



Outsourcing in Clinical Trials West Coast 2017

February 22-23 2017, Burlingame, CA

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SPEAKERS INCLUDE:

- Adrian Otte**, Vice President, Development Operations, **Amgen**
Sameena Sharif, Vice President, Business Operations, and Portfolio Management, **Astex Pharma**
Don Kellerman, Vice President, Clinical Development, **Zosano Pharma**
Ramani Aiyer, Executive Director, **TheraBiol**
Brian Nugent, Director, Clinical Operations, **Gilead**
Ken Kengatharan, Chief Executive Officer, **Armetheon**
Victoria Yeager, Head of Contracts and Compliance, **Genentech**
Jessica Kaman, Executive Director, Development Outsourcing, **Exelixis**
Joe Golemme, Chief Financial Officer, **Topica Pharma**
Mike Breton, Director, Clinical Contracts & Finance, **Gilead**
David Larwood, Chief Executive Officer, **Valley Fever Solutions**
Hayley Lane, Executive Director, Clinical Program Operations, **Iconic Therapeutics**
Deirdre BeVard, Vice President, Development Operations, **Nektar Therapeutics**
Barbara Wuebbels, Vice President, Patient Advocacy, **Audentes Therapeutics**
Emily Hergenreter, Senior Director, Clinical Affairs, **NeoTract**
Joel Rothman, Vice President, Development Operations, **Raptor Pharmaceuticals**
Salvador Rico, Vice President, Clinical Research & Medical Affairs, **Cerus**
Jacquie Mardell, Senior Director, Clinical Operations, **Ascendis Pharma**
Kathleen Smith, Senior Director, Clinical Operations, **QT Ultrasound**
Lian Cunningham, Vice President, Clinical Affairs, **BAROnova**
David Hinds, Vice President, Clinical Operations, **Tioma Therapeutics**
Paulette Niemyski, Senior Director, Clinical Affairs, **Direct Flow Medical**
Bruno Gagnon, Global Head, Clinical Operations, **Raptor Pharma**
Karen Long, Executive Vice President, Clinical Research and Regulatory Affairs, **OvaScience**
Sue Naim, Director, Clinical Operations, **Astex Pharma**
Craig Coffman, Executive Director, Clinical Business Operations, **Nektar Therapeutics**
Mena Niakian, Global Director of Clinical Operations, **SanBio**
Mark Milberg, Director, Clinical Procurement and Outsourcing, **Ultragenyx**
Lisa Sergas, Associate Director, Clinical Outsourcing, **Medivation**
Jason Krzeszak, Director, Clinical Operations, **Providence Medical Technology**
Angie Maurer, Director, Clinical Operations, **Gilead**
Shelby Young, Director, Clinical Operations, **Versartis**
Thomas Tremblay, Head of Clinical Operations, **Apexigen**
Ed Jones, Regional Vendor Manager, **Genentech**
Michael Cox, Associate Director, Clinical Contracts and Outsourcing, **FibroGen**
Mike Huston, Program Chair, Clinical Trials Design & Management, **University of California**

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Arena International's 9th Annual Outsourcing in Clinical Trials West Coast Conference
Burlingame, CA
Program Day One – Wednesday February 22nd 2017

