Outsourcing in Clinical Trials West Coast

Hyatt Regency San Francisco Airport, USA

6th-7th February 2024
www.arena-international.com/octwestcoast/

'This conference will bring industry professionals together to share knowledge, with a focus on collaboration, advancing clinical development and concentrating on clinical operations, innovation, and technology.'

For the 16th Annual event, our flagship show will focus on providing delegates with practical take-aways and solutions to their most current operational and outsourcing challenges in clinical trials, this is an event not to be missed.

2024 Speakers

Gurinder S. Sidhu, Senior Medical Director, Pfizer
Abdel Dridi, Global Head of Digital Healthcare Technologies (DHT), Personalized Healthcare, Product Development, Roche Robert J. Boland, MBA, Global Head of Digital Innovation R&D, Haleon
Christine Von Raesfeld, Founder & CEO, People with Empathy
Gwen Valencia, Senior Manager Clinical Diversity & Inclusion, Takeda
Archana Sah, Oncology Board Member, Society for Clinical Research Sites
Gabriel Luciano, Vice President, Clinical Operations, Corvus Pharmaceuticals
Jasmina Jankicevic, Clinical Development, RAPT Therapeutics
Harman Hansra, Sr. Director, Global Clinical Ops, Annexon Biosciences
Amy Finnigan, Head of IT R&D, Ultragenyx Pharmaceutical
Scott McCulloch, Executive Director, Global Clinical Quality & Pharmacovigilance, Recode Therapeutics
Edward Kuczynski, Director, Human Research Protection Program at University of California
Jenny Wakefield, Senior Director- Quality Development Operations, Incyte
Allyson Gunsallus, Associate Director, Clinical Outsourcing, BridgeBio
TR Thirucote, Chairman & CEO, TesoRx Pharma
Jenny Wakefield, Senior Director- Quality Development Operations, Incyte
Marta Schumacher, Executive Director, Global Clinical Operations, Annexon Biosciences
Ghesal Razag, Sr. Director, GI Clinical Operations, Biora Therapeutics
Dave Borbas, Research VP, Head of Data Management, Abcuro
TR Thirucote, Chairman & CEO, TesoRx Pharma
Bruce Morimoto, VP, Drug Development, Alto Neuroscience
Shalini Mohan, Head, Health Equity and Inclusive Research, Genentech
Kolbi Brown, Director of Engagement, National Institute of Health (NIH) partner with Pyxis Partners
Kimberly Barnholt, Executive Director, Evidence Generation, Genentech
Kim Erby, Director Clinical Operations, Cytokinetics
Danielle McMullin, Director Clinical Operations, BridgeBio
Jane Myles, Program Director, Decentralized Trials & Research Alliance (DTRA)
Priya Ryali, Director, Head of Clinical Operations, ReCode
Rebecca Lin, Chief Strategy Officer, Potrero Medical
Dan Solis, Assistant Commissioner for Import Operations, FDA
Gordon Chu, Director of Investigations Branch, FDA
Dr Bill Chen, CISO, Natera
Laura Yecies, CEO and Board Member, Bone Health Technologies
Dr. Sanjay Shrivastava, CEO, Innova Vascular, Inc.
Anitha Achyutha, Director, Clinical Research (Farapulse PFA), Electrophysiology, Boston Scientific

Join our new community on LinkedIn
#OCTWestCoast | @ArenaIntPharma

Laura Moffett, Director of Clinical & Regulatory Affairs, VDyne, Inc.
Dorothy H. Kwok, Head of Clinical Operations, Bodyport
Dr. Bryan Cornwall, Executive Vice President, Research & Clinical Affairs, Surgalign
Chandramohan Thiruvamkulam, Director Quality Systems, Endologix
Abby Kennedy, Vice President of Clinical Operations, CymaBay Therapeutics
Mario Esquivel, Director of Clinical Affairs, RefleXion Medical
Chris Chan, Vice President, FP&A, IGM Biosciences
Catherine L. Caserza, Director, Clinical Operations, Daiichi Sankyo
Priya Nair, Senior Analyst, Clinical Trials Intelligence, GlobalData

