DAY 1

Wednesday | Oct 16th, 2024 | San Francisco, CA

EARLY CLINICAL DEVELOPMENT

Registration Time	8:00 AM - 8:45 AM
Chairperson Address	8:45 AM - 9:00 AM
Keynote 1	9:00 AM - 9:20 AM

Integration of Biomarkers in Early Clinical Development

- Explore the pivotal role of biomarkers in streamlining drug development and refining patient-centric approaches.
- Learn how biomarker integration optimizes dosing, accelerates decisions, and identifies target patient cohorts.
- Uncover the transformative potential of biomarker-driven strategies in revolutionizing drug discovery and refining treatment paradigms.
- Navigate hurdles and benefits, advancing precision medicine and optimizing clinical trials.

Stephen Huang
Executive Director of Clinical Biomarkers and Companion Diagnostics
Avenzo Therapeutics

Keynote 2	9:20 AM - 9:40 AM

Overcoming recruitment hurdles in rare diseases

Viji (VG) Senthilnathan
Associate Director Clinical Operations
PTC Therapeutics

SPONSOR PRESENTATIONS	9:40 AM - 10:05 AM

Revolutionizing Life Sciences: AI and Machine Learning in Direct Analysis of Dispersed Documents

Keith Parent
CEO
Court Square group

COFFEE BREAK	10:05 AM - 10:15 AM

NETWORKING SESSION

MEETING 1:	MEETING 2:	MEETING 3:	MEETING 4:
10:15 - 10:40	10:40 - 11:05	11:05 - 11:30	11:30 - 11:55

DAY 1

Wednesday | Oct 16th, 2024 | San Francisco, CA

LUNCH BREAK

11:55 AM - 12:45 PM

SPONSOR PRESENTATIONS

12:45 PM - 1:10 PM

How do you select your Vendors?

Kalyan Obalampalli (KO)
Founder
CLIN.AI

Sportlight Dicsussion

1:10 PM - 1:35 PM

Outsourcing Strategy for Small to Mid size Sponsors

- Explore best practices in selecting and managing CRO partnerships to enhance operational efficiency and cost-effectiveness in clinical trials.
- Address key considerations in vendor selection, quality oversight, and risk management to ensure trial success for smaller sponsors.
- Discuss the challenges and benefits of outsourcing in navigating global regulations, patient recruitment, and data management for small to mid-size sponsors.

Randy Brown
Vice President, Clinical Operations
Altimmune

CLINICAL DATA ANALYTICS

Keynote 3

1:35 PM - 1:55 PM

Why we still need programming support for Clinical Trials

- Why do we still need Programming support for Clinical Trials given that we have so many platforms and options.
- Impact of technology in Clinical Trials addressing data quality and efficacy paradox.
- Keep things simple by focusing on the signal and less on the noise.

Iuliana Constantin
Founder
CoE (Center of Excellence) Pharma

Keynote 4

1:55 PM - 2:15 PM

Banking Meets Biotech: How Anti-Fraud Technologies Can Protect Clinical Trials

- Leveraging data insights to optimize patient recruitment site selection, ensuring efficient resource allocation
- Using data analytics to pinpoint regions with high patient concentrations, streamlining recruitment efforts for maximum impact
- Employing predictive modeling to identify sites with the greatest recruitment potential, improving enrollment rates and trial efficiency.

