr Tal Zaks shares his experience and lessons learned through one of the biggest transitions a CMO can make in biotech:
- Expanding the role of the CMO to meet the requirements of a public company
- Insights into the experience
- Managing growth
- What role does the CMO have in articulating the data of clinical trials
- What role does the CMO have in business development opportunities
- What are the personal implications of being a CMO in a publicly traded company
- Lessons learned

Tal Zaks, MD, PhD
CMO, **Moderna Therapeutics**

10:00 am
Morning Networking Break

10:45 am
Annual Keynote Address
Ken Getz
Director of Sponsored Research, **Tufts CSDD** / *Founder,* **CISCRP**

11:20 am
Addressing the Talent Gap in Biotech – Recruit and Retain
In an increasingly competitive market, there is a growing need for efficiency in attracting and retaining top talent. This session addresses:
- How to source talent; pros and cons of recruiters versus word-of-mouth
- How to make the work environment optimal to keep employees satisfied
- How to compete with the competition banging on the door?
- How to ease or address relocation concerns of potential hires
- When is a good time to have consultants or contractors filling the gaps?
- How to access the untapped talent in academia, do they know we exist?
- Benefit/risk of having non-MDs fill the gaps and guided by a physician
- Does the industry need to evolve to attract and retain talent?
- How do you decide whom to recruit first?
- How to identify the right hire

Panelists:
Kara Coluccio Bern
Partner, **Perspective Group**

Julie Krop, MD
CMO, EVP, Clinical Development & Regulatory Affairs, **AMAG Pharmaceuticals, Inc**

James Lewis
Global Contract Director, **Barrington James**

11:55 am
Experienced CMO Insights on Building the R&D Team
This panel of experienced CMOs address:
- What factors impact the decision of who to hire and when?
- How to determine the order and priority of roles/functions
- Setting a timeline for completing your team
- What circumstances/factors might make you change your mind?
- What is your approach to consultants vs vendors/CRPs vs head-count hire?

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

Pedro Huertas, MD, PhD
CMO, **Sentien Biotechnologies Inc**

Ramon Mohanlal, MD, PhD, MBA
EVP, R&D and CMO, **BeyondSpring Pharmaceuticals**

John Paolini, MD, PhD
CMO, **Kiniksa Pharmaceuticals**

Jim Roach, MD
CMO, **Pulmatrix**

12:25 pm
Optimizing Development with Model-Informed Decision-Making
In this session, hear from Tina Checchio, Associate Director, Quantitative Pharmacology & Pharmacometrics, Cytel on the impact of pharmacometric modeling on R&D strategy. Highlights include:
- Increasing team confidence at critical development milestones
- Improving the probability of correct GO/NO GO decisions

Tina Checchio, PhD
Associate Director, Quantitative Pharmacology & Pharmacometrics, **Cytel**

12:40 pm
Lunch

1:45 pm
Track Session Choices – Addressing Unique Development Challenges in Novel Therapeutics Areas

Track 1A: Immuno-Oncology

1:50 pm — **When and How to Approach Strategic Collaborations and Partnerships**

How do you think about and approach a partnership as a small biotech when large pharma dominates the space? Here are a number of considerations:

- What is the relationship between where your drug is in development and the potential value you can obtain by partnering at that stage?
- Does your strategy change on partnering an asset depending on whether you have more than one asset and/or a platform technology to generate additional drug candidates?
- Timing; when do you partner/collaborate? After safety and efficacy data? Before phase 1? In between?
- Pros and Cons of supply agreements?
- Understanding your rights to negotiate for partnership of your compound

Moderator:
Rob Ross, MD, CMO, Surface Oncology

Panelists:
Christina Coughlin, MD, PhD, *EVP and CMO,* **Tmunity**

Ildiko Csiki, MD, PhD, *CMO,* **Sensei Bio**

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

Track 1B: Microbiome

2:30 pm — **Addressing Unique Development Challenges in the Microbiome**

- What does PK/PD mean in the context and what is the playbook?
- Considerations for developing dose-ranging studies for microbiome products?
- Determining suitable clinical endpoints and the most appropriate regulatory pathway
- How do you match traditional drug development structures with an emerging therapeutic area? Are there lessons from other technologies (e.g. CAR-T, etc)