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DAY ONE – TUESDAY FEB 6th, 2024

07:30	Registration & Refreshments		
08:20	**Chairman's Opening Remarks** Abby Kennedy, Vice President of Clinical Operations, CymaBay Therapeutics		
08:30	**Keynote** **The use of technology to accelerate early drug discovery and reduce the burden for patients.** Building personalized digital healthcare solutions to support clinical claims is of great importance to the drug industry. Medical Insights generated from digital healthcare clinical studies emerged as a promising approach to help with: • Patient engagement and retention. • Collecting richer data to drive insights and accelerate drugs' early research and developments to make better drugs and early medical decisions. • Increase efficacy of therapies through continuous monitoring. *This session details a case study on challenges using Digital Healthcare Technologies in the clinical trials ecosystem and use of medical devices to help patients better manage their conditions.* **Abdel Dridi**, Global Head of Digital Healthcare Technologies (DHT), Personalized Healthcare, Product Development, **Roche**		
09:00	Session Reserved for Medidata		
09:30	*Session Reserved for Event Sponsor*		
10:00	Morning Refreshments & Networking		
	Stream A: Outsourcing & Clinical Operations **Chair:** Abby Kennedy, Vice President of Clinical Operations, CymaBay Therapeutics	**Stream B: Clinical Innovation & Technology** **Chair:** Priya Nair, Senior Analyst, Clinical Trials Intelligence, GlobalData	**Stream C: Patient Engagement and Diversity & Inclusion** **Chair:** Christine Von Raesfeld, Founder & CEO, People with Empathy

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10:30	**State of Affairs on Excellence in Clinical Development** The talk will explore the current state of affairs in Clinical development, the most pressing challenges in 2024 and solutions to address them. • Learn about the most pressing challenges and solutions in both early to late stage clinical development- at big pharma as well as small biotechnology companies • strategies for increasing representation and diversity, • share best practices for patient enrollment and retention, data standards and latest regulatory considerations/guidelines • How can technology be leveraged in patient centric drug development **Archana Sah,** Oncology Board Member, Society for Clinical Research Sites	**How are we digitally moving us into the next generation of laboratories for clinical trials** • NextGen Labs • Digital transformation **Robert J. Boland,** MBA, Global Head of Digital Innovation R&D, **Haleon**	**Diverse and Equitable Participation in Clinical Trials (DEPICT) Act** **Legislation aiming to increase diversity in clinical trials by requiring enhanced data reporting on clinical trial participant demographics.** • What does a Diversity Plan look like? • Determining the dynamic and strategy of such a plan • Highlighting a diverse trial that could be emulated • Addressing the requirement to include information about the demographic diversity of the clinical trial population and address related issues • Practical experience – submitting your diversity plan **Gwen Valencia**, Senior Manager Clinical Diversity & Inclusion, **Takeda**
11:00	Session Reserved for Worldwide Clinical Trials	Session Reserved for Clario	Session Reserved for Paraxel
11:30	**CRO Cost Control and Smart Contracting** • Examining how CRO contracts are structured. • Handling CRO advantage and focusing on the components Sponsors can control. **Gabriel Luciano,** *Vice President, Clinical Operations, Corvus Pharmaceuticals*	**Great expectations and how to meet them – connected devices and ePRO in clinical trials** • Focusing on design considerations • Understanding the best framework for your study • Considering patient ePRO assessments needed for a specific study • Highlighting best practice for data collection • Avoiding expensive mistakes that undermine your trial outcome or delay your timeline	**The Patient's Perspective:** *'Why are patient's voices so important in drug development?'* • Discussing the personal experiences of the patient • Defining 'patient centricity' **Christine Von Raesfeld**, Founder & CEO, People with Empathy

