DAY ONE - Monday, April 4th, 2022

8:00 am
Registration Opens Social Distance Tea/Coffee

8:30 am
Co-Chairs Opening Remarks
Nerissa Kreher, MD, MBA
CMO, Entrada Therapeutics
Ed Tucker, MD, MBA
CMO, Goldfinch Bio

ANNUAL KEYNOTE

8:45 am
Annual Keynote Address about the State of the Drug Development Industry
Ken Getz, MBA
Director and Professor, Tufts Center for the Study of Drug Development, Tufts University School of Medicine /Founder and Board Chair, CISCRP

9:45 am
CMO-CEO Fireside Discussion on Working Through Challenges
In this fireside chat, Drs Alise Reicin and Marcella Ruddy discuss what makes their collaboration work and advice on what not to do as an MD CEO and CMO.
Alise Reicin, MD
CEO & President, Tectonic Therapeutic
with
Marcella Ruddy, MD
CMO, Tectonic Therapeutic

10:05 am
Grand Opening Break
• Coffee / Tea & Breakfast
• Meet the Exhibitors
• Peer-to-Peer Networking

KEYNOTE

10:45 am
Keynote: Taking on the CMO Role at Moderna and Looking to the Future of Biotech R&D and Global Medical Engagement
In this session, Dr Paul Burton shares his experience leading Moderna as CMO since June 2021:
• Transitioning from pharma to biotech
• Leveraging data science and digital technologies to reimagine medical engagement
• Thoughts on the future of clinical trial innovation
• Lessons Learned
• Q&A
Paul Burton, MD, PhD, FACC, MRCS
CMO, Moderna
11:10 am
The Changing Environment Around Accelerated Approvals and Regulatory Pathways
In this session, panelists share strategy trends and opportunities around accelerated approvals and regulatory designations. Additionally, they will discuss:
• How to approach the FDA based on the different types of meetings
• How these trends and pathways affect trial design
• Implications after approval based on the pathway
Led by:
Edith Perez, MD
CMO, Bolt Biotherapeutics
Panelists:
Jeffrey Bornstein, MD
CMO, Eledon Pharmaceuticals
Amy Blawas, PhD
Principal Consultant, NDA Group

11:30 am
The Seven Essentials of Clinical Development
Several essential components of successful drug development are often inadequately considered or overlooked. In this session, Dr. Modell shares best practices in approaching objectivity and transparency in clinical trial design, conduct, analysis, reporting and disclosure to regulatory agencies.
Jack Modell, MD
CMO, Rho

11:45 pm
What Statisticians Wish They Could Tell Their CMOs
What CMOs need to know about statistics, common mistakes and how to avoid them, strategies for clinical development, the strengths and weaknesses of complex trial designs like Bayesian, and how to maximize the use of your statisticians.
Led by:
Sheela Kolluri, PhD
Global Head of Clinical & Real World Evidence Statistics, Specialty R&D, Teva Pharmaceuticals
Panelists:
Marcia Levenstein, ScD, MBE
Senior Advisor, Vivli
Natalia “Natasha” Mühlemann, MD, MBA
VP, Strategic Consulting, Cytel

12:15 pm
Lunch
Attendees will have access to a choice of boxed lunches with social distance seating.

12:35 pm
Optional CMO Skill Development Roundtable Discussions During Lunch
Attendees will then have the option to choose a roundtable discussion. See below for the topic choices:

Roundtable #1: Adapting to the Role as a First-Time CMO
In this roundtable discussion, first-time and veteran CMOs are invited to share their experiences, questions and advice adapting to the position.
Emil Chuang, MBBS
CMO, Intrinsic Medicine

Roundtable #2: Operating as a CMO in the Virtual Environment
As remote working options become more mainstream, CMOs need to learn how to manage their teams virtually, including:
• Communicating effectively with the team
• Maintaining good relationships
• Balancing hybrid work models
Howard Kaufman, MD
President & CEO, Ankyra Therapeutics
Donna Skerrett, MD
CMO, Interim CEO & Executive Director, Paradigm Biopharma

