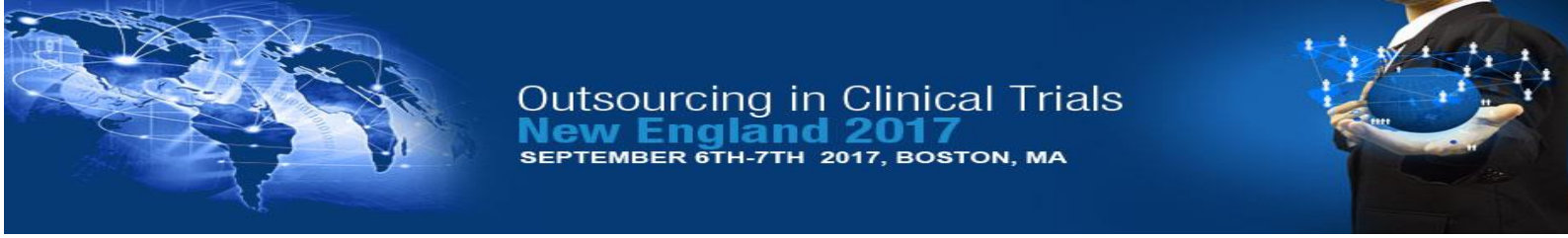

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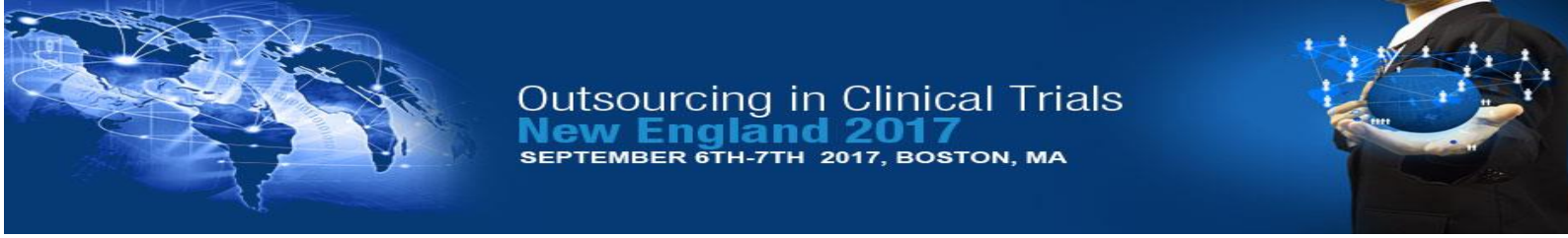
Speakers Include

Abraham Thariath, Executive Director/Head, Process Development and Manufacturing, ContraFect Corporation
Amanda Hayden, Director Global Clinical Services, Alkermes
Amanda J. Moore, Associate Director Clinical Operations & Development, Sage Therapeutics
Amy Cohen, Senior Director Clinical Operations, Agenus
Annette Valles-Sukkar, Associate Director, Clinical Project Lead, Global Clinical Operations, Alexion Pharmaceuticals
Carrie Melvin, VP Clinical Operations, Kura Oncology
Christine Tosone, Executive Director, Clinical Operations, Allena Pharmaceuticals
Denise Tilton, Global Head Clinical Operations and Project Management, ERYTECH Pharma
Jennifer Goodfellow, Executive Director, Head of Procurement, Boston Pharmaceuticals Inc.
Eyal Ron, Chief Technical Officer, Gelesis
Georgia Mitsi, Sr. Director, Search & Evaluation, Digital Healthcare, Sunovion Pharmaceuticals
Guy Bolton, AVP Head of US Clinical Operations, Ferring
Hyun Kim, Head Clinical Operations, AoBiome
Jeff Sabados, CEO, Resilience Therapeutics
John Hogan, Director Clinical Operations, Momenta Pharmaceuticals
Karen Correa, Senior Director Clinical Operations, Adare Pharmaceuticals
Karen Gardner, Senior Director Clinical Development Operations, Seqirus
Kate Hoffman, Strategic Alliance Director, GE Healthcare
Kenneth Getz, Director and Associate Professor, Tufts Center for the Study of Drug Development
Kevin J. Anderson, Associate Director, Global Clinical Operations, Alexion Pharmaceuticals
Loralie Brennen, Director Clinical Operations, Flexion Therapeutics
Mahlet Woldemariam, Director Project Management, Sanofi