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		• Outlining Regulatory restrictions around ePro with a focus on EU & UK GDPR concerns, ethical questions in the US • Comparison vs Paper Reported Outcomes – why are companies not transitioning fully to ePro? **Dave Borbas,** Research VP, Head of Data Management, Abcuro	
12:00	Session Reserved for Novotech	Session Reserved for ICON	Session Reserved for Medical Research Network (MRN)
12:30	Lunch & Networking		
	Stream A: Outsourcing & Clinical Operations **Chair:** Abby Kennedy, Vice President of Clinical Operations, CymaBay Therapeutics	**Stream B: Clinical Innovation & Technology** **Chair:** Priya Nair, Senior Analyst, Clinical Trials Intelligence, GlobalData	**Stream C: Patient Engagement & Inclusion, Diversity, Equity, and Access** **Chair***:* Christine Von Raesfeld, Founder & CEO, People with Empathy
1:30	**PANEL** **Maximising your Sites Productivity & how to lessen the burden** Sites are increasingly challenged with workload and resource constraints. This panel will discuss ways in which to get the best output from sites. *What can we do for them beyond an inflated budget?* • Addressing challenges the sites are currently facing • An overview of the repercussions of such challenges, and a focus on what we can do to overcome them. • Forward thinking to strengthen site output. • Limitations with electronic applications **Moderator: Jasmina Jankicevic,** Clinical Development, RAPT Therapeutics	**PANEL** **FUTURE FORWARD: What's broken and what's working when deploying technology in clinical trials** • Current state of affairs in clinical trials technology • Understanding what is really working • Deploying technology for informed consent ePro, wearable sensors for remote patient monitoring • Sharing best practice and case studies from across the sector **Moderator: Priya Nair,** Senior Analyst, Clinical Trials Intelligence, GlobalData **Panellists:** **Allyson Gunsallus,** Associate Director, Clinical Outsourcing, **BridgeBio** **Amy Finnigan,** Head of IT R&D, **Ultragenyx Pharmaceutical**	**PANEL** **Patient centricity**: *What does patient centric clinical trial development look like in 2024?* • Looking at what is working and what can be done better. • Highlighting the patient perspective, providing a platform to share one's story. • Discussing opportunities of further development **Moderator:** Christine Von Raesfeld, Founder & CEO, People with Empathy **Panellists:** **Archana Sah,** Oncology Board Member, Society for Clinical Research Sites **Jenny Wakefield,** Senior Director- Quality Development Operations, Incyte **Catherine L. Caserza** RN, MS, MPH Director, Clinical Operations, **Daiichi Sankyo**

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	Panellists: Marta Schumacher, Executive Director, Global Clinical Operations, Annexon Biosciences **Harman Hansra**, Sr. Director, Global Clinical Ops, Annexon Biosciences	Panel position reserved for **Merative** .	
2:15	Session Reserved for PCM Trials	Session Reserved for YPrime	Session Reserved for Session Sponsor

2:45	**Trial Execution Excellence for small & medium biotechnology companies**
	
	• Outlining the outlook for the future on what sponsors & CROs could do to embrace a more strategic and partnership approach to clinical trials for mutual benefits
	• Looking at the use and integration of new tools and technologies to improve our knowledge about the origin of the disease and to identify new therapeutic strategies
	• Approaching product management that emphasizes getting the right products to market faster through deep user insight, a clear product strategy, and an inspiring roadmap.
	
	Scott McCulloch, Executive Director, Global Clinical Quality & Pharmacovigilance, Recode Therapeutics
		Expanded Responsibilities for IRBs when Reviewing AI Protocols
		
		• Protecting Third Parties in Human Subjects Research
		• Ethical, Privacy, and Safety Considerations for:
		  ○ Direct Research Participants
		  ○ Participant Community, Subpopulation, Race, Ethnicity, Gender
		  ○ Society at Large
		• Assessing AI Tool Bias
		
		Edward Kuczynski, Director, **Human Research Protection Program at University of California**
			FIRESIDE CHAT
			Have you developed an understanding of the patient journey as part of your clinical trial design? Bringing the patient's practical perspective to your trial operations especially for rare disease indications
			
			• Building clinical trials with the perspective of the patient in mind (the patient journey).
			• Discussing the collaboration that must exist between patient advocacy groups, study site staff, patients, care givers in order to have a successful trial.
			• Highlighting the importance of effective communication to patients and how this can streamline trial timelines.
			• Exploring how patients could, and should, be influencing decisions and the R&D process.
			• Regulatory situation in support of patient-centred development
			• What are the benefits of using multi-stakeholder approaches?
			
