# OUTSOURCING IN CLINICAL TRIALS SOUTHERNCALIFORNIA 2023

Hyatt Regency La Jolla at Aventine, USA

26th – 27th September 2023

## Key Speakers

Jennifer Lee, Board of Director, Enzyme by Design
Dr Yuchen Wang, Associate Director, Biologics Product Development, Calidi Biotherapeutics
Sormeh Mahjouri, Program Director, Imagion Biosystems, Inc
AJ Bergmann, Chief Financial Officer, Capricor Therapeutics
Jiao Song, Director, Early Clinical Science, Janssen
Ken Kobayashi, Senior Vice President, Formerly of Kinnate Biopharma
Brandi Roberts, Chief Financial Officer, Longboard Pharmaceuticals
Patty Law, Sr. Director, Clinical Affairs, Hologic
Veronica Sandoval, Principal, Inclusion & Health Equity, Genentech
Wendy Pizarro, Chief Administrative Officer and Chief Legal Officer, Calidi Biotherapeutics
Kerry Clancy, Director of Outsourcing, AnaptysBio
Chad Orevillo, Executive Vice President, Head of Operations, Longboard Pharmaceuticals
Barbara Birch, Associate Director, Clinical Procurement & Outsourcing, Ultragenyx Pharmaceutical Inc.
Mirta Grifman, Vice President, Clinical Development and External Innovation, Biosplice Therapeutics
Emily Solomon, Vice President, Clinical Operations, Biosplice Therapeutics
Tanja Obradovic, Vice President, Scientific Affairs, ICON
Grace Indyk, Director Clinical Operations, Aptose Biosciences
Joseph Shan, VP, Clinical Research, Mosaic ImmunoEngineering
Sverre Bengtsson, Co-Founder, Senior Vice President Strategic Relations, Viedoc
Robert Loll, SVP, Business Development & Strategic Planning, Praxis
Dorothy Blythe, Principal Clinical Data Manager, TFS Health Science
Roel van der Heijde, Facilitator & Trainer, Patient Experience Association
Zachary Bynum, B.A. Biological Sciences Sr. Manager, Regulatory Affairs, Regulatory Science, PPD
Amanda Murphy, Senior Director Data Intelligence and Solutions, GlobalData
Shyam Banuprakash, Senior Vice President, Data Science, Clario
Sanjay Shrivastava, CEO, Innova Vascular
Gina Fulgar, Executive Director, Development Operations, eFFECTOR Therapeutics, Inc.
Nonna Snider, VP Clinical and Operations, JeniVision Inc
Krishna P. Allamneni, Chief Development Officer, Concarlo Therapeutics, Inc
Bryan Cornwall, Former Executive Vice President, Research and Clinical Affairs, Surgalign
James Rock, President and Chief Clinical Officer, AriBio
Nicole Rems, Recruitment Specialist, AriBio
Sahar Roshan, Director Clinical Operations, Mirati Therapeutics
Steven Cummings, M.D. PCM Trials
Dan McGann, Solutions Consultant, eClinicalSolutions
Melissa Mooney, Director, eCOA Sales Engineering, IQVIA eCOA Technologies
Nicole Stansbury, Senior Vice President and Head ofGlobal Clinical Operations, Premier Research
Roberta Vezza Alexander, Director, ClinicalResearch, Biological Dynamics Inc.
Aditya Kotta, Regional Director Business Development, Novotech