07:45	Registration and refreshments
08:20	Chairman's Opening Remarks Chair: Joel Rothman , Vice President, Development Operations, Raptor Pharmaceuticals
08.30	<p>Implementing quality management strategies from the outset of your trial to ensure data and processes meet required standards</p> <ul style="list-style-type: none"> • Evaluating different approaches to measuring quality and highlighting the fact that each trial needs to be treated differently • Taking both a 'people-focused' and 'technology-focused' approach to quality oversight and management to develop effective quality control strategies • Capitalizing on risk-based as a way of implementing a more cost-efficient monitoring system • Aligning SOPs to ensure they can be integrated with any vendor's processes to facilitate comparison and analysis • Identifying different roles and responsibilities of internal teams, and realising where specific teams can have the most impact on quality • Encouraging data transparency with vendors to promote openness and allow for any issues with quality to be raised quickly <p>Speaker: Brian Nugent and Angie Maurer, Directors of Clinical Operations, Gilead</p>
09.00	<p>Exploring strategic development considerations and operational study solutions to get your oncology molecule to proof of concept</p> <ul style="list-style-type: none"> • Options for accelerated regulatory approvals in US and Europe • Considering which study designs could be used in the early phases of development • Selection of the "right" patients for the study • Planning biomarkers into the molecule development program • Overcoming specific challenges for immune-therapeutics <p>Speaker: Colin Hayward, Chief Medical Officer, Premier Research</p>
09.30	<p>Panel Discussion: Exploring the impact of effective strategic outsourcing models to enable an effective partnership</p> <p>Examining the strategic outsourcing options for large, mid-size and small companies</p> <ul style="list-style-type: none"> • Considering the impact of vendor size on your choice of strategic partner • Exploring how a change in mindset can be implemented across your whole company to move beyond the idea of customer-service provider relationships • Investigating the benefits and dangers of risk-sharing contracts as a way of strengthening strategic partnerships • Examining strategic outsourcing as a way of enabling greater cost predictability and budget forecasting • Debunking the myth that smaller companies cannot benefit from such alliances <p>Panellists: Adrian Otte, VP Global Development Operations, Amgen, Victoria Yeager, Head of Contracts</p>



	and Compliance, Genentech , Krista Armstrong , Vice President of Strategic Development, Premier Research & Deirdre BeVard , Vice President, Development Operations, Nektar Therapeutics	
10.00	What Does a Patient-First Enrollment Model Look Like? <ul style="list-style-type: none"> • Leveraging enrollment feasibility predicated on quantitative pre-screening data and qualitative patient insights • Reducing your reliance on sites and countries while increasing data quality • Reducing your trial operations costs/CRO fees via shortened timelines • Obtaining enrollment certainty, along with budget certainty via per-patient commercial terms Todd Albin , Senior Director, Site Enrollment Optimization, Acurian	
10.30	Morning Refreshments & Networking	
	Stream A	Stream B
11.00	Balancing the need for embracing new technologies such as ePRO systems with the usability of such technology with study participants <ul style="list-style-type: none"> • Ensuring internal and external buy-in when adopting this strategy to promote chances of success • Embracing new clinical trial technology while avoiding the dangers of disenfranchising some segments of the population • Considering the eNaïve study participant's 'journey' and interface with BYODs to avoid technological discrimination • Summarizing the pros and cons of the improved reliability of ePROs to identify where this technology can best be implemented Speaker: Thomas Tremblay , Head of Clinical Operations, Apexigen	Investigating effective project planning and budgeting strategies to promote effective cost control <ul style="list-style-type: none"> • Ensuring in-depth planning to develop a Scope of Work with all roles defined with a thorough Work Breakdown Structure • Considering how best to forecast investigator fees to highlight the impact this has on site selection and start-up • Exploring the impact of third party vendors on trial costs to investigate what sponsors can do to regain control here • Working with your CRO to understand their major costs to identify any cost-saving strategies within your partnership • Identifying strategies in budget negotiation to ensure you are getting the best deal Speaker: Jessica Kaman , Executive Director, Development Outsourcing, Exelixis
11.30	Emerging Strategies for More Cost-Effective Product Development in the NASH Indication Session content TBC	Key considerations for selecting a safety services provider <ul style="list-style-type: none"> • Overview of considerations



