

Chief Medical Officer Summit

April 3 - 4, 2023 | Boston Park Plaza, Boston, MA

2023 KEYNOTES AND SPECIAL GUEST







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DAY ONE - MONDAY, APRIL 3, 2023

7:50 am Registration Opens, Tea/Coffee

8:20 am Co-Chairs Opening Remarks

Nerissa Kreher, MD, MBA

CMO, Entrada Therapeutics

Ed Tucker, MD, MBA Former CMO, Goldfinch Bio

8:30 am ANNUAL KEYNOTE

Annual Clinical Development Landscape Keynote

- Overview of the changing drug development landscape
- Review of underlying trends and practices and their current and anticipated impact
- Discuss strategies and practices addressing challenges and pain points
- Highlight transformational opportunities to optimize drug development performance

Kenneth Getz, MBA

Executive Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine/ Founder and Board Chair, CISCRP

9:00 am CEO KEYNOTE

Reflections on Alnylam and Biotech Leadership

The CMO Summit is honored to have for the first time, bioentrepreneur, Dr John Maraganore, founding CEO, Alnylam Pharmaceuticals, as a keynote presenter. Dr Maraganore will share highlights and lessons learned from his 19 years as a CEO leading a team that conquered some very difficult drug development challenges.



John Maraganore, PhD Founding CEO Alnylam Pharmaceuticals

9:30 am FINANCIAL ANALYST KEYNOTE

Keynote Fireside Discussion with JP Morgan Executive Director of Healthcare Investment Banking

In this fireside discussion, Dr Elena Lovo shares her thoughts on:

- Biotech investment trends in 2023
- What American biotechs should consider about the European biotech finance environment
- How CMOs can support the overarching process of a fundraising
- The hard and soft skills needed to succeed in investor interactions

Elena Lovo, PhD

Executive Director, Healthcare Investment Banking, **JP Morgan**



Nerissa Kreher, MD, MBA CMO, Entrada Therapeutics

10:00 am

Grand Opening of the CMO Summit 360° Cafe & Networking Break

- Breakfast
- Meet the Exhibitors
- Peer-to-Peer Meetings

GRAND OPENING

10:45 am An Update on Regulatory Trends and Best Practices in Navigating FDA Interactions

Moderated by:

Anna Berkenblit, MD, MMSc VP, CMO, ImmunoGen

Panelists:

Matteo Levisetti, MD CMO, Cue Biopharma

Laurie Smaldone, MD Chief Medical & Scientific Officer, NDA Group

Laura Williams, MD, MPH CMO, Ardelyx

Scott Harris, MD CMO, Altimmune

11:15 am Leveraging Patient Advocacy Groups for Successful Trial Recruitment

- Provide an educational experience and build knowledge to help patients decide to enroll into clinical trials
- Overcoming lack of diversity in clinical trials by directly reaching out the patient communities

Andreas Reiff, MD

SVP, Immunology & Inflammation, Parexel

11:30 am Regulatory Case Study: Getting FDA Approval in a Cell & Gene Therapy

Richard Colvin, MD, PhD *CMO,* **Bluebird Bio**

11:50 am Strategies to Design Development Plans for Adoption, Access and Approval

In this session, Dr Murphy shares strategies to design clinical development plans that incorporate a mix of observational and interventional research to address divergent needs for data in order to facilitate adoption, access and approval, including:

- Demonstrating "value," efficacy and safety
- Tailoring your approach to different phases of development and with diverse stakeholders in mind
- How to best leverage Clinical Research Organizations to facilitate this process

Michael Murphy, MD, PhD

Chief Medical & Scientific Officer, Worldwide Clinical Trials

12:05 pm Prioritizing Development Programs and Pipelines that Align with Fundraising Catalysts

In this session, panelists discuss how they prioritize and optimize their development portfolios for success and make development decisions in the current resource-constrained environment. Should you prioritize assets with the best quality science? Lowest cost? Fastest? Biggest ROI?