Katrina Paz
Director of Clinical Programming
Denali Therapeutics

DAY 1

Wednesday | Oct 16th, 2024 | San Francisco, CA

SPONSOR PRESENTATIONS

2:15 PM - 2:40 PM

Becoming a Lean CRO – 5 years into the making

Julie Martin
CEO
Scimega

NETWORKING SESSION

MEETING 1:	MEETING 2:	MEETING 3:
2:40 - 3:05	3:05 - 3:30	3:30 - 3:55

SPONSOR PRESENTATIONS

3:55 PM - 4:20 PM

Exploring Hidden Challenges to On-time Study Start-up

On-time site initiations and study startup is one of the biggest challenges affecting the cost-effective conduct of clinical trials globally. When interviewing clinical operations executives at sponsor companies, they are most vocal about the challenges they experience with their CROs getting study sites initiated on time and the study started. Most CROs are equipped to run trials for sponsors and clinical operations teams at sponsors have the skill set to guide trials successfully. Yet, we are still seeing pervasive delays across the trial spectrum. Unfortunately, there are critical gaps in study conduct that neither of these groups support. When they do support these areas, not all do it particularly well. These gaps are in areas like supply chain (materials, ancillary supplies, equipment), on-time patient recruitment, translation and localization challenges. Finally, these groups are struggling significantly with management of the complexities of increasingly globalized trials.

Alejandro Serricchio
Director Of Business Development
IMPERIAL CLINICAL RESEARCH SERVICES

Keynote 5

4:20 PM - 4:40 PM

Generative AI: Revolutionizing Document Workflow in Clinical Trials

Amir Emadzadeh
Director of Software Engineering
Genentech

DAY 1

Wednesday | Oct 16th, 2024 | San Francisco, CA

CLINICAL COMPLIANCE AND REGULATORY AFFAIRS

SPONSOR PRESENTATIONS 4:40 PM - 5:05 PM

Custom FSP models for biotechs

Successful FSP partnerships for biotechs are grounded in a shared vision of success, empowering sponsors with the confidence to advance their projects. Traditional FSP models often fall short in addressing the unique programmatic needs of biotechs, leading to the development of Custom FSP models. These models are designed to navigate the dynamic development landscape and complex program requirements. Driving optimal outcomes hinges on ease of access to specialized expertise, seamless transitions, and enhanced efficiencies enabled by onshore-offshore teams, along with greater flexibility in resourcing. Additionally, robust governance and oversight aligned with sponsor operational teams ensure that project goals and timelines are consistently met.
In this session, we will discuss how custom FSP solutions can optimize resource allocation, enhance operational efficiency, and ensure robust program outcomes. Attendees will also gain insights into the benefits of dedicated and blended teams, as well as the importance of aligned oversight in achieving biotech objectives.

Stephen Boccardo
VP Business Development

Nithiya Ananthakrishnan
Senior Vice President

PRECISION for medicine

Keynote 6 5:05 PM - 5:25 PM

Convergence of Big Data and AI in Drug Discovery and Development

- Transformative potential of Artificial Intelligence in optimizing processes within the medical writing landscape.
- Insights into how AI is revolutionizing regulatory writing, enhancing efficiency, and ensuring compliance

Dr. Prasun Mishra
CEO and Founder
Precision Biopharma

END OF DAY 1

COCKTAIL PARTY

5:30 PM - 6:00 PM

DAY 2

Thursday| Oct 17th, 2024 | San Francisco, CA

OPTIMIZING CLINICAL OPERATIONS

Registration Time 8:00 AM - 8:45 AM

Chairperson Address 8:45 AM - 9:00 AM

Keynote 1 9:00 AM - 9:20 AM

Don't Sweat the Small Stuff: Tips for Efficient Execution of Clinical Pharmacology Studies

- Optimize patient recruitment and retention through targeted strategies.
- Prioritize meticulous planning and adaptive trial designs to address uncertainties.

Mindy Sivasubramanian
Clinical Program Director
Genentech

Keynote 2 9:20 AM - 9:40 AM

Patient-Reported Outcomes (PROs) for the Win: Bringing the Patient Voice to Your Drug Development Programs

- The session focuses on the importance of integrating Patient-Reported Outcomes (PROs) into drug development programs to better understand the patient experience and enhance treatment efficacy.
- By incorporating PROs, pharmaceutical companies can align their drug development strategies with the real-world needs and experiences of patients, leading to more successful outcomes and improved patient satisfaction.