Maria Makarovskaya, Director, Clinical and Strategic Sourcing, Akebia Therapeutics
Mark Tepper, President and CSO, Corbus Pharmaceuticals
Mary-Lynn Fulton, Head of Clinical Operations Study Management, Vertex Pharmaceuticals
Ramon Mohanlal, CMO, BeyondSpring Pharmaceuticals
Reena Lynam, Associate Director Clinical Operations, Leap Therapeutics
Rene L Myers, VP Clinical Affairs, scPharmaceuticals
Ross Pettit, Senior Vice President, Development Operations, Beigene
Sondra Smyrnios, Vice President Clinical Development Operations, Alkermes
Steven Kates, VP R&D, Ischemix
Susan Doleman, Vice President, Clinical Development, Replimune
Terence Hall, Investigator—Translational Medicine, Arqule
Patrecia Valone, Clinical Operations Group Head, Novartis Institutes of Biomedical Research, Translational Clinical Oncology
Steven P. Sweeney, Vice President, Quartet Medicine
Roberta Duncan, Head of Business Operations, Shared Services and Clinical Compliance, Seqirus

Further Information

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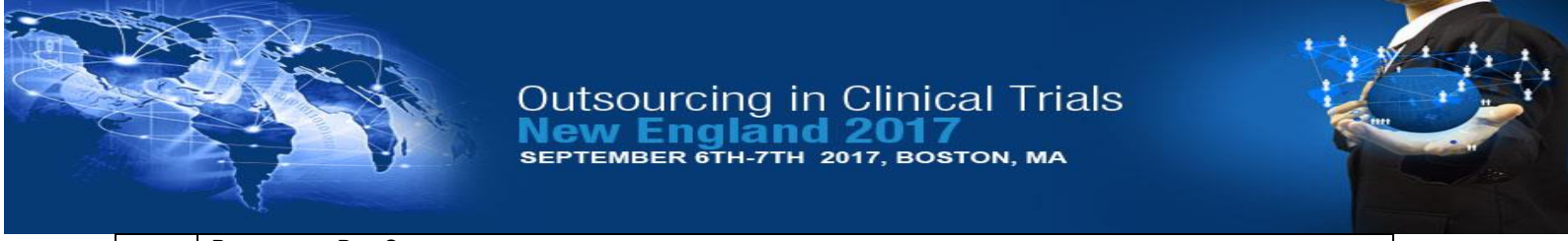

	Programme Day One **6th September**		
8:00	Registration and Refreshments		
8:20	Chairperson's Opening Remarks **Maria Makarovskaya, Director, Clinical & Strategic Sourcing, Akebia Therapeutics, Inc.**		
8:30	**Panel Discussion: Developing strategies for maximising CRO engagement in your study to ensure efficient time and resources are allocated** • Underlining the importance of highlighting to your CRO the importance of the study to your wider clinical programme to ensure they are aware of the significance of their work • Evaluating how to foster an internal culture which enables employees to view CROs as partners and not just service providers to encourage a collaborative relationship **Panellists: Jennifer Kawula, Clinical Operations, Ferring Pharmaceuticals & Jill Hayes, Outsourcing Clinical Operations, Ferring Pharmaceuticals & Mary-Lynn Fulton, Head Study Management, Vertex Pharmaceuticals & Krista Armstrong, Vice President & Head of Neurosciences, Premier Research**		
9:00	**Evaluating how to increase cost transparency between you and your CRO to ensure adequate resources and budget are allocated to your trial** • Highlighting the need for both parties to agree on definitions of processes and tasks to increase cost transparency • Defining the importance of CROs forecasting their budget needs for the study as accurately as possible to ensure they have enough resources to support each element of the trial • Underlining the need for trial sponsors to interrogate whether the defined budget matches up with protocol to minimise change orders • Evaluating the importance of reviewing contracts to test that all provisions are realistic **Speaker: Reena Lynam, Associate Director Clinical Operations, Leap Therapeutics**		
9:30	**Developing best practices for forging Strategic Sponsor-CRO Partnerships** • Navigating the sponsor-CRO relationship: setting expectations, establishing responsibilities, meshing cultures • Appreciating different sponsors, different needs: from large companies with defined processes to small sponsors that need full-range support • Being a partner, not just a vendor: promoting long-term relationships, valuing collaboration over transactions, embracing shared goals • Determining the DNA of a successful partnership: longevity, effective governance, regular assessments, appropriate risk-sharing **Speaker: Krista Armstrong, Vice President & Head of Neurosciences, Premier Research**		
10:00	**Keynote: Examining how a single IRB model will dramatically accelerate treatment delivery** **Speaker: Michelle Culp, Director of Clinical Operations, National Institutes of Health**		
10:30	*Networking and Refreshments*		
	Stream A ***Partnering for Success*** **Chairperson: Steven Kates, CSO,**	***Stream B*** ***Clinical Trial Technology & Innovation***	***Stream C*** ***Improving Operational Efficiency in Clinical Trials***