Moderated by:

Bernard Ravina, MD, MS Entrepreneur in Residence, Atlas Venture

Panelists:

Albert Kim, MD, PhD CMO, Cytel

Mustafa Noor, MD CMO, Olatec Therapeutics

Mauro Avanzi, MD, PhD CMO, Shoreline Biosciences

AGENDA

12:35 pm Getting Hard Feasibility Data: How To Do It

This presentation offers key insights with answers that speak to the following:

- How do you access current, hard feasibility data?
- Does your CRO have a stable, permanent clinical team with trial legacy capability and expertise in your domain?
- Are your sites and vendors audit proof?
- Does your CRO act like a SMO with a dedicated site network?
- Are you confident your CRO has the capacity to achieve your study milestones on or before deadline?
- Is your CRO independent, and well-rounded in regard to systems, with a collaborative vendor team of specialized expertise to support your program?

Patrick Smith, MSc

Feasibility Manager & Clinical Trial Leader, Scimega Research

12:50 pm CMO Summit Founding Advisor on the Biotech Landscape

Dr Stoner shares her thoughts on the biotech investment landscape and what investors look for in a CMO.

Elizabeth Stoner, MD

Executive Partner, MPM Capital

1:00 pm Lunch and Optional Roundtable Discussions

- Lunch
- Meet the Exhibitors
- Peer-to-Peer Meetings

For those of you joining a roundtable, please get your lunch and make your way to your roundtable of choice at 1:20pm.

Roundtables require an RSVP. If you have not secured your spot, please see the registration desk.



Optional Roundtable Discussions			
Roundtable #1: Challenges & Opportunities in CNS	Roundtable #2: New Regulatory Initiative in Oncology	Roundtable #3: Challenges & Opportunities in Cell & Gene Therapy	Roundtable #4: Challenges & Opportunities in Rare Disease
Shaheen Lakhan, MD, PhD CMO, Click Therapeutics	Alessandra Cesano, MD, PhD CEO, ESSA Pharma	Todd Druley, MD, PhD CMO, Mission Bio	Ottavio Vitolo, MD CMO, Cerevance
Richard Malamut, MD CMO, MedinCell	Kartik Krishnan, MD, PhD CMO, OncoNano	Mohammed Asmal, MD SVP, Head of Clinical, Prime Medicine	Raymond Urbanski, MD, PhD SVP, Head of Clinical
Timothy Peters- Strickland, MD VP, Global Medical Officer, Biotech Solutions, PPD, Part of Thermo Fisher Scientific	Medicine		Development & Medical Affairs, PharmaEssentia

2:00 pm Two Track Choices		
TRACK A: Early Stage Companies / Development	TRACK B: Late Stage Development / Medical Affairs	
Track Chair: Anna Frostegård, MD, PhD Co-Founder, Chief Scientific & Medical Officer, Annexin Pharmaceuticals	Track Chair: Ed Tucker, MD, MBA Former CMO Goldfinch Bio	
2:00 pm What CMOs Get Right and Get Wrong About Early Development	2:00 pm Preparing for Late-Stage Development	
Barry Ticho, MD, PhD CMO, Stoke Therapeutics	Seemi Khan, MD, MPH, MBA SVP, CMO, Reata Therapeutics	
David Davidson, MD Chief Medical & Development Officer, Tessera Therapeutics		
2:20 pm Intro to Finance & IPOs for CMOs The financial side of leading a biotech can often seem like a different language to CMOs. In this session, panelists representing the CMO, CFO, investor and	2:20 pm Interacting with Different Types of Investors as a CMO In a constrained financial environment, presenting effectively to investors and analysts becomes	
analyst perspectives explain what CMOs need to know about the IPO process from drafting an S-1 through bake-offs, TTWs, pitch deck drafting, the roadshow and stock issuance.	paramount. In this session, panelists discuss how best to interact with specialist and generalist investors and analysts. Topics include:	
Moderated by:	 Tailoring your message to bulls and bears What do you do if they don't believe in your company? 	
Joanne Lager, MD CEO, iTeos Therapeutics	 What types of data are investors looking for? What exasperates investors and analysts about biotechs and how to rise above 	
Panelists:	Moderated by:	
Timothy Lu, MD, PhD CEO, Dice Therapeutics	Alex Snyder, MD CMO, Generate Biosciences	
Josh Schimmer, MD, MBA Senior Managing Director, Evercore ISI	Panelists:	
Sanjay Subramanian, MS, MBA CFO, Inozyme Pharma	Jatin Shah, MD CMO, EVP and Global Head of Development, Sumitomo Pharma Oncology	
Bernard Cooney, MBA Senior Partner, Capital Formation Flagship Pioneering	Randall Stanicky CFO, Click Therapeutics	
	Timothy Peters-Strickland, MD VP, Global Medical Officer, Biotech Solutions PPD, Part of Thermo Fisher Scientific	
	Stefan Vitorovic, MS, MBA Co-Founder & Managing Director, Vida Ventures	