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	<p>Speaker: Randy Anderson, PhD, SVP, Scientific Affairs-Endocrinology & Metabolic, Chiltern</p>	<ul style="list-style-type: none"> • Pitfalls of outsourcing to the wrong vendor • Benefits of outsourcing to the right vendor • Review of several case studies • Considerations through the product lifecycle <p>Speaker: Erin Parker, Senior Director, Global Medical Operations, SynteractHCR</p>
12.00	<p>Promoting the idea of a true clinical trial team, involving all internal and external stakeholders for the benefit of your trial and ultimately the patient</p> <ul style="list-style-type: none"> • Assembling an effective team, ensuring internal staff, CROs, sites and investigators truly understand the value of your trial and the potential impact on patients • Emphasizing the need for trust and transparency when outsourcing as a smaller to mid-sized company • Involving all parties, including patients, as early as possible to promote more effective budgeting and forecasting • Growing your 'clinical trial team' as your trial grows and additional vendors and sites are involved <p>Speaker: Deirdre BeVard, Vice President, Development Operations, Nektar Therapeutics</p>	<p>Case Study: Exploring the Gilead approach to developing effective contracts to maintain costs whilst strengthening relationships</p> <ul style="list-style-type: none"> • Identifying the need for different contract templates to be used depending on vendor size and capability • Considering where and when you can be flexible to minimize impact of contract delays on trials • Evaluating strategies for developing multi-trial contracts as a way of saving time and money • Implementing timelines focusing on starting contract development early, in order to minimize delays to study start-ups • Negotiating the difficulties of developing contracts on an international scale to keep up with demand for global trials <p>Speaker: Mike Breton, Director, Clinical Contracts & Finance, Gilead</p>
12.30	<p>Networking Lunch: Please take this time to visit exhibitor booths and obtain stamps for the incentive giveaway!</p>	
1.45	<p>Interactive Debate: Exploring the pros and cons of working with consultants vs hiring FTEs to meet the needs of the trial</p> <ul style="list-style-type: none"> • Performing a cost analysis on both options to identify which has least impact on trial budgets • Highlighting the ability to hire very specific skill sets for specific periods when working 	<p>Interactive Debate: Exploring best practices to help create accountability and meet project deadlines</p> <ul style="list-style-type: none"> • Exploring what taking a risk-sharing approach means to your trial and your partnership • Highlighting the use of penalties and bonuses as a way of promoting the



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	<p>with consultants</p> <ul style="list-style-type: none"> Recognizing the benefits of having team members with buy-in who are invested in your trial Considering best practices for the end of a trial when staff may no longer be requires <p>Panellists: Salvador Rico, Vice President, Clinical Research & Medical Affairs, Cerus & Mike Huston, Program Chair, Clinical Trials Design, University of California</p>	<p>partnership mindset</p> <ul style="list-style-type: none"> Considering how to come up with KPIs and metrics that are reasonable and effective for both parties <p>Identifying the risks associated with penalties and the impact to your relationship with your vendor</p> <p>Panellists: Sameena Sharif, Vice President, Business Operations, Portfolio and Project Management & Sue Naim, Director, Clinical Operations, Astex Pharmaceuticals</p>
<p>2.15</p>	<p>Investigating the need for, and application of, disease natural history data in rare disease orphan drug development</p> <ul style="list-style-type: none"> Exploring considerations for small companies working on orphan indications that rely on small, open label trials for registration Identifying the value of natural history of disease data to regulators for interpretation of limited trial results Considering additional challenges in the rare disease space with post-approval requirements for safety and exposure data and how natural history data plays an important role <p>Speaker: Haley Kaplowitz, Executive Director, Safety, Epidemiology, Registries & Risk Management, UBC: An Express Scripts Company</p>	<p>Delving into results from the Veeva 2016 Paperless TMF Survey: Annual CRO Report</p> <ul style="list-style-type: none"> Exploring the results of this annual survey that analyzes the observations of TMF owners both at sponsors a CROs to identify the barriers, business drivers, and benefits of moving to fully paperless TMFs Understand how CROs and sponsors each approach TMF management See how desired benefits of an eTMF align with benefits experienced Learn the importance of performance metrics when evaluating eTMF systems <p>Speaker: Mike Burton, Director, CRO Alliances, Veeva Systems</p>
<p>2.45</p>	<p>What to do when things go wrong? Taking a practical approach when requirements are not met and relationships break down</p> <ul style="list-style-type: none"> Determining how many change orders one trial can undergo before having to review key vendor processes Ensuring an effective escalation process is in place for when things go wrong to expedite solutions being found Implementing a 'red flag system' to alert you to when you need to start considering drastic action Considering the impact of changing CRO midway through a trial to identify when this 	<p>Exploring cost optimization strategies for partnering with CROs from a small to mid-sized company perspective</p> <ul style="list-style-type: none"> Identifying how long term relationships and a strategic outsourcing model can be a more cost-effective approach Outlining the key differences between working with niche and global CROs to determine the impact on cost Exploring how best to embrace long-term relationships when dealing with a relatively unpredictable future Highlighting the need for a dedicated clinical outsourcing team to ensure effective relationship management



