OUTSOURCING IN CLINICAL TRIALS SOUTHERN CALIFORNIA

September 26th & 27th 2023, Hyatt Regency La Jolla Aventine, CA

2023 Speakers

Jennifer Lee, Vice President, Clinical Operations and Data Management, **Elevar Therapeutics**
Roger Davies, Vice President Operations, **Aptose Biosciences**
Betsey Zbyszynski, Director, Clinical Operations**, Arcutis**
Maribelle Guloy, Director, Clinical Development, **HBT LABS - A Wholly Owned Subsidiary of American Regent**
Kenneth Kleinhenz, Chief Operating Officer, **Lorem Cytori USA**
Saeid Yazdani, Vice President Portfolio Management - Therapeutics Product Development, **Caribou Biosciences**
Amish Patel, VP of Technical Operations, **Calidi Biotherapeutics**
Peter B. Heifetz, President and CEO, **OrPro Therapeutics**
Sormeh Mahjouri, Program Director, **Imagion Biosystems, Inc**
Rupesh Kanchi Ravi, Senior Director, **Pfizer**
Majid Ghoddusi, Senior Director, Clinical Biomarkers, **Poseida Therapeutics**
Anusha Perera, Senior Director, IT, **Acadia Pharmaceuticals**
AJ Bergmann, Chief Financial Officer, **Capricor Therapeutics**
Ken Wilson, Outsourcing Lead, **Pfizer**
Jiao Song, Director, Early Clinical Science, **Janssen**
Tracy Lawhon, Chief Development Officer, **Biotheryx**
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, Vice President, Head of Operations, **Longboard Pharmaceuticals**
Prasun Mishra, Founding Partner, **World Investors and Entrepreneurs Society**
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**
Joseph Shan, Executive Director, Clinical Development Operations**, MEI Pharma**
Sverre Bengtsson, Co-Founder, Senior Vice President Strategic Relations, **Viedoc**

Brand New Features for 2023!

- MORE SPEAKERS THAN EVER BEFORE
- NEW INTERACTIVE FORMATS
- NEW NETWORKING OPPORTUNITIES
- FIRESIDE CHATS, WORKSHOPS, LIVE DEBATES & MANY MORE

Biopharma/ Device Companies |Contact Douglas Webber: Email: douglas.webber@arena-international.com
Clinical Trial Service Providers |Contact Nick McCudden : Email: nicholasmccudden@arena-international.com

	Outsourcing in Clinical Trials Southern California **Day 1 | 26th September 2023**	
07:45	Registration and Refreshments	
08:20	Chair's Opening Remarks	
08:30	**KEYNOTE PANEL** **Patient engagement - What we as an industry need to do to promote trust** • How other experts are boosting engagement across therapeutic indications • Talking the good, the bad and the ugly of recruitment • Discussing innovative patient recruitment tools being used in the industry **Veronica Sandoval**, Principal, Inclusion & Health Equity, **Genentech** **Wendy Pizarro**, Chief Administrative Officer and Chief Legal Officer, **Calidi Biotherapeutics** **Tanja Obradovic**, Vice President, Scientific Affairs, **ICON**	
09:00	*Session Reserved for Novotech*	
09:30	**Oversight of clinical studies in India & Eastern Europe** • What are the main hurdles to overcome to run a trial here • Balancing the cost efficiency of running trials here with the extra work needed to ensure good clinical quality data • Managing compliance in the region **Maribelle Guloy,** Director, Clinical Development, **HBT LABS - A Wholly Owned Subsidiary of American Regent**	
10:00	Morning Refreshments and Networking	
	Stream A: Outsourcing & Clinical Operations ***CHAIR:***	**Stream B: Clinical Trial Technology & Innovation** ***CHAIR:***
10:45	**What is your competitive secret sauce – a talk from an expert sharing tips to speed up trials** • Competitive clinical operations, being the best you can be • Risk mitigation and vendor management? • How quickly can you activate your sites? • How do you reduce your risks **Jennifer Lee,** Vice President, Clinical Operations and Data Management, **Elevar Therapeutics**	**PANEL DISCUSSION - Evaluating the use of modern technology in clinical trials in a post-COVID landscape** • Are we better off now with technology or were we better off before • What useful changes have we received since the pandemic • What is here to stay and what should be left behind? **Majid Ghoddusi**, Senior Director, Clinical Biomarkers, **Poseida Therapeutics** **Anusha Perera**, Senior Director, IT, **Acadia Pharmaceuticals**
11:30	*Session Reserved for PCM Trials*	**Optimizing early development to maximize success probability in the late stage development**