AGENDA

TRACK A:	TRACK B:	
3:00 pm Developing Internal and External Communication Strategies	3:00 pm What CMOs Need to Know About Medical Affairs	
In this panel, perspectives from corporate communications, CMOs and CEOs discuss best practices in effectively sharing your story with different audiences focusing on: • Authentic messaging • Press releases • Sharing new data • Social media • Managing bad news	 Publication management Internal interactions KOL interactions Working with MSL organizations When to officially kick off medical affairs Moderated by: John Yee, MD, MPH CMO, Sobi – North America	
Moderated by:	Panelists:	
Jodie Gillon, MPH SVP, Corporate Affairs & Patient Advocacy, Peptilogics	Daniel Chung, DO, MA CMO, SparingVision	
Panelists:	Joseph Elassal, MD, MBA CMO, Ankyra Therapeutics	
Karla MacDonald Chief Corporate Affairs Officer, Entrada Therapeutics	Peg Crowley-Nowick, PhD, MBA President, Medical Affairs Consulting and Head of Medical Affairs, Lumanity	
Austin Chiang, MD, MPH CMO, Medtronic GI		
Stephen Kanes, MD, PhD CEO, EmbarkNeuro		
Daniel Gold President, Fairway Consulting Group		

3:30 pm Afternoon Ice Cream Break & Networking

- Refreshments with Social Distance
- Meet the Exhibitors
- Peer-to-Peer Meetings

4:00 pm Two Track Choices		
TRACK A:	TRACK B:	
Innovations in Clinical Development & Remote Work	Outsourcing & Workforce Development	
Track Chair:	Track Chair:	
Anna Frostegård, MD, PhD	Ed Tucker, MD, MBA	
Co-Founder, Chief Scientific & Medical Officer,	Former CMO	
Annexin Pharmaceuticals	Goldfinch Bio	

TRACK A:	TRACK B:	
4:00 pm Implementing Patient-Centricity Throughout Clinical Development and Preparing for Launch	4:00 pm CRO Selection & Assigning Accountability	
This session provides CMOs with updated trends and best practices to avoid pitfalls and maximize collaboration throughout the development continuum to benefit patients and caregivers, the trial and the biotechs. Specifically:	Arguably the most important and expensive decision a biotech makes is around choosing a development partner. In this session, CMOs and CROs share how to navigate the RFP process in selecting a partner as well as how to avoid costly change orders and prevent common pitfalls.	
 Protocol development, trial execution Preparing for reimbursement at launch Novel ways to engage patients and caregivers 	Moderated by:	
Patient fair market valueTrial endpoint decisions	Edwin Rock, MD, PhD CMO, GlycoMimetics	
Moderated by:	Panelists:	
Serena Hung, MD CMO, Arkuda Therapeutics	David Huang, MD, PhD SVP & CMO, Peptilogics	
Panelists:	Raul Lima, MBA EVP, Strategic Clinical Operations, inSeption Group	
Rolf Benirschke Patient Advocate & Former NFL Player, Legacy Health Strategies		
Sarah Gheuens, MD, PhD, MMSc CMO, Head of R&D, Agios Pharmaceuticals		
Amy Simon, MD CMO, Beam Therapeutics		
4:30 pm Clinical Trials Outside the Office: DCTs and RWE in 2023 and Beyond	4:30 pm Best Practices in Building Out Your Clinical Development Team	
 Panelists share experiences and best practices in designing and running decentralized clinical trials focusing on: Ensuring data integrity and patient safety Usability for sites & patients Changing regulatory implications Empowering patients Justifying the investment in these technologies and models 	 This session addresses the following key issues: How do you incorporate FTEs, consultants and CROs as your company grows? What are the pivot points around which you hire inhouse expertise? How do you think about partnering with boutique CROs versus the big box CROs? How do finances tie into these decisions? 	
Moderated by:	Moderated by:	
Jeffrey Bornstein, MD CMO, Eledon Pharmaceuticals	Vicki Goodman, MD CMO, Exelixis	
Panelists:	Panelists:	
Joseph Kim, MBA Chief Strategy Officer, ProofPilot	Marcella Ruddy, MD CMO, Tectonic Therapeutic	
Ali Hariri, MD SVP, CMO, Eloxx Pharmaceuticals	Hunter Smith Executive Recruiter, Govig & Associates	
Chelsey Ryan Director of Clinical Operations and Pharmacovigilance, PROMETRIKA	Raul Lima, MBA EVP, Strategic Clinical Operations, inSeption Group	
	A	