	<p>becomes necessary</p> <ul style="list-style-type: none"> Summarizing the key aspects to consider when sourcing a rescue CRO <p>Speaker: Jacquie Mardell, Senior Director, Clinical Operations, Ascendis Pharma</p>	<ul style="list-style-type: none"> Considering how to achieve a 'win-win' situation for both sponsor and vendor <p>Speaker: Lisa Sergas, Associate Director, Clinical Outsourcing, Medivation</p>
3.15	<p>Identifying what we have learned when implementing risk-based monitoring</p> <ul style="list-style-type: none"> Undertaking a recap of guidance for risk-based monitoring Dynamically selecting data for source documentation verification and completing an overview of system functionality Sharing statistics from production trials to identify resulting trends and successes Unpicking the rationale and process in remote monitoring with real sponsor experience and observations <p>Speaker: Neil Vivian, Senior Director of Business Solutions, OmniComm Systems</p>	<p>Session Reserved for INC Research</p> <p>Speaker: Eric Distad, Executive Director, Medical Device and Diagnostics Business Unit, INC Research</p>
3.45	<p>Afternoon Refreshments & Networking</p>	
4.10	<p>Exploring best practices in vendor auditing to ensure potential vendors meet the needs of your trial</p> <ul style="list-style-type: none"> Investigating service provider's feasibility assessments to see how they plan to meet your timelines and budgets Exploring strategies to effectively test CRA knowledge to elucidate the amount of training vendor staff will require Analyzing geographical reach of a vendor to qualify if they have the regional regulatory and cultural knowledge to facilitate smooth running of the trial Balancing the need for quality with cost saving pressures from senior management to ensure a strong partnership for the duration of the trial Considering the importance of having a 'back-up' option of a service provider throughout the negotiation stage to allow for increased flexibility 	<p>Developing strategies for increasing patient awareness of clinical trials to the benefit of both industry and patients</p> <ul style="list-style-type: none"> Developing a mindset within your company, from CRA to CEO that patients are more than just a number or a target to be hit Evaluating the role of patient advocacy groups to identify what they do and their influence on a patient population Considering how to engage with patient advocacy groups to capitalize on this goldmine of expertise and experience Designing trials with the patient in mind, ensuring impact of the trial on the patient's lifestyle is kept to a minimum Identifying how patient advocacy groups can be effectively bought in to assist and advice in protocol development <p>Speaker: Barbara Wuebbels, Vice President of</p>