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| | **Outsourcing in Clinical Trials Southern California**<br><br>**Day 1 \| 26th September 2023** | |
| **07:45** | **Registration and Refreshments** | |
| **08.20** | Chair's Opening Remarks<br>**Robert Loll, SVP, Business Development & Strategic Planning, Praxis** | |
| **08:30** | **KEYNOTE PANEL**<br>**Patient engagement - what we as an industry need to do to promote trust**<br>• How other experts are boosting engagement across therapeutic indications<br>• Talking the good, the bad and the ugly of recruitment<br>• Discussing innovative patient recruitment tools being used in the industry<br><br>**Moderator: Robert Loll, SVP, Business Development & Strategic Planning, Praxis**<br><br>**Panelists:**<br>**Veronica Sandoval**, Principal, Inclusion & Health Equity, **Genentech**<br>**Wendy Pizarro**, Chief Administrative Officer and Chief Legal Officer, **Calidi Biotherapeutics**<br>**Tanja Obradovic**, Vice President, Scientific Affairs, **ICON** | |
| **09:15** | **State of the global biotech landscape: where the opportunities lie**<br>• Perspective on investment landscape<br>• Biotech workforce current trends & the implications for clinical trials<br>• M&A activity in the CRO landscape & how that impacts sponsors<br><br>**Aditya Kotta,** Regional Director Business Development, **Novotech** | |
| **09:45** | **The upcoming importance of diversity in clinical trials and how it can promote patient recruitment**<br>• A look into the new requirements made bythe FDA and what you need to be aware of<br>• How to most efficiently enroll the right patients needed for your trial to be approved<br>• Looking at all aspects of diversity and whythey are important for clinical trials<br><br>**Wendy Pizarro**, Chief Administrative Officer andChief Legal Officer, **Calidi Biotherapeutics** | |
| **10:15** | Morning Refreshments and Networking | |
| | **Stream A: Outsourcing & Clinical Operations**<br><br>***CHAIR:*** **Robert Loll, SVP, Business Development &Strategic Planning, Praxis** | **Stream B: Clinical Trial Technology & Innovation**<br><br>***CHAIR:*** **Amanda Murphy, Senior Director, Data Intelligence and Solutions, GlobalData** |
| **10:45** | **Finding CROs and partners as a small to medium sized company: challenges and considerations**<br>• Finding the right match for your | **How to implement and control your social media campaign to maximize study exposure and reach more patients**<br>• Sharing a case study of a phase 3 study outline |

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| | specific indication<br>• The dos and don'ts of who to work with as a small biotech<br>• Discussing how to enter contract negotiation on the right footing<br><br>**Chad Orevillo,** Executive Vice President, Head of Operations, **Longboard Pharmaceuticals** | • Improving your digital presence by focusing on study branding (POLARIS-AD), study website & digital campaigns<br>• Discussing the importance of;<br>o Performance Marketing<br>o Strategy & Implementation<br>o Management and Analysis<br><br>**James Rock,** President and Chief Clinical Officer, **AriBio**<br><br>**Nicole Rems,** Recruitment Specialist, **AriBio** |
| **11:15** | **Simplifying protocols to enable home-Base trial activities**<br><br>• How simplification of a protocol for Parkinson's disease enabled a home-based trial<br>• Lean Design approach to radical simplification:results for Merck protocols<br>• Overcoming resistance to simplification:common issues<br><br>**Steven Cummings,** M.D. **PCM Trials** | **Optimizing early development to maximize success probability in the late stage development**<br><br>• Dose escalation: Critical elements to support informative drug safety profile and initial efficacy<br>• Selection of the dose for the late-stage development: decisions around monotherapy, combination regimens<br>• Incorporation of the patient voice, alignment with medical quality measures, considerations around existing treatment options landscape<br><br>**Tanja Obradovic**, Vice President, Scientific Affairs, **ICON** |
| **11:45** | **Identifying cost drivers in early clinical study planning, recognizing implications of protocol requirements to find greater efficiency for long-term clinical projects and mitigate time-driven costs**<br>• Highlighting the need for alignment in clinical planning for program/study objectives, understanding vendor-specific requirements and dynamics and how these impact cost in an environment where resources are finite<br>• Recognizing the importance of attention to vendor relationship management and governance, featuring:<br>▪ mutual trust in collaborative relationships<br>▪ early, fulsome engagement in full-scope planning, risk identification, and risk mitigation strategies addressing "the known unknowns"<br>▪ shared accountability for budget control and budget optimization strategies | **Dealing with Phase 3 data challenges; how to get data collection back on track**<br><br>• Handling adversity when challenges arise in your study<br>• Highlighting the value of hands-on experience when managing a complex study<br>• How to negotiate with a partner after issues have arisen, getting your money's worth<br>• Lessons learned when managing large data sets<br>• Advice for future trials, how to ensure data collection and quality is on point<br><br>**Brandi Roberts,** Chief Financial Officer**, Longboard Pharmaceuticals** |

