CLINICAL OPERATIONS CLINICAL TRIAL SUPPLY CHAIN PHARMA COVIGILANCE

STRATEGY MEETING WEST COAST

11th MAY 2020

Hard Rock HOTEL SAN DIEGO

OUR UNIQUE MEETING FORMAT

- **Roundtable Discussions**
  These interactive and informal discussion groups are the hallmark of the meeting. The brightest minds in the industry are brought together in 60-minute sessions that enable participants to share ideas, challenges and lessons learned.

- **Personalised Agenda**
  Each delegate receives a personalised agenda with the roundtable discussions that you choose. You only attend sessions and meetings that fit your challenges and interests, ensuring your time out of the office is focused and well-utilised.

- **One-to-one Meetings**
  The most effective and time efficient way to assess potential partners at a strategic level. Gain access to our exclusive networking app to identify the people that you need to meet. The app suggests a suitable time and place, all you need to do is grab the coffee.

- **Strategic Networking**
  Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances is underscored by a host of networking programmes, from a buffet breakfast through to evening drinks, make lasting connections that benefit you.

CONTRIBUTORS TO THE AGENDA

Andrea Small-Howard
Chief Security Officer
GB Sciences

Anthony Zuccarello
Director, Dev. Supply Chain CMC
Rocket Pharmaceuticals

Atif Abbas
Vice President, Oncology Clinical Dev.
Spring Bank Pharmaceuticals

Ben Exter
VP & Head of Pharmacovigilance
Unum Therapeutics

Jack Fernandes
CEO
Regenica Biosciences

Dale Dhanoa
CEO
INVENT Pharmaceuticals

Kevin Ryan
VP & Chief Compliance Officer
ACADIA

Mohammed Ahmad
Medical Director
Head of Medical Clinical Quality
Takeda Pharmaceuticals