Nina Hill
Senior Director
Puma Biotechnology

SPONSOR PRESENTATIONS 9:40 AM - 10:05 AM

AI, Simulation and Avatars: Increasing Content Velocity in Clinical Trial Training

Brad Stefanovic
Vice President, Clinical Operations
Pro-ficiency

Keynote 3 10:05 AM - 10:25 AM

Real World Evidence and Artificial Intelligence in Clinical Trials, with a specific focus on usage of pharmacogenetics powered by AI

- Introduction to Real World Evidence (RWE) and Artificial Intelligence (AI)
- Pharmacogenetics Overview and it's Integration.
- Application in Clinical Trials
- Real World Evidence (RWE) Utilization

Allan Gobbs
Co-Founder
ATEM Capital

DAY 2

Thursday| Oct 17th, 2024 | San Francisco, CA

SHORT BREAK 10:30 AM - 10:40 AM

NETWORKING SESSION

MEETING 1:	MEETING 2:	MEETING 3:
10:45 - 11:05	11:05 - 11:30	11:30 - 11:55

LUNCH BREAK

11:55 AM - 12:45 PM

Panel Dicsussion 12:50 PM - 1:15 PM

Accelerating Drug Development: Streamlining Clinical Trial Phases and Processes

Christine Von Raesfeld
Patient Advisor
Aurinia Pharmaceuticals

Peter Kim
Panelist
MAIA Biotechnology

Steven Vann Smith
Panelist
Dey Pharma

Keynote 4 1:15 PM - 1:35 PM

Role of "AI" in shaping the Future of Clinical Trials

- Revolutionizing clinical trials by optimizing patient recruitment through predictive analytics and real-time data processing, ensuring a more targeted and efficient participant selection.
- Enhances trial monitoring and data analysis by automating processes and identifying patterns that might be missed by traditional methods, thus increasing the accuracy and speed of outcomes.

Saumya Srivastava
Medical Science Leader
Ascentage Pharma

Keynote 5 1:35 PM - 1:55 PM

RWE and its usefulness and insights

- RWE reveals how treatments perform in diverse, real-world settings, complementing clinical trial data.
- RWE informs regulatory and healthcare decisions by providing evidence on long-term safety and effectiveness.

Dr.Jennifer Onwumeh Okwundu
Director of Clinical Science
Pfizer

DAY 2

Thursday| Oct 17th, 2024 | San Francisco, CA

Keynote 6 1:55 PM - 2:15 PM

Importance of Patient Equity and Diversity in Clinical Trials

- Ensuring diversity in clinical trials allows for better understanding of how various populations respond to treatments, leading to more effective and personalized healthcare solutions.
- Promoting patient equity in clinical trials helps reduce health disparities by including underrepresented groups, ensuring they benefit from new medical advances.

Mallika Singh
DrPH Candidate
New York Medical College (NYMC)

2:15 PM - 2:35 PM

Addressing Regulatory Challenges in Clinical Trial Optimization

- Streamlining procedures for regulatory submissions, approvals, and amendments.
- Implementing robust pharmacovigilance systems and procedures to ensure timely reporting of adverse events and safety data.
- Establishing mechanisms to guarantee data integrity, transparency, and traceability in accordance with regulatory expectations.
- Continuously monitoring and adapting to changes in regulatory requirements and guidelines to maintain compliance throughout the trial.

Anthony Colenburg, Sr.
Site Head of Quality
Sutro Bio

Keynote 8 2:35 PM - 3:00 PM

Clinical Operations Strategies for Seamlessly Transitioning from Early to Late Phase

- Adaptable strategies facilitate smooth transitions from early-phase exploration to late-phase validation.
- Exploring the evolution of clinical operations across trial phases, optimizing for patient-centricity and data quality.
- Discovering the critical role of streamlined operations in advancing clinical trials across all development stages.

Camisha Harge
Clinical Development & Operations Specialist

CLOSING REMAKRS

END OF DAY 2