	VP Regulatory Affairs, Lakewood Amedex	**Chairperson: Kathryn Hoffman, Director Clinical Development, GE Healthcare**	**Chairperson: Maria Makarovskaya, Director, Clinical & Strategic Sourcing, Akebia Therapeutics, Inc.**
11:00	**Session Reserved for Ross Pettit, Senior Vice President, Development Operations, BeiGene**	**Exploring the challenges of including mobile technologies in your clinical trials** • Determining how effectively wearables link into other systems utilised during the clinical trial such as IVRS and EDC systems to evaluate potential challenges and pitfalls in the use of this technology • Emphasising the benefits of factoring into timelines a test period for patients to get used to the technology to ensure data accuracy **Speaker: Loralie Brennen, Director Clinical Operations, Flexion Therapeutics**	**Determining how to budget study costs effectively to ensure efficient allocation of resources** • Evaluating strategies for analysing protocols to ensure effective forecasting of study costs • Establishing the benefits of using metadata databases for budgeting to facilitate administration and increase efficiency **Speaker: Hyun Kim, Head, Clinical Operations, AOBiome LLC**
11:30	**Increasing Enrollment While Reducing Sites** • Informing patient accrual costs and timelines with patient enrollment feasibility • Rethinking sponsors' reliance on in practice patients • Reducing sites and countries actually allows for faster patient enrollment • Introducing global site networks dramatically reduces study start-up times and costs, while increasing data quality • Leveraging this model to gain a competitive advantage in certain therapeutic indications **Elaina Haeuber, Executive Director, Strategic Operations, Acurian**	**Investigating unique approaches to site feasibility and engagement** • Underlining common challenges of site feasibility and engagement • Identifying unique and innovative approaches to ensure greater site engagement **Speaker: Amanda Hayden, Director, Global Clinical Services, Alkermes**	**Session Reserved for Worldwide Clinical Trials**
12:00	**Evaluating what considerations to take into account during the contract-writing phase to ensure both service providers and trial sponsors are both getting the**	**Overcoming the tension between traditional trial designs and new technology to discover how to best integrate tech innovations into your study**	**Panel Discussion: Exploring strategies for effective partnership building amongst CROs and small biopharma companies** • Determining how to best secure

	most out of the agreement • Describing an overview of what key areas you must consider when defining your contract to ensure a well-rounded and transparent agreement • Debating the finer details of the contract, such as patient travel reimbursement, to determine the responsible party **Speaker: Sondra Smyrnios, Vice President Clinical Development Operations, Alkermes**	• Identifying best practices for finding the right technology for your trial in a time-efficient manner • Evaluating the difficulties of working with established CROs on innovative projects to determine how providers' procedures could be made more flexible to accommodate innovative approaches **Speaker: Georgia Mitsi, Sr. Director, Search & Evaluation, Digital Healthcare, Sunovion Pharmaceuticals**	resources for your company in a competitive environment • Defining key considerations to take into account from a strategic sourcing perspective • Exploring strategies to mitigate risk and loss of resources when partnerships go wrong **Panellists: Maria Makarovskaya, Director, Clinical & Strategic Sourcing, Akebia Therapeutics, Inc.** **& Ross Pettit, Senior Vice President, Development Operations, BeiGene** **& Steven P. Sweeney, Vice President, Quartet Medicine**
12:30	**Transitioning to clinical trials: Identifying the do's and don't's for the uninitiated and detailing key insights for life science companies** • Evaluating the impact of increasing drug development complexity • Considering key factors when creating a transition plan • Identifying your risks to ensure you have an effective mitigation strategy in place • Highlighting the importance of discipline and avoiding the trap of emotions • Detailing the pitfalls of shopping around for advice • Assessing whether size and expertise always equate **Dr. Marc Hoffman,** Chief Medical Officer**, Celerion**	**Session Reserved for PSI**	**Optimizing sponsor/CRO relationships to ensure the success of your clinical trials** • Understanding key factors that drive Sponsor-CRO relationships • Providing tips for negotiation • Discussing financial management and reporting • Reviewing several short case studies **Kristen Snipes,** Project Director**, Rho**
1:00	Lunch and Networking		
2:00	**Lightning Round: Interrogating the benefits of different partnership models to assess which is best for your study** *This session will consist of 4x 15 minute case study presentations followed by an audience Q&A* • Defining your current	**Panel Discussion: Interrogating potential future innovations in clinical trials to discover what 2018 will bring for the industry** • Examining new developments in monitoring to determine what will be possible on-site and off-site in the future • Determining new methods of leveraging data to create predictive	**Workshop Session: Overcoming the challenges of site engagement from a small biotech perspective to ensure a connection is made with key sites despite increasing competition** *During this session, delegates will be split into small working groups and tasked to come up with best practices for site engagement. Strategies will*