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| | ▪ effective, timely and sufficient communication around continuous active management of finite resources<br><br>**Barbara Birch**, Associate Director, Clinical Procurement & Outsourcing, **Ultragenyx Pharmaceutical Inc.** | |
| **12:15** | **FSP agility & responsiveness through employee trust & empowerment**<br>• Flat structure empowers employees<br>• Empowerment allows for creative andrapid customized solutions<br>• Customized solutions apply to both technology and contracting<br><br>**Dorothy Blythe**, Principal Clinical Data Manager, **TFS Health Science** | **Tech Spotlight**<br><br>**Running up that hill: accelerate cycle times &reach patients faster with elluminate**<br>*Learn how the elluminate Clinical Data Cloud and Biometrics Services deliver*<br><br>• Operational insights across numerous data sources that provides definitive answers and analytics on enrollment, protocol compliance and safety<br>• Improved study oversight with a holistic view of risk across all data sources<br>• 50 out-of-the-box visualizations to support supports cross-study analysis for deeper insights with self-service access to clinical and operational analytics<br>• Increased productivity across data management, medical monitoring, clinical operations, clinical programming and statistical analysis roles<br>**Dan McGann,** Solutions Consultant, **eClinicalSolutions** |
| | | **Tech Spotlight**<br><br>eCOA: a necessity or a nice to have?<br><br>• What are COAs and why do they matter in clinical research<br>• How has the evolution of the use of COAs in clinical trials paved the way for adoption of eCOA<br>• Choosing the right eCOA partner<br><br>**Melissa Mooney,** Director, eCOA Sales Engineering, **IQVIA eCOA Technologies** |
| **12:45** | **Lunch and Networking** | |

<table>
<tr><td></td><td colspan="2">JOIN ONE OF OUR NETWORKING TABLES<br>Eat lunch with a like-minded group of industry colleagues by joining one of our lunchtime discussiongroups on the topics below:</td></tr>
<tr><td rowspan="2"></td><td>TABLE 1: Patient enrollment, what are we doing toimprove uptake in new trials.</td><td>TABLE 3: Managing your trial budget duringuncertain times.</td></tr>
<tr><td>TABLE 2: Finding the right CRO for your study.</td><td>TABLE 4: Decentralization, for or against?</td></tr>
<tr><td>1:45</td><td>PANEL DISCUSSION - Top tips and tricks for managing your trial budget during unstable times<ul><li>Understanding what the reality of the costs ofclinical trials are and what could happen to increase costs</li><li>Planning out the entire trial with a budget focus, what steps are truly needed</li><li>Everyone is undergoing cost savings, what are key areas to cut down in</li></ul>Moderator: Robert Loll, SVP, Business Development & Strategic Planning, Praxis<br><br>Brandi Roberts, Chief Financial Officer, Longboard Pharmaceuticals<br><br>Sahar Roshan, Director Clinical Operations, Mirati Therapeutics</td><td>Interactive Workshop - Exploring the use of innovative technologies in clinical studies<ul><li>Understanding the benefits and challenges of using newer technologies such as AI in clinical studies</li><li>Discussing the factors to consider when deciding whether to implement emerging technologies in clinical studies</li><li>Identifying the potential use cases of innovative technologies in clinical trials, and how they can improve study outcomes</li></ul>Mirta Grifman, Vice President, Clinical Development and External Innovation, BiospliceTherapeutics<br><br>Emily Solomon, Vice President, ClinicalOperations, Biosplice Therapeutics</td></tr>
<tr><td>2:30</td><td>Feeling pressure to curb costs? How central monitoring can stretch your budget without compromising quality<ul><li>Considerations for implementing a successful central monitoring strategy</li><li>The value proposition: Where central monitoring can have the greatest impact forreducing clinical trial costs</li><li>How central monitoring may impact the futurerole of the CRA</li></ul>Nicole Stansbury, Senior Vice President and Head ofGlobal Clinical Operations, Premier Research</td><td>Successfully navigating the regulatory complexities of EU CTR<ul><li>Provide in-depth knowledge and share practical experiences to help guide industry partners through the regulatory processes for clinical trial applications under EU CTR</li><li>Deep dive into key aspects such as new requirements, timelines, submission strategies, transparency requirements, naming conventions, managing RFIs, working in CTIS and CTD transitions</li><li>Highlight the latest challenges and discuss solutions for managing the regulatory processes under EU CTR</li></ul>Zachary Bynum, B.A. Biological Sciences Sr. Manager, Regulatory Affairs, Regulatory Science, PPD</td></tr>
<tr><td>3:00</td><td colspan="2">Working alongside your finance team from the clinical side to make your budget go further<ul><li>Handling the funding issues of newer trials inan unpredictable economy</li><li>Tips and tricks for small and medium pharmato work alongside your financial team</li></ul></td></tr>
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| | • Discussing alternative financing methods rather than compromise the quality of your trials<br>• Design changes to incorporate early in yourstudy cycle to reduce costs<br><br>**AJ Bergmann,** Chief Financial Officer, **CapricorTherapeutics** |
| **3:30** | Afternoon Refreshments and Networking |
| **4:00** | Boost your trials: expert shares insider tips for streamlining clinical operations and gaining a competitive edge!<br>• Navigating risk and vendor management: unveiling strategies to optimize clinical trials<br>• Risk reduction made easy: expert insights to safeguard your clinical trials and enhance success<br>• Mastering the art of efficient trials: strategies to minimize risks and maximize results<br><br>**Jennifer Lee,** Board of Director, **Enzyme by Design** |
| **4:30** | **The state of the biopharmaceutical industry - clinical technology mid-year update and 2024 outlook**<br>• Reviewing results from our annual State of the Biopharmaceutical Industry survey - were our 2023 predictions correct?<br>  ○ Key themes and technology advancements in biopharma industry that are expected to have the largest (positive and negative) impacts on the industry<br>  ○ Spotlight on clinical trial technologies - so far through 2023<br>  ▪ Trends of Cell and Gene Therapies, Virtual Trials and AI used in drug development<br>• Leveraging data to predict the outlook for 2024 clinical trial outsourcing<br>  ○ Trends, key players, opportunities and threat in biopharma, focusing on AI, DCTs, Cell & Gene Therapy, etc.<br>  ○ What the latest investment trends show for small and medium biotechs<br>  ○ New technology outlooks for 2024<br><br>**Amanda Murphy,** Senior Director Data Intelligence and Solutions, **GlobalData** |
| **5:00** | Chair's Summation and Drinks Reception  |