Moderator:
Zain Kassam, MD, MPH, *Co-Founder, EVP, Clinical Development and Translational Medicine*, **Finch Therapeutics**

Track 2A: Gene Therapy

1:50 pm — **Designing Clinical Trials for Gene Therapy – a Paradigm Shift**

- How to utilize adaptive trial design within the specific context of a gene therapy – are there any unique aspects of development conducive to this approach?
- How to ensure flexibility when pushing for an accelerated pathway?
- Communicating pros and cons of development options and your recommendation to your CEO
- De-risk identifying the primary efficacy endpoint without a proof of concept phase
- How to interpret the current FDA guidance
- Factors to consider around in-vivo and ex-vivo regulatory guidance
- How to use the guidance to direct the path of your program
- Global regulatory considerations and how to overcome them

Martin Childers, DO, PhD, *CMO*, **Asklepios BioPharmaceutical, Inc**

Kathleen Reape, MD, *CMO*, **Spark Therapeutics**

Track 2B: Case Study

2:30 pm — Speaker TBD

3:10 pm
Afternoon Networking Break

3:40 pm
How to Make Clinical Operations as Lean as Possible in a Small Biotech

Dr Zelenkofske comes with enormous experience from both large pharma to a biotech startup and brings his experience to help fellow CMOs best practices for sensible lean operations.

Murray Stewart, MD
CMO, **Rhythm Pharmaceuticals**

Steven Zelenkofske, DO
EVP, CMO, **Achillion Pharmaceuticals**

4:10 pm
The Dynamic Trial Design: The Missing Step Between Phase I and Phase II

Jennifer Keppler, MBA
VP, Translational Medicine, **Translational Drug Development**

4:25 pm
How can CROs Best Meet the Needs of Small/Emerging Biotech
CRO selection is enormously important for a small company. Many of the large CROs are evolving their approach to working with small companies. In this session, hear from the panel of CROs and CMOs on how the industry is reimagining this partnership.
- What are the key drivers of the evolution in these approaches and relationships?
- How are the new models different from traditional models?
- How successful have these new models been?
- What steps can both CROs and CMOs take to ensure success?

Jim Roach, MD
CMO, **Pulmatrix**

5:00 pm
Panel: Mobile and Scalable Clinical Operations Outsourcing Models
Panelists:
Steven Zelenkofske, DO
EVP, CMO, **Achillion Pharmaceuticals**

Speaker TBD
InSeption Group, LLC

5:30 pm
Networking Reception

6:30 pm
Day One Concludes

DAY TWO - FRIDAY, APRIL 5, 2019

8:00 am
Registration and Morning Coffee/Tea

8:30 am
Co-Chairs' Opening Remarks
Zain Kassam, MD, MPH
Co-Founder, EVP, Clinical Development and Translational Medicine, **Finch Therapeutics**

Julie Krop, MD
CMO, EVP, Clinical Development & Regulatory Affairs, **AMAG Pharmaceuticals, Inc**

Steven Zelenkofske, DO
EVP, CMO, **Achillion Pharmaceuticals**

8:45 am
Keynote: Astellas CMO on Navigating Biotech - Pharma Partnership
The path from first introduction to partnership or potential acquisition is a complex one, where the CMO plays a pivotal role. This keynote will follow the collaboration journey through the eyes of a global pharmaceutical CMO – providing in-depth perspectives on success stories, overcoming barriers and learnings from challenges. The session will also highlight the need for establishing mutual objectives early on to maximize value for patients and both partners.
Bernie Zeiher, MD
CMO and President, Development, **Astellas Pharma**

9:15 am
Fireside Chat with an R&D Veteran
Dr Chodakewitz for the first time is joining the CMO Summit to share his incredible journey as a CMO.
- The journey
- Prioritizing resources
- Successes and failures
- Overcoming hurdles
- Career decisions
- Transitioning from large pharma to small biotech
- Considerations for building your team in large and small companies