Roundtable #3: Media Training and Storytelling for CMOs
Effective storytelling is the key to attracting investors and motivating employees. In this session, presentation coach Donna Schwarz will provide a framework to quickly convey your product or service as a solution to a problem that demonstrates its value.
Donna Schwarz
Presentation Coach, Schwarz Consultants
1:15 pm
How to Build or Expand an Effective Clinical Development Organization
A CMO, HR and an outside partner perspective will join this session to address how they are managing rapid workforce development. This will include lessons learned in what to prioritize, challenges they faced and how they overcame them. Additionally:
- Culture and infrastructure to rapidly build a solid organization
- Who to hire first
- Developing junior talent
- When and how to outsource/insource

Led by:
Ulo Palm, MD, PhD, MBA
CMO, Vaxxinity

Panelists:
Gayle Gironda
SVP, Human Resources, Inozyme Pharma

Peyton Howell, MHA
EVP, Chief Commercial & Strategy Officer, Parexel

Seemi Khan, MD, MPH, MBA
SVP, CMO, Reata Pharmaceuticals

Hunter Smith
Executive Recruiter, Govig & Associates

1:45 pm
Selecting Outsourcing Partners and Navigating the Relationship
- What CMOs look and listen for throughout the RFP and bid defense process
- Devising an evaluation process when selecting a CRO so that you can be more confident
- Addressing the friction points and opportunities that arise throughout the development process and the role of each partner in addressing them

Led by:
Simon Cooper, MBBS
CMO, Keros Therapeutics

Panelists:
Christophe Arbet-Engels, MD, PhD
CMO, Neurogastrx

Meaghan Powers
Director, Clinical Practice Operations, Halloran Consulting Group

Lori Buckenmyer
Head of Clinical Operations and Project Management, inSeption Group

2:15 pm
Advance Analytics-Driven Solutions for Clinical Trial Matching and Enhanced Cancer Patient Outcomes
How to leverage advanced analytics to move oncology drug development through the clinical trials process more quickly and optimize early detection of response. This session will address use of advanced analytics for:
- Feasibility and research site selection
- Identify potential subject within healthcare provider workflow
- Include subjects with better likelihood of efficacy
- Precision medicine in the community oncology setting

Susan Night JD, LLM
VP, Site Engagement and Network Strategy, TD2

2:30 pm
Building a Work Culture that Attracts and Retains Talent in the Increasingly Competitive Emerging Biotech Space
- How to onboard hires who don’t have industry experience
- Retaining talent and managing expectations
- The role of flexible working models, title inflation, non-monetary incentives, etc. in this process

Led by:
Debora Barton, MD
CMO, Carisma Therapeutics, Inc

Panelists:
Patrick Burnett, MD, PhD, FAAD
CMO, Arcutis Biotherapeutics

Donna Higgins
CEO, The Higgins Group

Barbara Day
Principal, Pharmaceutical Practice, Penfield Search Partners

James Lewis
Executive Director, Barrington James

3:00 pm
Afternoon Break
- Ice Cream
- Meet the Exhibitors
- Peer-to-Peer Networking
3:35 pm
Adapting to Hybrid and DCT Modeling to Make Clinical Research More Efficient

In this session, panelists share how they identified where in medicine development a hybrid/virtual option can work well. They will also address the use of technology such as wearables, remote monitoring, e-visits among others, the challenges, realities and finding the balance that works best for the trial.

Led by:
Ed Tucker, MD, MBA  
CMO, Goldfinch Bio

Panelists:
Oscar Segurado, MD, PhD  
CMO, ASC Therapeutics
Timothy Peters-Strickland, MD  
VP, Regional Medical Officer, Biotech Solutions, PPD, part of Thermo Fisher Scientific
Graham Wylie, MBBS  
CEO, MRN
Joseph Kim, MBA  
Chief Marketing Officer, ProofPilot
Nina Anderson  
Associate Director, Clinical Science & Development, inSeption Group

4:15 pm
Building Effective Site Relationships: A Guide for CMOs

How to build an effective site relationship from site identification through the entire duration of a clinical trial to ensure the best possible outcome. Key insights include strategies to:
• Expedite suitable site identification using hard data sets
• Best practices to meet and surpass enrollment targets
• Achieve patient eligibility review efficiency
• Optimize site engagement to attain maximum effectiveness for quality, timely data entry and query resolution

Patrick Smith  
Feasibility Manager & Clinical Trial Leader, Scimega Research

4:30 pm
What CMOs Must Know About How Patient Engagement Supports the Entire Organization