	<p>Speaker: Mike Huston, Program Chair, Clinical Trials Design & Management, University of California</p>	<p>Patient Advocacy, Audentes Therapeutics</p>
4.40	<p>Presenting the successful study: a PI's perspective</p> <ul style="list-style-type: none"> Defining where to start to ensure you are adequately prepared for the course of the trial Sourcing your team and ensuring you fit the requirement for the trial Highlighting hallmarks of a good protocol to ensure you hit the mark Exploring how to translate to floor operations to ensure fluidity and efficiency from your protocol Handling issues during study conduct to stay on top of costs and timeline <p>Speaker: George J. Atiee, MD, Vice President, Medical Director, Site Director, Worldwide Clinical Trials</p>	<p>Exploring patient centricity; another passing fad in clinical research, or truly a watershed moment?</p> <ul style="list-style-type: none"> Exploring what this trend means for patients, the doctors and nurses caring for them and the industry in general Big data, Wearable technology and now Patient Centricity - is it just the latest method in Clinical Research or has something meaningful occurred? Evaluating the patient as stakeholder. With recent controversies over EpiPen and other drug pricing debates, how is this impacting the involvement of patients in drug delivery? Considering what realistic improvements have occurred in Clinical Research with respect to Patient Centricity Questioning if technology is the enabler or whether there is a balance between innovation and the "human element" <p>Speaker: Tom Ruane, Global Head, Patient Recruitment, PAREXEL</p>
5.10	<p>Exploring the benefits and risks of running early phase trials in Asia to identify the potential value it could add</p> <ul style="list-style-type: none"> Highlighting Asia as a viable choice for Phase I trials to meet budget requirements Considering Korea as a popular location for early phase trials due to its thriving biotech industry Ensuring due diligence and planning is implemented when considering Asia Exploring Taiwan and Hong Kong as routes to getting access to the Chinese market Identifying the roles of CROs when working in these regions to overcome issues within cultural differences and communication 	<p>Utilizing marketing and registry vendors in patient recruitment to ensure we as an industry are optimizing this process</p> <ul style="list-style-type: none"> Exploring considerations for utilizing specific patient recruitment vendors for rare diseases Investigating the role of social media in clinical trials to ensure we as an industry are capitalizing on all it can offer Discussing how search engines can be best used to improve patient recruitment efforts Overcoming common challenges of asking multiple vendors to work with each other to facilitate a smooth line of communication



	Speaker: Ramani Aiyer , Executive Vice President, TheraBiol	Speaker: Mena Niakian , Global Director of Clinical Operations, SanBio
5.40	Chairman's Closing Remarks Chair: Joel Rothman , Vice President, Development Operations, Raptor Pharmaceuticals	

Arena International's 9th Annual Outsourcing in Clinical Trials West Coast Conference Burlingame, CA Program Day Two – Thursday February 23rd 2017		
08.20	Registration and refreshments	
	Biopharmaceuticals Stream	Medical Device Stream
8.50	Chairman's Opening Remarks	Chairman's Opening Remarks
9.00	<p>Holding effective bid defense meetings to ensure the right partnership is formed and your project gets off to a good start</p> <ul style="list-style-type: none"> • Instilling an attitude of 'preparation is key' and setting an in-depth agenda so the key areas are covered • Considering who should be present at the meetings to ensure a streamlined approach whilst obtaining the required input • Exploring strategies to ensure the team you meet are who you get to allow you to accurately assess capabilities • Developing open and transparent governance and escalation mechanisms with input from both sides of the table on the process • Evaluating 'soft skills' such as cultural and personality fit to promote an idea of one clinical team across both sponsor and vendor <p>Speaker: Don Kellerman, Vice President, Clinical Development, Zosano Pharma</p>	<p>Recognizing what aspects of your trial can be kept in-house and what needs to be outsourced for an optimal approach to a hybrid outsourcing model</p> <ul style="list-style-type: none"> • Outlining during the protocol stage where internal capabilities lie to identify the key areas for outsourcing • Describing why a hybrid model is suitable for device trials due to higher levels of ambiguity • Determining when consultants should be hired and when it will be more effective to outsource work to a CRO team • Considering how vendors should be best used as the trial grows in size • Investigating how different approaches effect cost to discuss the most cost-effective approach to this sort of model <p>Speaker: Emily Hergenreter, Senior Director, Clinical Affairs, NeoTract</p>