Jeffrey Chodakewitz, MD
former EVP, Clinical Medicine and External Innovation, CMO, **Vertex Pharmaceuticals**
with
Julie Krop, MD
CMO, EVP, Clinical Development & Regulatory Affairs, **AMAG Pharmaceuticals, Inc**

9:45 am
Fireside Chat: How can we De-Risk the Incorporation and Interpretation of Data Collected via Wearable Technology?
Wearable technologies are now widely available for clinical trials but are still somewhat untested. How can small companies responsibly utilize these technologies while reducing the risk to their product and company?
Considerations:
- How to assess the quality of the technology and is it fit for purpose?
- How to ensure data integrity
- How to format and report the data
- Familiarize yourself with regulatory concerns around such data
- What safeguards can be implemented to make regulators more comfortable with the data?

Craig Lipset, MBA
Head of Clinical Innovation, **Pfizer, Inc**
with
Barry Ticho, MD, PhD
CMO, **Stoke Therapeutics**

10:10 am
Morning Networking Break

11:00 am

How to Navigate the Development Path from CMO to CEO

This panel gives insights in what it takes and how to navigate and what to expect in the CEO role.

- How can a CMO position themselves as a corporate leader?
- How to build a network of advisors and who should it include?

Moderator:

Nerissa Kreher, MD, MBA
CMO, **Avrobio**

Panelists:

Aoife Brennan, MB, BCh, BAO, MRCPI
CEO and CMO, **Synlogic**

Greg Fiore, MD
CEO, **Sollis Therapeutics**

11:45 am

Mechanisms for CMO Performance Improvement

Dr Kassam challenges the audience on performance improvement mechanisms for the CMO role. More specifically:

- How do CMOs think about growing within their role? How do you get better?
- How to build a network of advisors and who should it include?
- What are the structures/processes to assess your performance? Peer review, self-assessment, managerial review, an executive coach etc.?

Zain Kassam, MD, MPH
Co-Founder, EVP, Clinical Development and Translational Medicine, **Finch Therapeutics**

12:30 pm

Lunch

1:30 pm

The Role of the CMO when Interacting with the Board

Join us to explore:

- What are the different relationships? Direct contact, buddy system, CEO link?
- How to make sure the board understands the clinical objectives and your perspective?
- How can serving on a board make you a better CMO?

Panelists:

Elliot Ehrich, MD
CMO, **Expansion Therapeutics**

John Paolini, MD, PhD
CMO, **Kiniksa Pharmaceuticals**

2:10 pm

Best Practice for Preparing for Investors and Q&A

This is an area of the CMO job that requires constant improvement and the purpose of this session is to give you the opportunity to hear about best practices on:

- How can you present a unified front with your CEO while presenting your individual perspective on the science?
- How to strategize with your CEO prior to an investor meeting on topics to be covered
- The do's and don'ts
- What are appropriate materials to present?
- How to navigate conversations around the FDA
- What boundaries exist and how to overcome them?

Panelists:

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

Julie Krop, MD
CMO, EVP, Clinical Development & Regulatory Affairs, **AMAG Pharmaceuticals, Inc**

2:50 pm

Proving Value to Payors: Best Practices

What additional measures are needed to show value to payors and to justify price? In this session where we will be joined by a payor, we discuss:

- How can CMOs interact with payors to find out what info they want from a drug program in order to make their payment decisions?
- Are we overloading trials with extra info? We've doubled the number of assessments just to try and address needs of payors. How much is too much to put into a clinical trial?
- How does the CMO generate evidence and create value to present to payors?
- What kind of structural support is required to develop a value plan?
- Is there a structural cost and how to decide on a financial commitment to this process?
- How to build a value story; structurally, operationally and a pathway

Panelists:

Harry Leider, MD, MBA
EVP, CMO, **Gelesis**

Steven Zelenkofske, DO
EVP, CMO, **Achillion Pharmaceuticals**

3:30 pm

Conference Concludes