This session gives CMOs an update on current views on patient-centric medicine development, what it really means and the benefits for both the patient and trial. More specifically:
• Achieving timely recruitment by better selecting sites and writing good protocols
• Working with patient advocacy groups to integrate patient voice in trial design and drive better enrollment
• Achieving enrollment when there is so much competition for patients

Led by:
Jodie Gillon, MPH  
SVP Corporate Affairs & Patient Advocacy, Peptilogics

Panelists:
Barry Ticho, MD, PhD  
CMO, Stoke Therapeutics
Rolf Benirschke  
Patient Advocate & Former NFL Player, Legacy Health Strategies
Roger Waltzman, MD, MBA  
CMO, Molecular Templates

5:00 pm
Q&A With Experienced CMOs on People Management

Led by:
Jeffrey Humphrey, MD  
CMO, Magenta Therapeutics

Panelists:
Oscar Segurado, MD, PhD  
CMO, ASC Therapeutics
Howard Kaufman, MD  
President & CEO, Ankyra Therapeutics
Mark Eisner, MD, MPH  
CMO, FibroGen

5:30 pm
Networking Reception

6:30 pm
Day One Ends
DAY TWO - Tuesday, April 5th, 2022

8:00 am
Registration Opens Social Distance Tea/Coffee

8:30 am
Co-Chairs Opening Remarks

Nerissa Kreher, MD, MBA  
CMO, Entrada Therapeutics

Ed Tucker, MD, MBA  
CMO, Goldfinch Bio

9:15 am
How to Best Prepare for Meetings with Analysts and Investors

• Strategizing with your CEO and financial advisors
• How investors and Analysts evaluate companies and assess CMO interactions
• What inspires confidence and what to avoid
• Thoughts on telling a nuanced and compelling story to investors
• Lessons from the trenches

Led by:

Randall Kaye, MD, MPH  
CMO, Longboard Pharmaceuticals

Panelists:

Thurein Htoo, MS, MBA  
CEO & Co-Founder, Qlaris Bio

Christian Richard, MBA  
Head of Public Research, Samsara Biocapital

Seth Lewis  
SVP, Investor Relations, Communications & Strategy, Molecular Partners

Arvin Yang, MD, PhD  
SVP, CMO, Mersana Therapeutics

9:55 am
What Therapeutic Developers Should Look for in a Diagnostic Partner:

• The interplay between therapeutic and diagnostic development
• How molecular diagnostics impact therapeutic development
• How biotech CMOs can use these diagnostics to support revisiting data, global development and global regulatory strategy

Paul Billings, MD, PhD, FACP, FACMG  
CEO & Director, Biological Dynamics

Ed Tucker, MD, MBA  
CMO, Goldfinch Bio

10:10 am
Morning Day Two Break
• Coffee / Tea & Breakfast
• A Wide Choice of Chocolate
• Meet the Exhibitors
• Peer-to-Peer Networking

INVESTOR KEYNOTE

8:45 am
Keynote Fireside Discussion with Morgan Stanley’s Managing Director and Chair of Biotechnology Investment Banking

In this fireside chat, we are pleased to welcome Jessica Chutter to share her thoughts with the CMO audience on:
• Future of biotech M&A
• Trends, opportunities
• Thoughts on evaluating companies
• Strategic transactions
• Examples of how investors evaluate companies
• How clinical trials impact share prices
• How investors raise money
• Capital raising
• The importance of clinical trial design and readouts
• Thoughts on sustaining publicly traded companies
• Thoughts on regulatory pathways, and primary endpoints
• Q&A

Jessica Chutter, MBA  
Managing Director & Chair of Biotechnology Investment Banking, Morgan Stanley

with

Alise Reicin, MD  
CEO & President, Tectonic Therapeutic
10:50 am

**Biotech Financing Options and Their Implications**

- What CMOs need to know about series funding, crossover and IPO
- How to think about when to engage in these financing options based on the company stage, milestones, and budget
- How CMOs can best support the decision-making and fundraising processes

Led by:

**Nerissa Kreher, MD, MBA**
CMO, Entrada Therapeutics

Panelists:

**Geoff Meyerson, MBA**
Co-Founder & CEO, Locust Walk

**Tariq Kassum, MD**
CEO, Celsius Therapeutics

**Ann Barbier, MD, PhD**
CMO, CAMP4 Therapeutics

11:30 am

**How Can Your CRO Help With Investors? Three Ways to Build Investor Confidence in Your Development Program**

To invest with confidence, investors need a well-analyzed unmet need, a realistic development plan and a clear path to the next value inflection point. Drawing on insights collected through a primary research study of biotech investors, this presentation addresses what companies can do to better position themselves for investment opportunities, including:

- How to broaden the definition of unmet need.
- Opportunities to de-risk the development plan.
- Strategies to accelerate timelines with innovation.