			Moderator: Christine Von Raesfeld, Founder & CEO, People with Empathy
			
			Speaker: Marta Schumacher, Senior Director, Clinical Operations, Annexon Biosciences

3:15	Afternoon Refreshments, Networking & Apple Prize Draw in Exhibit Hall		
	Stream A: Outsourcing & Clinical Operations *Chair: Abby Kennedy, Vice President of Clinical Operations, CymaBay Therapeutics*	***Stream B: Clinical Innovation & Technology*** *Chair: Priya Nair, Senior Analyst, Clinical Trials Intelligence, GlobalData*	
3:45	Session Reserved for Premier Research	3:45 Session Reserved for eClinical Solutions – 15 min tech showcase	

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		4:00 Diligent Pharma - 15 min tech showcase Session Reserved for Event Sponsor
4:15	**PANEL DISCUSSION** **Outsourcing Strategies: how do you approach your outsourcing strategy?** • Determining the best strategy from your service providers • Uncovering if your offerings are competitive, and if this is indeed value for money. • Looking into what is driving the increasing costs of running your study, recognising the value associated with costs and their justifications. • Establishing what can be done to avoid increasing budgets including the evaluation of tools required for the type of study one is conducting. **Moderator: Abby Kennedy,** Vice President of Clinical Operations, CymaBay Therapeutics **Panellists:** **Kim Erby,** Director Clinical Operations, Cytokinetics **Scott McCulloch**, Executive Director, Global Clinical Quality & Pharmacovigilance, Recode Therapeutics **Dave Borbas,** Research VP, Head of Data Management, Abcuro	**PANEL DISCUSSION** **Focusing on today's Innovation & Technological Advancements** • Are we making the most of Technology & Innovation in the Clinical Trial space? • How are these tools being utilised? • What's next? • Considering the use of AI in healthcare & Clinical Trials **Moderator: Priya Nair,** Senior Analyst, Clinical Trials Intelligence, GlobalData **Panellists:** **Priya Ryali,** Director, Head of Clinical Operations, ReCode **Rebecca Lin,** Chief Strategy Officer, Potrero Medical **Shoaib Khan,** Medical Director, Pfizer
5:00	Chairman's Closing Remarks & Drinks Reception	

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DAY TWO – WEDNESDAY 7th FEB 2024

8:30	Registration and Refreshments		
	Stream A: Outsourcing & Clinical Operations *Chair: Bruce Morimoto, VP, Drug Development, Alto Neuroscience*	***Stream B: Clinical Innovation & Technology*** *Chair: Priya Nair, Senior Analyst, Clinical Trials Intelligence, GlobalData*	***Stream C: Medical Device*** *Chair: Undisclosed*

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9:00	**Building CRO Relationships. What are the critical factors to consider when procuring from a CRO?** • Establishing common ground with your CRO • Ascertaining the critical factors to think about when you collaborate with a CRO • Exploring how the concept of Co-development between Pharma & CRO is working best • Overcoming the differences between Pharma & CRO business models to work in harmony • Underlining the factors which could be limiting what choice you make? • Considering the benefit of CRO's adding a Small biotech division with personalized service to ensure all are valued **Jasmina Jankicevic,** Clinical Development, **RAPT Therapeutics**	**Tactical clinical operations in digital health studies** • Designing clinical operation workflows for studies with complex hardware and software components • Structuring real-time data insights into protocol focus and adherence • Focusing on improving data quality and data curation for product development **Amy Que-Xu,** Health Technology - Clinical Research, Meta	**Navigating the importation landscape for medical devices to gain and maintain competitiveness in a global market** • What industry should provide to a vendor to be able to import medical device • Understanding and avoiding medical device importation errors • Detained medical devices: How to overcome the violation to get product into commerce • Ensuring good manufacturing practice and compliance to domestic regulation **Dan Solis**, Assistant Commissioner for Import Operations, FDA **Gordon Chu,** Director of Investigations Branch, FDA
9:30	**Clinical Pharmacology at Scale to Reduce Risk and Increase Precision** **Oren Cohen, MD,** Chief Medical Officer and President, Clinical Pharmacology Services, **Fortrea Inc.**	*Session Reserved for 4G Clinical*	**Improving interactions with regulatory agencies on submission requirements and study results from a startup perspective** • Why collaboration with regulatories must remain paramount in the approval process for medical devices • Practical look at pre-submission meeting requirements with regulatory agencies • Knowing the expectations and aligning with the FDA for successful IDE approval **Laura Moffett**, Director of Clinical & Regulatory Affairs, VDyne, Inc.
10:00	**Design Concepts in effective product development and clinical outcomes – Expert Lessons** • Concept Target Product Profile (TPP) • Design of Product and Testing Methodology	**FIRESIDE CHAT** **Decentralised Clinical Trials; a discussion on modernising clinical trials whilst minimising site burden**	**Designing trials to demonstrate clinical efficacies while preparing for commercialization** • How to interpret preliminary data in order to choose an appropriate trial design