AGENDA

TRACK A:	TRACK B:	
5:00 pm Leading & Managing Hybrid Teams	5:00 pm Navigating the Urgent Workforce Shortage and Turnover	
 As companies have more time to thoughtfully explore evolving work environments, building and maintaining a corporate culture with an eye towards flexibility becomes both an opportunity to attract and retain talent and a challenge to manage geographically diverse teams. Panelists address: Different models of virtual and hybrid work Investing in corporate culture to ensure unity of mission Impacts on hiring practices, career development, retention and operations Lessons learned 	 With the growing trend of employees moving from company to company, the difficult financial environment and increased specialization of roles within biotech, effectively hiring and retaining staff is a top priority. Panelists discuss: Running operations effectively considering all the movement Hiring the right people quickly without selling yourself short Managing for title and salary creep Retaining talent through non-monetary incentives 	
Moderated by:	Moderated by:	
Simon Cooper, MBBS CMO, Keros Therapeutics	Patrick Burnett, MD, PhD CMO, Arcutis Biotherapeutics	
Panelists:	Panelists:	
Christophe Arbet-Engels, MD, PhD, MBA CMO, Neurogastrx	Barbara Day Principal, Pharmaceutical Practice, Penfield Search Partners	
Karen Ivester Executive Director Operations, Cell & Gene Therapy Programs, inSeption Group	Holly Schachner, MD SVP, Clinical Development, NorthSea Therapeutics	
Nushmia Khokhar, MD CMO, Pyramid Biosciences	James Lewis Executive Director, Barrington James	
	Cliff Miras Managing Partner, Miras Search Partners	

5:30 pm Networking Reception

6:30 pm Day One Ends



DAY TWO - TUESDAY APRIL 4, 2023

7:50 am Registration Opens, Tea/Coffee

8:20 am Co-Chairs Opening Remarks

Nerissa Kreher, MD, MBA CMO, Entrada Therapeutics

Ed Tucker, MD, MBA

Former CMO, Goldfinch Bio

8:30 am BIOTECH INVESTMENT BANKING KEYNOTE

Keynote Fireside Discussion with Morgan Stanley's Managing Director and Chair of Biotechnology Investment Banking

In this fireside chat, we are pleased to welcome back Jessica Chutter to share her thoughts on:

- The current state of the biotech financial environment
- Future of biotech M&A
- Trends, opportunities
- Thoughts on evaluating companies
- Strategic transactions
- Examples of how investors evaluate companies
- Thoughts on sustaining publicly traded companies
- The importance of clinical trial design and readouts
- Thoughts on regulatory pathways, and primary endpoints
- Q&A



Jessica Chutter

Managing Director and Chair of Biotechnology Investment Banking, Morgan Stanley

with



Alise Reicin, MD CEO & President, Tectonic Therapeutic

9:00 am CMO KEYNOTE

The Evolving CMO Role Through Moderna's Rapid Development

In this session, Dr Zaks will share how he adapted his role as CMO at Moderna through rapid vaccine development from pre-clinical through commercialization in an unprecedented time. He will also discuss views on the future of biotech drug development.