**Skip Sands, MD**
SVP, Senior Medical Director, Parexel Biotech

11:45 am

**Managing the Partnership Between Big and Small Pharma**

This session addresses the role of the CMO in how to best manage the relationship between your biotech and big pharma. More specifically:

- What are the leadership skills needed?
- Where are the friction points and how do you avoid them or fix them?

Led by:

**Joanne Lager, MD**
CMO, iTeos Therapeutics

Panelists:

**Thomas Davis, MD**
CMO, Genocea Biosciences

**Milan Zdravkovic, MD, PhD**
CMO, SNIPR Biome

**Eric Crombez, MD**
CMO, Gene Therapy & Inborn Errors of Metabolism, Ultragenyx

12:10 pm

**Lunch**

1:10 pm

**Positioning Yourself For Board Roles and What to Expect**

In this session, Board members share their experiences and discuss how CMOs can think about Board role opportunities including:

- Knowing why you want a seat on a Board and what you bring to the table
- The skills needed to succeed and excel in the role of Development representation on a Board, both private & public
- Working with your current CEO and Board while advising another company
- Identifying the reality of what you are getting into

Led by:

**Julie Hambleton, MD**
Biotech Executive & Independent Board Member, Public and Private Biotech Companies

Panelists:

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

**Holly Schachner, MD**
CMO, Double Rainbow Biosciences

**Jeffrey Humphrey, MD**
CMO, Magenta Therapeutics
1:40 pm
What CMOs Wished They Knew Before Transitioning into the CMO Role
CMOs and SVPs who previously worked in academia and big pharma in particular will address the following:
• Expectations and managing the transition
• Skills they took from previous roles
• What they wished they knew when they transitioned and how they learned those skills
• The opportunities and challenges
Led by:
Anna Frostegård, MD, PhD
CMO & CSO, Annexin Pharmaceuticals
Panelists:
James “Terry” Ferguson, MD
CMO, Matinas Biopharma
Cesar Cerezo, MD, PhD
CMO, Alkahest, a Grifols Company
Timothy Lu, MD, PhD
CMO, DICE Therapeutics
Nushmia Khokhar, MD
CMO, Umoja Biotherapeutics

2:10 pm
CMO Veterans on How They Navigated the Industry
This session focuses on what veteran CMOs learned in their first CMO role, brought to their second role and how they positioned themselves for a career in biotech. More specifically:
• What they would have done differently if they knew what they knew now
• How the roles differed from company to company and how they adapted when moving outside of their area of expertise
Led by:
Steven Zelenkofske, DO
CMO, SwanBio Therapeutics
Panelists:
Richard Malamut, MD
Former CMO, Collegium Pharmaceuticals
Barbara Wirostko, MD
CMO, Qliaris Bio
Randall Kaye, MD, MPH
CMO, Longboard Pharmaceuticals
Raphaël Rousseau, MD, PhD
CMO, Neogene Therapeutics

2:40 pm
How CMOs Can Engage Patients and the Scientific Community Through Social Media
Austin Chiang, MD, MPH
CMO, Medtronic GI
with
Ed Tucker, MD, MBA
CMO, Goldfinch Bio

3:00 pm
Best Practices for Cross Functional Communication Strategies for the CMO
It is vital for the CMO to have excellent communication awareness and skills to communicate externally with KOLs, investors, the scientific community and more. In this session, seasoned CMOs share their best practices and more specifically:
• How to sell a science story to scientists and non-scientists alike
• Preparing for and managing negative outcomes and weak signals
• Aligning communications from the CMO, CEO and Commercial
Led by:
Cadmus Rich, MD, MBA
CMO & Head of R&D, Aura Biosciences
Panelists:
Stephen Huhn, MD
CMO & SVP of Clinical Development, Pipeline Therapeutics
Anna Berkenblit, MD, MMSc
SVP, CMO, ImmunoGen
Margaret Koziel, MD
SVP, CMO, Axcella

3:30 pm
Conference Concludes