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	• Product Design and Clinical Outcomes **TR Thirucote,** Chairman & CEO, TesoRx Pharma	Perspectives from Sponsors & Sites; How to implement DCT's, addressing the challenges and lessons learnt, sharing best practice. Moderator: **Jane Myles,** Program Director, Decentralized Trials & Research Alliance (DTRA) Panellists: **Shalini Mohan,** Head, Health Equity and Inclusive Research, Genentech **Kimberly Barnholt,** Executive Director, Evidence Generation, Genentech	• Effectively assessing trial design to minimize risks and maximize benefits • Incorporating best practice in trial design to increase chances of success **Laura Yecies,** CEO and Board Member, Bone Health Technologies
10:30	Morning Refreshments & Networking		
11:00	**CASE STUDY** **ALL OF US Research programme** The All of Us Research Program is an historic effort to collect and study data from one million or more people living in the United States. The goal of the program is better health for all. **Kolbi Brown,** Director of Engagement, **National Institute of Health (NIH) partner with Pyxis Partners**	***Session Reserved for Priya Nair, Senior Analyst, Clinical Trials Intelligence, GlobalData***	**Collaborating with digital innovation: Data security and governance under a new age of AI** • Trends, opportunities, and challenges from AI • Finding the right balance between protecting data and enabling innovation • Preparing medical device applications amidst geopolitical changes and managing evolving cyber and privacy laws • Establishing long term foundations under cost control **Dr Bill Chen**, CISO, Natera
11:30	*Session Reserved for MMS Holdings*	*Session Reserved for IQVIA Technologies*	*Session reserved for Premier Research*
12:00	**The Elephant in the Room:** What is holding you back from developing key relationships when managing your trials and Vendor Relationships? Are you in your own way? How do you relate and interact with: • Your Study Team • Your Vendors • Your Manager • Yourself • Are you willing to face others' perceptions of you?	**Which Approach to Invest in?** With numerous emerging innovative solutions on the market, how are organisations assessing the right approach for the right trials? • What types of innovative approaches are trending? • How are organisations evaluating different approaches? • Establishing the best fit for your trial - how to optimize fit-for-purpose and fit-for-patient?	**Non-significant risk device studies: Designing pivotal studies for medical device approval in the US** • Understand how to identify and categorize the type of medical device you are evaluating • Collaborate with different stakeholders for alignment • Design a clinical study that fits the needs for the medical device regulatory approval