Tal Zaks, MD, PhD Partner, Private Equity, OrbiMed

AGENDA

9:30 am Visualizing Trade-Offs and Improving Decision-Making

This talk will discuss mitigation strategies to manage uncertainties improve decision-making in clinical development, with a focus on:

- Difficult choice of endpoints (multiple candidates) and study population
- Enabling better interim decisions
- Visualizing trade-offs to inform decisions

Natalia "Natasha" Mühlemann, MD, MBA

VP, Strategic Consulting, Cytel

9:50 am Morning Break & Networking

- Breakfast
- Meet the Exhibitors
- Peer-to-Peer Meetings



10:30 am C-SUITE FIRESIDE CHATS

For the first time at the Summit, CMOs are joined by their C-Suite colleagues in fireside discussions to share how CMOs can best engage with their peers, overcome pain points, agree and disagree effectively and collaborate cross-functionally.

СМО – СОО

Mark De Rosch, PhD COO, Aura Biosciences Cadmus Rich, MD CMO & Head of R&D, Aura Biosciences

CMO – CFO

Richard Wanstall, MBA *CFO*, **Oncorus** John Goldberg, MD CMO, Oncorus

CMO – CSO

Philip Ashton-Rickardt, PhD CSO, Sigilon Therapeutics May Orfali, MD, MBA EVP, CMO, Sigilon Therapeutics

11:30 am Crash Courses on Topics Every CMO Should Learn About:

Patient Adherence, Global Regulatory Strategy, Quality Assurance & Pharmacometrics

Moderated by:

Ed Tucker, MD, MBA Former CMO, Goldfinch Bio

Lessons Learned in Implementing Digital Adherence Monitoring in a Late-Stage Drug Development Clinical Trial

- An introduction to the ramifications of poor adherence in clinical trials
- Tell-tale signs that poor adherence is present
- People, process, and tech involved in digital monitoring implementation
- Lessons Learned

Bernard Vrijens, PhD

CEO & Scientific Lead, AARDEX Group

Ning Yu, PhD, MBA

Director, Technical Development, Biogen

Implementing Digital Adherence Monitoring in a Late-Stage Drug Development Clinical Trial

- Application of early regulatory engagement in Europe & UK
- Benefits of regulatory alignment across EMA, FDA & UK
- Building your PV, QA & REG teams at the right time

Peter Embley

Chief Regulatory Officer, Ariello

Establishing a Culture of Quality: What Every CMO Must Know

- Five key elements of a culture of quality
- Four strategies for enabling a culture of quality
- Three risks of not adopting a culture of quality
- Positive business impact of a culture of quality

Sheila Gwizdak, MS

VP, Organizational and Quality Solutions, Halloran Consulting Group

Exposure-Response Analysis to Find the Right Dose for the Right Patient

The key to successful drug development is finding the drug exposure that maximizes efficacy and minimizes side effects. Pharmacometrics integrates complex pharmacological and biological information from various sources into exposure-response models. This session will address how CMOs can leverage highly skilled pharmacometricians and clinical pharmacologists to create actionable insights for making informed dose decisions, including:

- Finding the right dose for the general patient population and special populations using exposure-response models
- Utilizing these regulatory compliant analyses at all stages of drug development.
- Leveraging these tools to improve the probability of success throughout the drug development process.