		• Dose escalation: Critical elements to support informative drug safety profile and initial efficacy • Selection of the dose for the late-stage development: decisions around monotherapy, combination regimens • Incorporation of the patient voice, alignment with medical quality measures, considerations around existing treatment options landscape **Tanja Obradovic**, Vice President, Scientific Affairs, **ICON**
12:00	**Finding CROs and partners as a small to medium sized company: challenges and considerations** • Finding the right match for your specific indication • The do's and don'ts of who to work with as a small biotech • Discussing how to enter contract negotiation on the right footing **Chad Orevillo,** Vice President, Head of Operations, **Longboard Pharmaceuticals**	**Dealing with Phase 3 data challenges; how to get data collection back on track** • Handling adversity when challenges arise in your study • Highlighting the value of hands-on experience when managing a complex study • How to negotiate with a partner after issues have arisen, getting your money's worth • Lessons learned when managing large data sets • Advice for future trials, how to ensure data collection and quality is on point **Brandi Roberts,** Chief Financial Officer**, Longboard Pharmaceuticals**
12:30	*Session Reserved for TFS Health Science*	*15 Minute Tech Spotlight by eClinical Solutions* *15 Minute Tech Spotlight by IQVIA*
1:00	**Lunch and Networking** **JOIN ONE OF OUR NETWORKING TABLES** *Eat lunch with a like-minded group of industry colleagues by joining one of our lunchtime discussion groups on the topics below:*	
	TABLE 1: Patient enrollment, what are we doing to improve uptake in new trials.	**TABLE 3:** Managing your trial budget during uncertain times.
	TABLE 2: Finding the right CRO for your study.	**TABLE 4:** Decentralization, for or against?
2:00	**PANEL DISCUSSION - Top tips and tricks for managing your trial budget during unstable times** • Understanding what the reality of the costs of clinical trials are and what could happen to increase costs	**The upcoming importance of diversity in clinical trials And how it can promote patient recruitment** • A look into the new requirements made by the FDA and what you need to be aware of • How to most efficiently enrol the right patients needed for your trial to be approved

	• Planning out the entire trial with a budget focus, what steps are truly needed • Everyone is undergoing cost savings, what are key areas to cut down in **Betsey Zbyszynski,** Director, Clinical Operations**, Arcutis** **Brandi Roberts,** Chief Financial Officer**, Longboard Pharmaceuticals** **Sahar Roshan,** Director Clinical Operations, **Mirati Therapeutics**	• Looking at all aspects of diversity and why they are important for clinical trials **Wendy Pizarro**, Chief Administrative Officer and Chief Legal Officer, **Calidi Biotherapeutics**
2:30	**Feeling Pressure to Curb Costs? How Central Monitoring Can Stretch Your Budget Without Compromising Quality** • Considerations for implementing a successful central monitoring strategy • The value proposition: Where central monitoring can have the greatest impact for reducing clinical trial costs • How central monitoring may impact the future role of the CRA **Nicole Stansbury,** Senior Vice President and Head of Global Clinical Operations, **Premier Research**	*Session Reserved for YPrime*
3:00	**Working alongside your finance team from the clinical side to make your budget go further** • Handling the funding issues of newer trials in an unpredictable economy • Tips and tricks for small and medium pharma to work alongside your financial team • Discussing alternative financing methods rather than compromise the quality of your trials • Design changes to incorporate early in your study cycle to reduce costs **AJ Bergmann,** Chief Financial Officer, **Capricor Therapeutics**	**Interactive Workshop - Exploring the use of innovative technologies in clinical studies** • Understanding the benefits and challenges of using newer technologies such as AI in clinical studies. • Discussing the factors to consider when deciding whether to implement emerging technologies in clinical studies. • Identifying the potential use cases of innovative technologies in clinical trials, and how they can improve study outcomes. **Mirta Grifman,** Vice President, Clinical Development and External Innovation, **Biosplice Therapeutics** **Emily Solomon,** Vice President, Clinical Operations**, Biosplice Therapeutics**
3:30	Afternoon Refreshments and Networking	
4:00	**Navigating the perfect storm as a small biotech company: what you need to know to succeed** • How macro-political and economic issues affect clinical trials and mitigating risk surrounding this • Cutting costs and maximizing resources: the financial consequences of the storm on small biotech organizations • Understanding the changing regulatory environment for trials in 2023 • Keeping the patient at the center of changes to clinical trials: navigating the storm while minimizing patient impact **Barbara Birch**, Associate Director, Clinical Procurement & Outsourcing, **Ultragenyx Pharmaceutical Inc.**	

4:30	**Is Outsourcing Clinical Trials with Multiple Consultants Right for My Company? Balancing the Tradeoffs vs a Full Service CRO** • Fostering co-operation between different vendors on one clinical study • How to manage the tradeoffs of multiple consultants against the use of a full service strategy **Tracy Lawhon**, Chief Development Officer, **Biotheryx**
5:00	Chair's Summation and Drinks Reception 