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<p>9.30</p>	<p>Discussing privacy and performance in the cloud</p> <ul style="list-style-type: none"> • Presenting database basics to ensure optimum performance with the cloud • Delving into hosting 101 to ensure literacy on premise and cloud, including public and private cloud • Measuring privacy when using the cloud to ensure optimum security • Highlighting your performance on the cloud to ensure effective resource allocation <p>Speaker: Scott Weidley, Chief Executive Officer, ClinCapture</p>	<p>Developing strong partnerships to ensure success with global medical device trials</p> <ul style="list-style-type: none"> • Identify the core group of stakeholders who will evolve throughout the course of the trial • Understand the landscape of a global medical Device Trial within the different regions • Ensure that the Infrastructure is adapted to deliver on the ambition of a global study • Continuously measure of project progress and instigate pro-active adaptability based on experience and data analytics <p>Speaker: Thelma Bueno, Senior Clinical Project Manager, Genae</p>
<p>10.00</p>	<p>Interactive session – Developing a checklist of things to consider when starting your study</p> <ul style="list-style-type: none"> • Considering when and how to involve your CRO in your start-up processes to capitalize on their experience and expertise • Discussing best practices for deciding on a study location which would be the best fit for your trial • Emphasizing the importance of accurately forecasting enrolment rates to avoid the need for additional sites being included midway through the trial • Involving international regulatory experts to avoid delays when launching trials on a global level • Evaluating the smaller company perspective to identify key challenge areas <p><i>This is an interactive session – please come prepared to share ideas and experiences!</i></p> <p>Panellists: Bruno Gagnon, Global Head, Clinical Operations, Raptor Pharma, Hayley Lane, Executive Director, Clinical Program Operations, Iconic Therapeutics & Shelby Young, Director, Clinical Operations, Versartis</p>	<p>Establishing in-depth vendor selection processes to enable a strong partnership to be built from the outset</p> <ul style="list-style-type: none"> • Determining the best strategies for sourcing vendors with proven expertise in device trials • Considering when the vendor selection process should start to elucidate when vendors can start having a positive impact on your trial • Building strict Request for Proposal templates to allow for effective comparison of potential vendors • Taking an in-depth person by person auditing approach to ensure your new external team have the required know-how to take on your trial • Exploring key preparation aspects to consider before the Bid Defense Meeting to ensure the right partner is found for your trial <p>Speaker: Kathleen Smith, Senior Director, Clinical Operations, QT Ultrasound</p>
<p>10.30</p>	<p>Morning Refreshments & Networking</p>	



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<p>11.00</p>	<p>Developing functional trial protocols and strategies to overcome challenges in orphan drug programs</p> <ul style="list-style-type: none"> • Emphasizing the need for vendors with specific experience in orphan drug trials to ensure they have the required expertise • Considering working with KOLs and Advocacy groups as routes to finding suitable vendors • Recognizing the need for more in-depth oversight and management when working within rare diseases • Implementing effective international trial protocol to overcome issues with complex global regulations • Developing site selection strategies to enable you to find investigators and sites with the expertise and facilities to accommodate your trial • Encouraging an approach of collaboration rather than competition across the industry <p>Speaker: Ken Kengatharan, Chief Executive Officer, Armetheon</p>	<p>Regulatory Update: Discussing the key requirements from the FDA to facilitate the approval of your device</p> <ul style="list-style-type: none"> • Identifying how to manage complex regulations with a limited regulatory department • Demanding that due preparation is taken in terms of documentation to ensure you have all that is required and to avoid delays • Promoting the idea of communication with the FDA to avoid misunderstandings • Ensuring your CRO can assist in regulatory demands in a timely manner to capitalize on their expertise, contacts and to ensure you are getting enough value from your vendor • Investigating how consultants can be an invaluable addition to a team when approaching regulatory hurdles <p>Speaker: Karen Long, Executive Vice President, Clinical Research and Regulatory Affairs, OvaScience</p>
<p>11.30</p>	<p>Exploring how to select the right imaging solution for your clinical trial to reduce your image data risk</p> <ul style="list-style-type: none"> • Evaluating imaging data plays an invaluable role in assessing disease status and drug efficacy • Investigating your imaging solutions provider's therapeutic expertise, technology, track record, project management support, availability, flexibility, transparency and out-of-the-box thinking to promote successful outcomes and reduced risks • Consider what's important when selecting the imaging solutions provider to ensure they will best meet the needs of your trial <p>Speaker: Nicholas Campbell, Chief Commercial Officer, Median Technologies</p>	<p>Session Reserved for MD Sponsor 2</p>
<p>12.00</p>	<p>Interactive Session: Ensuring effective budget</p>	<p>Panel Discussion: Ensuring effective vendor management for the duration of your trial to</p>