	partnership model to explain the rationale behind it • Debating which form of alliance gives trial sponsors the most control over the quality of the study **Speaker 1: Annette Valles-Sukkar, Associate Director, Clinical Project Lead, Global Clinical Operations, Alexion Pharmaceuticals** **Speaker 2: Christine Tosone, Executive Director, Clinical Operations, Allena Pharmaceuticals** **Speaker 3: Jill Hayes, Outsourcing Clinical Operations, Ferring Pharmaceuticals** **Speaker 4: Mary-Lynn Fulton, Head Study Management, Vertex Pharmaceuticals**	models • Exploring the use of social media tools to aid the conduct of clinical trials **Panellists: Ramon Mohanlal, Chief Medical Officer, BeyondSpring Pharmaceuticals** **&** **Patrecia Valone, Clinical Operations Group Head, Novartis Institutes of Biomedical Research, Translational Clinical Oncology**	*be presented to the audience at the end and compiled into a master document.* • Determining innovative methods of increasing visibility of your company to engage sites and stand out from competitor studies • Discussing strategies for structuring contracts that mitigate risks for institutions and enable small companies to engage key sites **Moderator: Denise Tilton, Global Head Clinical Operations & Program Managment, Erytech Pharma**
3:00	**Designing a new model for improving outcomes in impairment studies** • Highlighting how a built-for-purpose model for executing impairment studies can result in a 36% reduction of time for end-to-end services • Evaluating how the right medical and scientific oversight can positively influence your clinical trial outcome • Emphasizing how best to build a dedicated site network • Highlighting the various benefits an experienced project management team can bring to your trial **Geoffrey Roske, Director, Project Management, Covance Clinical Pharmacology Services**	**Reducing your image data risk: How to select the right imaging solution for your clinical trial** • 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, out-of-the-box thinking and cultural fit 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 **Nicholas Campbell,** Chief Commercial Officer, **Median Technologies**	**Changing the paradigm of the clinical study procurement and distribution process for medication and supplies** • Exploring existing challenges and difficulties with current supply processes to establish a new process • Analysing where the new process can provide benefit to gain the best results • Identifying what benefits the new process provides to clinical study procurement and distribution • Highlighting how the new process works to best implement for your clinical trial **Tom Gottschalk,** Executive Director Business Development**, RxSolutions**

3:30	**Session Reserved for Karen Correa, Senior Director, Clinical Operations, Adare Pharmaceuticals**	**Determining how to make data review more efficient by utilising visualisation tools** • Examining the shortcomings of traditional approaches to data review to identify potential quality gaps • Demonstrating the need to define the scope of your requirements in order to effectively reach data review goals **Speaker: Susan Doleman, Vice President Clinical Development, Replimune**	**Determining best practices for translating preclinical development into the clinical stage of your program to prevent delays due to lack of data** • Optimizing the preclinical / clinical interface to maximize coherence between the preclinical and clinical stages of development • De-risking strategies to minimize clinical trial delays due to changing preclinical data • Exploring case studies highlighting the right and wrong ways to incorporate evolving preclinical data into the framework of a clinical trial **Speaker: Terence Hall, Investigator, Translational Medicine, ARQULE**
4:00	*Afternoon refreshments and networking*		
4:30	**Interactive Session: Determining best practices for building good working relationships with inherited CROs to maintain trial quality** • Highlighting the benefits of meeting face-to-face as soon as possible to encourage team-building • Establishing how to deal with differences in procedure to ensure both parties are comfortable with their work processes **Speaker: Steven Kates, CSO, VP Regulatory Affairs, Lakewood Amedex**		
5:00	**Investigating alternative funding sources for your drug development programme** • Identifying the benefits and pitfalls of Collaborative Development Financing to determine whether this is the best route forward for your company • Evaluating the difficulty of engaging investors when working in an uncommon disease area to establish the importance of engaging with KOLs to identify alternative funding strategies **Speaker: Mark Tepper, President & CSO, Corbus Pharmaceuticals**		
5:30	Chairperson's summation and close of day one **Maria Makarovskaya, Director, Clinical & Strategic Sourcing, Akebia Therapeutics, Inc.**		