Abhit Singh
Chief Regulatory Officer
Intrommune Therapeutics

Atul Deshpande
Chief Strategy Officer & Head US Operations
Harbour Biomed

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AGENDA AT A GLANCE

TRACK & ROOM	01 RISK BASED MONITORING	02 PATIENT RECRUITMENT & CENTRICITY	03 OUTSOURCING	04 EMERGING BIOPHARMA	05 CLINICAL DATA & IRT	06 STORAGE & DISTRIBUTION	07 SIGNAL DETECTION	08 ADVERSE EVENTS CASE PROCESSING	09 A.I. & MACHINE LEARNING
08:00 - 08:30	REGISTRATION & BREAKFAST NETWORKING					REGISTRATION & BREAKFAST NETWORKING			
08:30 - 09:00	WELCOME SPEECH & INVESTOR'S PANEL DISCUSSION								
09:00 - 10:00	How to develop a Monitoring Plan to incorporate a risk-based approach **Kevin Ryan - VP & CCO ACADIA**	Implementation of innovative approaches to achieve Proof-of-Concept results in record time in Early Phase Clinical Trials? **Abhit Singh - Chief Regulatory Officer Intrommune Therapeutics**	How are the CROs addressing the demand for specialized services? **Atif Abbas - Vice President Spring Bank Pharmaceuticals**	How a shared-risked partnership model can improve the success rates of getting to IND and beyond **Dale Dhanoa - CEO INVENT Pharmaceuticals**	How IRT integrations can support global multilingual studies, streamlining delivery and eliminating multi vendor coordination to improve clinical trials **Anthony Zuccarello - Director Rocket Pharmaceuticals**	The need for smarter and more advanced storage and distribution facilities as part of the supply chain **Ankush Argade - Founder & President Amarit Biosciences**	Signal Management meeting the needs of all stakeholders **Reddy Tummala - Vice President Karyopharm Therapeutics**	How improving performance while reducing complexity can enable real-time signal detection for pro-active monitoring **Mohammed Ahmad - Director & Head Takeda Pharmaceuticals**	The A.I Paradigm Shift -Is It Just a Hype **Atul Deshpande - CSO & Head Harbour Biomed**
10:00 - 11:00	1 - 1 MEETING *10:00-10:20		NETWORKING BREAK	1 - 1 MEETING *10:20-10:40		NETWORKING BREAK	1 - 1 MEETING *10:40-11:00		
11:00 - 12:00	IMS Health & Quintiles are now IQVIA	IMS Health & Quintiles are now IQVIA	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	SanaClis	Sharp	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR	IMS Health & Quintiles are now IQVIA	IMS Health & Quintiles are now IQVIA
12:00 - 13:00	1 - 1 MEETING *12:00-12:20			1 - 1 MEETING *12:20-12:40			1 - 1 MEETING *12:40-13:00		
13:00 - 13:30	KEYNOTE PRESENTATION	IMS Health & Quintiles are now IQVIA	KEYNOTE PRESENTATION		IMS Health & Quintiles are now IQVIA	KEYNOTE PRESENTATION		IMS Health & Quintiles are now IQVIA	
13:30 - 14:30	1 - 1 MEETING *13:30-13:50		3 COURSE NETWORKING LUNCH		1 - 1 MEETING *13:50-14:10	3 COURSE NETWORKING LUNCH		1 - 1 MEETING *14:10-14:30	
14:30 - 15:00	KEYNOTE PRESENTATION	CrO Biosciences	KEYNOTE PRESENTATION		CrO Biosciences	KEYNOTE PRESENTATION		CrO Biosciences	
15:00 - 16:00	Exploring how RBM data can be used to drive study quality	Strategies to successfully match and recruit eligible patients to clinical trials **Gabriel Lazarin - Vice President Deepcell**	The impact of future technology on the design and execution of Phase I/II trials. New technologies, Remote Clinical trials. New technologies & Remote Clinical trials. **Melissa Morandi - Vice President Aegerion Pharmaceuticals**	Emerging biopharma growth by partnering with VC, Pharma companies and CDMO/CRO **Gajanan Bhat - Vice President Spectrum Pharmaceuticals**	How eConsent can improve sponsor and CRO oversight and ensure enrollment are meeting timelines **Joanne McCaigue - Director Posieda Therapeutics**	How the explosive growth of Biologics has changed the Cold-Chain Clinical Supplie Chain landscape	Identifying the latest development & innovation approach for effective signal management **Benjamin Exter - VP & Head Unum Therapeutics**	Discovering solutions for drug counterfeiting issues & analyzing viable measures to combat & protect consumers **Melissa Rossi - Senior Director Moderna Inc**	Enhancing patient safety with A.I. **Oliver Steinbach - VP R&D Imagion Biosystems**
16:00 - 16:10	AFTERNOON COFFEE BREAK			AFTERNOON COFFEE BREAK			AFTERNOON COFFEE BREAK		
16:10 - 16:30	1 - 1 MEETING *20min		NETWORKING BREAK	1 - 1 MEETING *20min		NETWORKING BREAK	1 - 1 MEETING *20min		
16:30 - 17:30	Develop a monitoring plan which focuses on mitigating risks at both the program and study levels decision-making	Patient recruitment using field-based advocacy **Jack Fernandes - CEO Regencia Biosciences**	Turning 'High Value Study' Feasibility into successful trial execution **Ketty Belizaire - Senior Director Mylan**	Does one size fit all when you are an EBP? The pros and cons in working with a Small CRO vs a Large CRO **Andrea Small-Howard - CSO GB Sciences**	How to better leverage the power of multiple disparate systems and access real-time data to make better informed decisions	Centralized or Decentralised Warehousing: The pros and cons for each solution **Catherynne Cruz - Scheckner Ionis Pharmaceuticals**	Applying signal detection proficiency in the Sentinel System **Renu Weerasinghe - Global Lead Takeda**	PV: Maintaining compliance through advanced drug safety surveillance **Ashraf Yousef - Sr. Med. Director Shire**	Enabling PVO in predictive science with the application of A.I. **Kevin Buckley - Sr. VP HUYA Bioscience Int.**
17:30 - 18:00	INVESTOR'S PANEL			INVESTOR'S PANEL			THE INVESTOR PANEL		
18:00 - 19:00	DRINKS & CANAPE RECEPTION			DRINKS & CANAPE RECEPTION			DRINKS & CANAPE RECEPTION		