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| | **Outsourcing in Clinical Trials Southern California**<br>**Day 2 \| 27th September 2023** | |
| **08:15** | Registration and Refreshments | |
| **08:55** | **Stream A: Outsourcing & Clinical Operations**<br><br>***CHAIR:*** **Robert Loll, SVP, Business Development &Strategic Planning, Praxis** | **Stream B: Clinical Trial Technology & Innovation**<br><br>***CHAIR:*** **Amanda Murphy, Senior Director, Data Intelligence and Solutions, GlobalData** |

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| **09:00** | **Fear reduction as the core of the patient experience strategy in clinical trials**<br>• Understanding where patient concerns lie when participating in clinical trials and what pharma companies can do to mitigate against these<br>• Aiming to reduce the burden of trial participation on patients as much as possible: where are pharma companies falling short?<br>• What more needs to be done when it comes to patient accessibility for clinical trials?<br><br>**Roel van der Heijde,** Facilitator & Trainer, **PatientExperience Association** | **Hybrid trials using DCT technology and processes; focus on patients and the sites**<br>• Highlighting the complexity that Hybrid/DCT brings whilst moving away from the common brick-and-mortar sites<br>• Discussing the rise in regulator concerns in areas such as investigator oversight, and participant's safety when face to face contact is limited<br>• How we tend to focus too much on technology when it's actually the processes for the patients and the sites that matter even more<br>• Major points to consider in designing hybrid/DCT trials; building blocks and practical examples to best prepare you to meet the needs of regulators whilst keeping the patient and sites front of mind<br><br>**Sverre Bengtsson,** Co-Founder, Senior VicePresident Strategic Relations, **Viedoc** |
| **09:30** | **PANEL DISCUSSION - Talking through vendor management tips and tricks**<br>• Tips to manage your relationship with your CRO<br>• Working with new staff turnover and how tomaintain high data quality<br>• A refresher on metrics and KPIs, how weanalyze our partnerships with CROs<br>• How to maintain a positive relationship withyour CRO<br><br>**Moderator: Robert Loll, SVP,** Business Development & Strategic Planning, **Praxis**<br><br>**Panelists:**<br>**Sormeh Mahjouri**, Program Director, **Imagion Biosystems, Inc**<br>**Grace Indyk,** Director Clinical Operations, **Aptose Biosciences**<br>**Nonna Snider,** VP Clinical and Operations, **JeniVision Inc**<br>**Aditya Kotta,** Regional Director Business Development, **Novotech** | **IVD, combining the regulatory & clinical strategy to improve clinical trial outcome**<br>• General regulatory strategy to consider when planning your clinical trials<br>• Cross functional work between the regulatory and clinical teams to achieve a strong regulatory submission package<br>• Key global IVD clinical regulatory changes to take note of in the coming years<br><br>**Patty Law,** Sr. Director, Clinical Affairs**, Hologic** |
| **10:00** | **Cutting-edge solutions and innovations in early clinical development operations for emerging professionals within sponsor's product development teams** | **How to leverage data standards and machine learning for more efficient Imaging oncology clinical trials**<br>• Discuss how unstandardized data poses challenges within oncology clinical trials in |