	Programme Day Two **7th September**
8:30	Registration and Refreshments
8:50	*Chair's Opening Remarks* **Mahlet Woldemariam, Director Project Management, Sanofi US**
	Biopharmaceutical Stream
9:00	**Developing strategies for dealing with a study that runs over budget to mitigate loss of resources and time** • Evaluating the benefit of considering timeline delays as inevitable in studies in certain therapeutics areas such as oncology or rare diseases in order to determine the percentage of resources which should be reserved for these scenarios • Highlighting the need to maintain a good relationship with sites to ensure honesty and transparency when issues do occur and therefore enable timely rectification of the problem • Determining common pitfalls that cause studies to run over budget to determine methods of pre-empting and preventing these occurrences • Highlighting the importance of liaising with all internal departments to find creative solutions • Emphasizing the advantage of having strong relationships with sites in order to quickly identify the source of the problem • Identifying the cost of changing vendors as opposed to repairing partnerships to evaluate which is the most cost-effective option **Speaker: Mahlet Woldemariam, Director Project Management, Sanofi US**
9:30	**Exploring case studies in EDC innovation and integrations** • Evaluating what has been achieved in risk based monitoring • Developing an overview of functionality when dynamically selecting data for SDV • Interrogating some statistics from production trials • Asking 'are we there yet?' in terms of EHR to EDC integration • Exploring the benefits and challenges of various implementation options **Speaker: Neil Vivian, Senior Director of Business Solutions, OmniComm Systems**
10:00	**Fireside Chat: Exploring how trial sponsors and service providers can work together to better maintain quality throughout a trial** *An informal discussion on-stage between the moderator and speaker. Delegates will have the opportunity to submit questions beforehand* • Establishing what the quality 'touch points' should be for the duration of the trial so you can measure the success of your partnership • Interrogating what tools can be used to measure quality throughout the trial to ensure you have an accurate picture of how the service provider is performing on key deliverables • Discussing best practices for developing well-defined SOPs to ensure service providers are best equipped to execute the clinical trial to a high standard • Developing innovative training strategies for service providers to ensure information is reaching all employees undiluted • Highlighting the need to have a retraining strategy in place to ensure data quality is maintained at every stage

	Speaker: Karen Gardner, Senior Director, Clinical Development Operations, Seqirus, A CSL Company
10:30	**Exploring key considerations for selecting a safety services provider** • Providing an overview of key considerations • Outlining the pitfalls of outsourcing to the wrong vendor • Highlighting the benefits of outsourcing to the right vendor • Reviewing several case studies to determine successes and lessons learned • Developing best practices for transitioning safety work to another vendor mid trial • Evaluating considerations through the product lifecycle **Laura Hopper, Director, Safety Surveillance, Medical Operations, SynteractHCR**
11:00	*Morning Refreshments and Networking*
11:30	**Idea Pool Session: Debating best practices for the RFP to ensure you are able to analyse potential partners effectively** *In this session, the host will share current practices and compile creative ideas from the audience to create better strategies for navigating the RFP process* • Developing a standardised bid grid to ensure all significant factors of the service providers' capabilities are taken into account equally • Establishing the importance of using weighted scoring when reviewing the RFP to determine which aspects of a service provider's capabilities are most important for your study **Speaker: Jennifer Goodfellow, Executive Director, Head of Procurement, Boston Pharmaceuticals Inc.**
12:00	**Evaluating the implications of the ICH GCP E6 regulation on clinical outsourcing to determine how to best align with the update** • Outlining amendments to the sponsor's responsibilities as detailed in the regulation to evaluate how you can integrate the updates into your processes • Identifying to what extent trial sponsors need to make their QA more robust to comply fully with the regulations • Evaluating the benefits of expanding your internal QA department to ensure an efficient QMS is in place • Assessing the changes in CRO oversight requirements to determine how sponsors can efficiently document CRO sub-contracting • Evaluating whether the updated regulation makes risk-based approaches to trial design inevitable in order to efficiently comply with all requirements **Speaker: Rene Myers, Vice President Clinical Affairs, scPharmaceuticals**
12:30	*Lunch and Networking*
1:30	**Exploring technologies for site and patient recruitment-Now and in the Future** • Covering a number of innovative technologies that either can now or will at a future point assist us with both site and patient recruitment. • Investigating available technologies that are utilized by many but not enough companies • Exploring technologies that are utilized by some but far fewer companies • Discovering technologies that have yet to be embraced by the industry **Speaker: Kevin J. Anderson, Director, Global Clinical Operations, Alexion Pharmaceuticals**