Klaas Prins, PhD

Head of Business Development & Partner, qPharmetra

AGENDA

12:30 pm M&A From the CMO Perspective

In this session, panelists share their experiences as CMOs leading up to and during mergers. They specifically address:

- How to frame yourself for pharma and when to approach them
- Fostering a great relationship and balancing priorities
- Avoiding negative outcomes including delays and loss of knowledge
- What's next for CMOs

Moderated by:

Barbara Klencke, MD CMO, Sierra Oncology, a GSK Company

Panelists:

Howard Rutman, MD, MBA

CMO, Xalud Therapeutics

Tadaaki Taniguchi, MD, PhD CMO, Astellas Pharma

1:00 pm Lunch and Optional Roundtable Discussions

 Lunch Meet the Exhibitors Peer-to-Peer Meeting 	For those of you joining a roundtable, please get your lunch and make your way to your roundtable of choice at 1:20 pm. Roundtables require an RSVP. If you have not secured your spot, please see the registration desk.		
Roundtable #1: Adapting to the Role as a First-Time CMORaphaël Rousseau, MD, PhDFormer CMO, Neogene TherapeuticsChin Lee, MD, MPH CMO, Connect Biopharma	Roundtable #2: Compensation Contracting 101 for CMOs Navigating CMO Compensation and Negotiations Joseph Palumbo, MD, MACPsych CMO, BioVie Hunter Smith Executive Recruiter, Govig & Associates Donna Higgins CEO, The Higgins Group	Roundtable #3: Career Coaching for CMOs Roger Waltzman, MD, MBA CMO, Molecular Templates Debora Barton, MD CMO, TScan Therapeutics	Roundtable #4: Making an Impact Through Storytelling Effective storytelling is the key to attracting investors and motivating employees. In this roundtable discussion, presentation coach Donna Schwarz will provide a framework to quickly convey a compelling story that influences and inspires. Donna Schwarz Presentation Coach, Schwarz Consultants
2:00 pm		Panelists:	
Unexpected Skill Sets Needed to Succeed as a CMO CMOs share what skills they had, what they needed to learn and how they figured out the unknown unknowns based on their backgrounds in academia, pharma or biotech.		Sarah Grant, MD CMO, Celsius Therapeutics	
		Arvin Yang, MD, PhD CMO, Mersana Therapeutics	
Moderated by:		Deyaa Adib, MD CMO, Triumvira Immunologics	
James "Terry" Ferguson, MD CMO, Matinas Biopharma		Donna Higgins CEO, The Higgins Group	

2:30 pm

Navigating Board Interactions from Startup through Commercialization

In this session, CMOs and board members share how to best have influence and communicate simply and effectively with your Board around development, regulatory pathways, and justifying spending. Additionally, they discuss best practices around evolving boards, hiring/firing board members and independent board members.

Moderated by:

Randall Kaye, MD, MPH CMO, Longboard Pharmaceuticals

Panelists:

Elliot Ehrich, MD CMO, EVP, Translational Science, LifeMine Therapeutics

Iman El-Hariry, MD, PhD CMO, Erytech

Michele Gerber, MD, MPH CMO, Myeloid Therapeutics

Mary Spellman, MD Principal, Panclarity

3:00 pm Gathering Expertise in New Indications and Modalities

Over the course of one's career as a CMO, there is inevitably exposure to new indications or modalities of treatment whether as one transitions from company to company or as a biotech expands its asset and study portfolio. In this session, panelists share how they achieved competence and expertise in new areas as well as best practices in leveraging external experts.

Moderated by:

Alessandra Cesano, MD, PhD CMO, ESSA Pharma

Panelists:

Samuel Falsetti, PhD Global Chief Biotechnology & Innovative Solutions Officer, Inizio Biotech

Barbara Wirostko, MD CMO & Co-Founder, Qlaris Bio

3:30 pm The CMO's Role as Mentor

In addition to the CMO's responsibilities as an executive within their company, there is also a desire to provide mentorship and growth opportunities to both direct and indirect reports. In this session, panelists share how they think about and provide professional development to their teams.

Moderated by:

Barbara Troupin, MD Independent Director, Equillium

Panelists:

Eslie Dennis, MD, MBChB SVP, CMO & Head NA Medical Affairs, Kyowa Kirin

David Feltquate, MD, PhD CMO, Palleon Pharmaceuticals

Oscar Segurado, MD, PhD CMO, ASC Therapeutics

4:00 pm Town Hall on CMO Career Development

Steve Zelenkofske, DO President/Principal, SLZ Consulting

Randall Moreadith, MD, PhD President & CEO, Serina Therapeutics

4:30 pm Conference Concludes