	Outsourcing in Clinical Trials Southern California **Day 2 | 27th September 2023**	
07:50	Registration and Refreshments	
	Stream A: Outsourcing & Clinical Operations ***CHAIR:***	**Stream B: Clinical Trial Technology & Innovation** ***CHAIR:***
08:25	Chair's Opening Remarks	
08:30	**Mining for Gold: Looking at trends and budget analysis to find cost savings** • How to monitor and record cost savings in a clinical stage business • Proving your net worth through your negotiations • Finding savings in hidden places • Quick hits for savings **Ken Wilson,** Outsourcing Lead, **Pfizer**	**MDR – a deep dive into the complexity of the problem** • How Did We Get Here and is it Really Fixing the Problem? • What Happens to Innovation • Unintended Consequences: Long Term and Short Term Downstream Effects • Who are the Winners and Losers? • Where are we Now and What to Expect Next **Kenneth Kleinhenz**, Chief Operating Officer, **Lorem Cytori USA**
09:00	*Session Reserved for Event Sponsor*	**Hybrid trials using DCT technology and processes; focus on patients and the sites** • Highlighting the complexity that Hybrid/DCT brings whilst moving away from the common brick-and-mortar sites. • Discussing the rise in regulator concerns in areas such as investigator oversight, and participant's safety when face to face contact is limited. • 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. • 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. **Sverre Bengtsson,** Co-Founder, Senior Vice President Strategic Relations, **Viedoc**

09:30	**PANEL DISCUSSION** **Talking through vendor management tips and tricks** • Tips to manage your relationship with your CRO • Working with new staff turnover and how to maintain high data quality • A refresher on metrics and KPIs, how we analyze our partnerships with CROs • How to maintain a positive relationship with your CRO. **Betsey Zbyszynski,** Director, Clinical Operations**, Arcutis** **Sormeh Mahjouri**, Program Director, **Imagion Biosystems, Inc**	**IVD, Combining the regulatory & clinical strategy to improve clinical trial outcome** • General regulatory strategy to consider when planning your clinical trials • Cross functional work between the regulatory and clinical teams to achieve a strong regulatory submission package • Key global IVD clinical regulatory changes to take note of in the coming years **Patty Law,** Sr. Director, Clinical Affairs**, Hologic**
10:00	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
10:30	Morning Refreshments and Networking	
11:00	**PANEL DISCUSSION - Working closely with your site to achieve a mutually beneficial relationship** • How to curate a positive relationship with your site • Data collection in sites –what can you do as a sponsor to bring it back up to speed? • What lessons have we learnt when moving in and out the clinic, a reflection from the past few years • How to make your IMP stand out amongst the crowd **Ken Kobayashi**, Senior Vice President, **Formerly of Kinnate Biopharma** **Roger Davies,** Vice President Operations**, Aptose Biosciences** **Roberta Vezza Alexander,** Director, Clinical Research, **Biological Dynamics Inc.**	**Modern issues with sample and data reconciliation and how to get around them** • Relationship with site and your central lab • Between labs, working with central and focused analytical labs • Managing your data post analytics **Rupesh Kanchi Ravi**, Senior Director, **Pfizer**
11:45	*Session Reserved for Event Sponsor*	*Session Reserved for Event Sponsor*
12:15	**How do you build your clinical team – people leadership development** • How to train your team as future leaders from the beginning • How we as an industry can work together to develop the next generation of leaders • Maintaining a competitive team, how to create an environment for a championship team **Saeid Yazdani,** Vice President Portfolio Management - Therapeutics Product Development, **Caribou Biosciences**	**Precision clinical trials in the era of big data, artificial intelligence, and precision medicine** • Exploring the innovations in modern clinical trials that have made a difference in precision medicine. • In the modernising world of AI how much impact can we expect that to have on clinical trials. • Identifying the future of Precision trials and highlighting the big players in the fie **Prasun Mishra,** Founding Partner, **World Investors and Entrepreneurs Society**

12:45	Lunch and Networking
1:45	**PANEL DISCUSSION - What are the lessons learned from decentralizing – what takeaways do we have as an industry from the last few years** • Weighing the advantages and disadvantages of having decentralized • What do both the sponsor and vendor want to gain from decentralizing trials and how can we balance that • Look at the real costs of DCT, does it impact your data quality **Jiao Song,** Director, Early Clinical Science, **Janssen** **Ken Kobayashi**, Senior Vice President, **Formerly of Kinnate Biopharma**
2:15	**The journey of Drug Product from Manufacturing to Clinical Administration** • Challenges of Supply chain logistics across the globe with different biologics • Selecting Storage and Supply Depot across the globe • Robustness around Clinical in-use study design and Clinical administration **Amish Patel**, VP of Technical Operations, **Calidi Biotherapeutics**
2:45	Afternoon Refreshments and Networking; Apple Prize Draw
3:15	**Speaker Hosted Roundtables** 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 to build your personal network and learn from the experience and expertise of others.  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** **Joseph Shan,** Executive Director, Clinical Development Operations**, MEI Pharma**
RT 2	**Managing CRO relationships, what we are doing to work with our future partners.** **Kerry Clancy,** Director of Outsourcing**, AnaptysBio**
RT 3	**The state of current biotech financing: navigating uncertain times** **Peter B. Heifetz,** President and CEO, **OrPro Therapeutics**
4:15	Close of conference