2:00	**Outsourcing mitigations for small biotechs working with CROs: Increasing the value-added within various provider models.** • Demonstrating how small companies can remain cost-effective through proactive mitigations to ensure a realistic budget is maintained • Determining whether small CROs or large CROs can offer biotechs more concentrated expertise to evaluate how best to gain deep knowledge on a specific therapeutic area • Establishing effective collaboration in a small biotech environment to increase team-work and value-added from a chosen outsourcing strategy **Speaker: Amanda J. Moore, Associate Director, Clinical Operations & Development, Sage Therapeutics**
2:30	**Determining best practices for effective oversight of international partners to ensure key deliverables are completed on time** • Evaluating the benefits of utilising time and resources to physically visit your international partners on a regular basis to double-check their work to ensure errors are corrected quickly • Weighing up the benefits of hiring a full-time employee based in your key international market(s) to oversee international service providers **Speaker: Eyal S. Ron, Chief Technical Officer, Gelesis**
3:00	*Afternoon Refreshments and Networking*
3:30	**Discussing methods for navigating customs clearance on an international scale to increase your chances of successful import/ export of IMP** • Establishing the importance of building realistic timelines to avoid disruptions affecting the rest of the clinical supply chain • Ascertaining what documentation should be in place before the import/ export license application to expedite the customs process • Debating the benefits and challenges of working with a local courier as opposed to an international courier in emerging markets to determine the most efficient and cost-effective method • Appreciating the need to have supply orders placed well in advance to prevent costly delays • Defining an efficient framework for communication with all stakeholders to improve time-effectiveness at this stage of the clinical supply chain **Speaker: Abraham Thariath, Executive Director, Process Development and Manufacturing, ContraFect Corporation**
4:00	**Examining the Impact of, and the Role of CROs in Supporting, Patient Engagement** • Providing an update on sponsor company adoption of patient centric initiatives in clinical development • Reviewing the strategic and tactical role of CROs in facilitating and optimizing patient engagement initiatives • Describing an overview of the changing CRO landscape and its association with emerging patient engagement practices • Review of new research quantifying the return of patient engagement investment on development program value **Session Reserved for Ken Getz, Director and Associate Professor, CSDD, Tufts University School of Medicine**

Keynote

4:30	**Roundtables** ***Each roundtable session lasts for 30 minutes, and delegates may attend 2 roundtables. The roundtables will be allocated on a "first come first serve" basis.***
RT1	**Establishing strategies for finding the right partner for your study to ensure a long-term, collaborative relationship** **Host: Kathryn Hoffman, Director Clinical Development, GE Healthcare**
RT2	**Developing a comprehensive approach to CRO selection to reduce time to study start-up** **Host: Christopher LaFarge, President & CEO, MedicaMetrix, Inc.**
RT3	**Discussing the common pitfalls when working towards IDE approval** **Host: John A. DeLucia, VP, Regulatory Affairs, Clinical Affairs and Quality Assurance, iCAD Inc.**
RT4	**Developing strategies for managing resources as a small, start-up company to ensure that you are remaining cost and time-effective** **Host: Jeffrey R Sabados, President, Resilience Therapeutics**
RT5	**Establishing best practices for minimising change orders during your trial** **Host: Roberta Duncan, Head of Business Operations, Shared Services and Clinical Compliance, Seqirus**
5:30	*Chair's Closing Remarks and End of Conference* ***Mahlet Woldemariam, Director Project Management, Sanofi US***