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INVESTMENTS & VENTURE CAPITAL

Introducing The New **'Investment & Venture Capital'** Track - Proventa International's latest evolutionary step in developing our signature Strategy Meetings. Now not only providing essential operational strategy solutions but also aiding in equally important fundraising and investment seeking strategy.

09:00 - 10:00	Key considerations when approaching investors - investor insights
11:00 - 12:00	ROUNDTABLE TOPIC CONFIRMED FOR SPONSOR
15:00 - 16:00	An investor perspective on building a strong portfolio to best showcase your company
16:30 - 17:30	Current key therapeutic areas which investors are focusing on and why?

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SPONSORS

LEAD

IMS Health & Quintiles are now IQVIA™

VISIT WEBSITE

IQVIA is a leading integrated information and technology-enabled healthcare service provider, dedicated to helping its clients improve their clinical, scientific and commercial results. QuintilesIMS's approximately 50,000 employees conduct operations in more than 100 countries. Companies seeking to improve real-world patient outcomes and enhance clinical trial outsourcing through treatment innovations, care provision and access can leverage QuintilesIMS's broad range of healthcare information, technology and service solutions to drive new insights and approaches. QuintilesIMS solutions span clinical to commercial, bringing clients a unique opportunity to realize the full potential of innovations and advance healthcare outcomes.

CO-HOST

Sharp

VISIT WEBSITE

Sharp Clinical's IRT platform manages patient interactions and drug supplies during clinical trials and perform a range of functions for sponsors, drug depots and investigative sites. Our solution includes simple to complex randomization schemes, a warehouse returns system and a supply forecaster which will predict patient enrolment and clinical supply consumption. Sharp Clinical also offers a full complement of clinical trial services, including analytical, formulation development, clinical manufacturing and packaging, storage and distribution. Our creative packaging design capabilities help to save time, costs and ensure on-time deliveries for your trial. We have a global dept network that covers every region of the world as well as Qualified Person (QP) services for European distribution.

SanaClis

VISIT WEBSITE

SanaClis was founded in 2000 by seasoned industry experts all of whom have had executive level positions in leading pharma companies and large global CROs and is one of the very few full-service CROs for clinical trials mainly in Central and Eastern Europe (CEE) offering a comprehensive range of services including: regulatory, clinical monitoring, IMP & CTS management, customs clearance & brokerage, site contracting & payments, project management, quality management, training, central laboratory Russia - including bioequivalence studies, data management, statistics and medical writing. Its facilities, depots and processes meet the most stringent international standards and local requirements. Moreover, SanaClis developed its own software solution to track warehouse operations in real time internally and externally for clients.

CrO Biosciences

VISIT WEBSITE

CrO Biosciences is an information management company that's at the forefront of Regulatory Submissions and Trial Master File (TMF) Management. Our team of experts know the ins and outs of the agency regulatory application approval process. In fact, we know the process so well that we have an inside advantage when it comes to knowing exactly how to complete all of the documentation properly for submission. Why settle for working with another company when you can work with the best in the business? CrO's knowledgeable staff helps you become an expert in the process so you can then become an expert in the system.

PRO-PARTNERS

AtoZ-CRO GmbH Clinical Research Overath/Germany

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10 YEAR ANNIVERSARY ARENSIA EXPLORATORY MEDICINE ON A MISSION TO IMPROVE PATIENTS' LIVES!

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HOTEL & TRAVEL

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DIRECTIONS

AIRPORT TO HOTEL

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