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	This will be a brief presentation followed by an Open discussion on some barriers to communication that Clinical Operations professional experience. **Jenny Wakefield,** *Senior Director- Quality Development Operations,* ***Incyte***	• Underlining the risk between huge benefits and wasted time • Uncovering longevity: here one-minute and gone the next **Kimberly Barnholt,** Executive Director, Evidence Generation, Genentech	**Dorothy H. Kwok,** Head of Clinical Operations, Bodyport
12:30	**Session reserved for RadMD** **Moderator: Rick Patt, MD, Co-founder and Director of Medical and Scientific Affairs at RadMD**	**Session reserved for Viedoc**	**Levelling up CRO partnerships for medical device companies so that both sides win** • How to effectively request a bid from a CRO and how to streamline this process • Why CRO flexibility and ability to customize is mission critical for sponsors • Optimizing regional partnerships with CROs to best support clients and avoid dissatisfaction • Ensuring alignment of incentives to avoid delays in trial execution **Dr. Bryan Cornwall,** Executive Vice President, Research & Clinical Affairs, Surgalign
01:00	Networking Lunch		
2:00	**A look at the CTR – European Submission** • Understanding the process from start to finish to minimise delays in your study start-up. • Uncovering the European Union Clinical Trials Directive. As of Jan 31st, 2022-23, sponsors may submit trials under EUCTR • Outlining the Clinical Trial Information System (CTIS) and looking into the EU's expeditious plan to role this out **Danielle McMullin,** Director Clinical Operations, **BridgeBio**	**Clinical Trials Budgeting & Forecasting: 7 Key Areas of Focus (that should be "givens"!)** • Multi-Variables • Outsourcing • PTS (Probability of Technical Success) • FTE (Full-Time Equivalent) Rate • Accruals • Change • Exuberance **Chris Chan,** Vice President, FP&A, IGM Biosciences	**Presentation of paper on data integrity: Reducing the impact of increased data privacy requirements under GDPR on medical device companies** • Managing all considerable factors when it comes to data handling • Ensuring an additional language is included in contracts • Do the sites or vendors have a Data Privacy Officer or SOPs around data handling? • How to review data in an efficient way **Chandramohan Thiruvamkulam,** Director Quality Systems, Endologix
2:30	**PANEL DISCUSSION** **Diversity & Inclusion in Clinical Trials**	**Chris Chan,** Vice President, FP&A, IGM Biosciences **INTERACTIVE SESSION WITH Q&A**	**PANEL DISCUSSION** **Sharing best practice for improving patient enrolment and engagement for successful medical device clinical trials**

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	• Diversity in clinical trials; Definitions and The Why • Critical barriers in recruiting and retention • Action for increasing diversity • Regulatory Updates Panellists **Kolbi Brown**, Director of Engagement, National Institute of Health (NIH) partner with Pyxis Partners **Kim Erby,** Director Clinical Operations, Cytokinetics **Shalini Mohan,** Head, Health Equity and Inclusive Research, Genentech **Gurinder S. Sidhu,** U.S. Senior Medical Director, Pfizer **Edward Kuczynski,** Director, Human Research Protection Program at University of California	**How are today's patients coping with modernized trials?** • A firsthand insight onto what it is like participating in a trial • Which key things helped make my time simpler on a trial • How even minor things from the protocol can have a huge impact on patients **Catherine L. Caserza** RN, MS, MPH Director, Clinical Operations, **Daiichi Sankyo**	• How to expedite enrolment through interface with the sites in medical device studies • Collaborating with patients to ensure patient-centric clinical trials and improved engagement • Getting enrolment interest back to where it was before the pandemic • Incorporating hybrid decentralized trials as a potential solution to decreased patient enrolment • Understanding how much patients value the human touch to tend to their needs better • Being aware of the implications of cultural differences on how medical device instructions are understood globally during decentralized clinical trials Moderator: Panelists: **Dr. Sanjay Shrivastava,** CEO, Innova Vascular, Inc. **Anitha Achyutha,** Director, Clinical Research (Farapulse PFA), Electrophysiology, Boston Scientific
3:15	Afternoon Refreshments, Networking & Prize Draw in Exhibition Room		
3:45	**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	***Managing the workload of a small biotech with limited resources*** **Ghesal Razag**, Sr. Director, GI Clinical Operations, Biora Therapeutics		
RT 2	***Leveraging global trial footprint to accelerate clinical development*** ***Priya Ryali,*** *Director, Head of Clinical Operations, ReCode*		
RT 3	**Deciding between outsourcing clinical studies versus managing them in house** ***Anitha Achyutha,*** *Director, Clinical Research (Farapulse PFA), Electrophysiology, Boston Scientific*		
4:45	**Close of Conference**		

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