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| | • Early Career ClinOps Rep role on Sponsor Product Development Teams (PDTs)<br>• Clinical Trial Technology: Streamlining operations through innovative tools and solutions<br>• Strategic Outsourcing in Early Development PDTs: Maximizing efficiency and effectiveness<br>• Fostering Cross-Functional Collaboration: Communication tools for PDT awareness and decision-making<br><br>**Krishna P. Allamneni**, Chief Development Officer, **Concarlo Therapeutics, Inc** | Imaging<br>• How to utilize Clario Data Standards and automated data mapping of studies to optimize the workflow<br>• Demonstrate how an automated workflow and data cleaning offers a unified interface for review and resolution<br>• Present a machine learning project that utilizes AI models and standardized data for late phase clinical trials<br>**Shyam Banuprakash**, Senior Vice President, Data Science, **Clario** |
| **10:30** | Morning Refreshments and Networking | |
| **11:00** | **Clinical studies & clinical professionals in the medical device industry**<br>• Background of medical device industry with a focus on musculoskeletal<br>• Regulatory environment effect on clinical:<br>  ○ US: 510k vs IDE/PMA<br>  ○ EU: MDD to MDR<br>• State of clinical research in US & EU<br>• Industry sponsored research<br>  ○ Stats<br>  ○ CME rules<br><br>**Bryan Cornwall,** Former Executive Vice President, Research and Clinical Affairs, **Surgalign** | |
| **11:30** | **PANEL DISCUSSION - Working closely with your site to achieve a mutually beneficial relationship**<br>• How to curate a positive relationship with your site<br>• Data collection in sites – what can you do as a sponsor to bring it back up to speed?<br>• What lessons have we learnt when moving inand out the clinic, a reflection from the past few years<br>• How to make your IMP stand out amongst the crowd<br><br>**Moderator: Robert Loll, SVP,** Business Development & Strategic Planning, **Praxis**<br><br>**Panelists:**<br>**Ken Kobayashi**, Senior Vice President, **Formerly of Kinnate Biopharma**<br>**Roberta Vezza Alexander,** Director, ClinicalResearch, **Biological Dynamics Inc.**<br>**Sanjay Shrivastava,** CEO, **Innova Vascular** | |
| **12:15** | Lunch and Networking | |
| **1:15** | **PANEL DISCUSSION - What are the lessons learned from decentralizing – what takeaways do we have as an industry from the last few years**<br><br>• Weighing the advantages and disadvantages of having decentralized<br>• What do both the sponsor and vendor want to gain from decentralizing trials and how can we | |

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| | balance that<br>• Look at the real costs of DCT, does it impact your data quality<br><br>**Moderator: Robert Loll, SVP,** Business Development & Strategic Planning, **Praxis**<br><br>**Panelists:**<br>**Jiao Song,** Director, Early Clinical Science, **Janssen**<br>**Ken Kobayashi**, Senior Vice President, **Formerly of Kinnate Biopharma** |
| **2:00** | **The journey of drug product from manufacturing to clinical administration**<br>• Challenges of supply chain logistics across the globe with different biologics<br>• Selecting storage and supply depot across the globe<br>• Robustness around clinical in-use study design and clinical administration<br><br>**Dr Yuchen Wang**, Associate Director, Biologics Product Development, **Calidi Biotherapeutics** |
| **2:30** | Afternoon Refreshments and Networking; Apple Prize Draw |
| **3:00** | **Speaker Hosted Roundtables**<br><br>Interactive roundtable sessions offer a unique opportunity to come together with your peers to share best practice and develop solutions to critical challenges facing the industry as a whole. Hosted by industry experts and each focused on a single issue, roundtables are an exciting, interactive way tobuild your personal network and learn from the experience and expertise of others.<br><br>  <br><br>Each roundtable session lasts for 30 minutes, and delegates may attend up to 2 roundtables |
| **RT 1** | **Talking all things study design, how to have a clear end point when designing your study**<br>**Joseph Shan,** VP, Clinical Research, **Mosaic ImmunoEngineering** |
| **RT 2** | **Managing CRO relationships, what we are doing to work with our future partners**<br>**Kerry Clancy,** Director of Outsourcing**, Anaptys Bio** |
| **RT 3** | **Patient enrollment: what are we doing to improve uptake in new trials**<br>**Gina Fulgar,** Executive Director, Development Operations, **eFFECTOR Therapeutics, Inc.** |
| **RT 4** | **Considerations when choosing your site: pros, cons and pitfalls to avoid**<br>**Nonna Snider,** VP Clinical and Operations, **JeniVision Inc** |
| **4:00** | **Close of conference** |