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	<p>management and site performance through CROs</p> <ul style="list-style-type: none"> • Managing CROs' performance on site contracts to avoid issues both with budget control and site performance • Exploring how budgets and payments can be effectively managed through vendors to ensure budget control • Identifying internal and external infrastructures to ensure effective control of budget management and site performance <p>Speaker: Michael Cox, Associate Director, Clinical Contracts and Outsourcing, FibroGen</p>	<p>ensure timelines are met</p> <ul style="list-style-type: none"> • Developing current metrics to measure successes and quality of trial partners to clarify when a sponsor would need to intervene • Encouraging one point of contact from service providers and the internal clinical team to avoid any issues with miscommunication • Exploring the advantages to working with vendors based locally to benefit from more face-to-face meetings • Discussing how best to manage change orders to understand the role of all parties in these cases • Considering how best to change a service provider midway through the trial in case this is required <p>Panelists: Paulette Niemyski, Senior Director, Clinical Affairs, Direct Flow Medical. Lian Cunningham, Vice President, Clinical Affairs, BAROnova & Jason Krzeszak, Director, Clinical Operations, Providence Medical Technology</p>
12.30	<p>Networking Lunch Please take this time to visit exhibitor booths and obtain stamps for the incentive giveaway!</p>	
1.45	<p>Investigating different strategies to take when it comes to obtaining investment for trials from a start-up perspective</p> <ul style="list-style-type: none"> • Outlining how and when companies should start considering funding approaches • Evaluating what companies can do at an early stage to make themselves more attractive to potential funders • Considering private investors as a source of trial funding to discover the key pros and cons of this method of funding • Identifying roles within your organization and with any external partners and consultants to ensure effective communication with potential funders • Developing funding strategies in case of growth through trial phases <p>Speaker: David Larwood, Chief Executive Officer, Valley Fever Solution</p>	
2.15	<p>Developing effective outsourcing strategies for early phase trials to assess the different needs of this sort of study</p>	



	<ul style="list-style-type: none"> • Involving vendors at the earliest stages to obtain their insight on protocol development and clinical study report issues • Ensuring enough vendors are on file to meet a larger variety of geographical and therapeutic requirements • Overcoming challenges arising from asking one vendor to work with another • Highlighting the advantages of utilizing the same vendor to bridge the gap between Phase I and larger scale trials • Ensuring vendor and sponsor are talking the same language <p>Speaker: David Hinds, Vice President, Clinical Operations, Tioma Therapeutics</p>
2.45	<p>Exploring different approaches to improve patient recruitment rates to avoid trial delays</p> <ul style="list-style-type: none"> • Determining how best to motivate investigators to increase their enrolment rates • Considering the impact of subject compliance incentives within patient recruitment • Identifying the standards expected by IRBs to ensure compliance with their requirements <p>Speaker: Joe Golemme, Chief Financial Officer, Topica Pharma</p>
3.15	<p>Afternoon Refreshments & Networking</p> <p>The Incentive Giveaway will be announced in the Exhibition Room at 3.00. Please note that for some prizes you need to be in the room to win!</p>
3:40	<p>Speaker Hosted Roundtables</p> <p>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.</p> <p>Each roundtable session lasts for 30 minutes, and delegates may attend up to 2 roundtables</p>
Roundtable 1	<p>Investigating how we can improve clinical trial budget forecasting Facilitator: Craig Coffman, Executive Director, Clinical Business Operations & Outsourcing, Nektar Therapeutics</p>
Roundtable 2	<p>Unlocking Asia's advantages: Identifying and building opportunities in the world's most dynamic region Facilitator: Dr Maria Ali, Associate Director, Medical and Regulatory Services, George Clinical</p>
Roundtable 3	<p>Optimizing the preferred provider model to ensure successful partnerships Facilitator: Ed Jones, Regional Vendor Manager, Genentech</p>
Roundtable 4	<p>Exploring the challenges of implementing an effective CTMS Facilitator: Mark Milberg, Director of Clinical Operations, Ultragenyx Pharmaceuticals</p>
4:40	<p>Chair's summation and close of conference</p>