







Proventa International's 4th Annual

CLINICAL OPERATIONS STRATEGY MEETING EUROPE 2022

Improving Patient Experience, Decreasing Adverse Implications, Detecting and Treating Clinical Trends Through Data and Analytics







Telemedicine



Patient Recruitment



Remote Monitoring



Management



AI/ML



eCOA



Patient Centric



Technology



Site Selection

Featuring Industry Leaders and Decision Makers



Jean-Philippe Kunz Gnubiotics Sciences



Domenico Merante Nephrology & Orphan Diseases **CSL Vifor**



Haider Alleg Global Head of Digital **Ferring** Pharma



Anja Urban



Christian Biberger Clinical Center CSL Vifor



Michal Konstacky Biotechnology

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> STRATEGY **MEETINGS!**









Proventa International's Strategy Meetings are a completely unique experience.

Our Vision



To be a platform for creating life-saving therapies and to facilitate the creation of a completely patient centric pharmaceutical industry.

Our Mission



By encouraging key leaders and their companies to put the patient at the very heart beat of every innovation. Sharing valuable insights and strategies to assist in the discovery, development and commercialisation of life saving therapies.

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 from all over the world 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 spent is focused and well-utilised.



INNOVATIVE SOLUTIONS

The most effective and time efficient way to assess potential partners at a strategic level. Identify key solution providers that can take your business to the next level and we will help arrange private meetings so you can connect.



STRATEGIC NETWORKING

Strategic networking opportunities form a key benefit of the meeting. Our proven format for building and strengthening alliances to make lasting connections that benefit you.

Although the pandemic response has expedited technology adoption in clinical trials, our purpose is clear in the face of changing clinical strategy: It's time to build a better system. The significant changes towards decentralized, in-home patient care, along with easing regulation restrictions on centralized in-person trial execution, have created new opportunities for more patient-centric and diverse trials. Now is the time to set new industry expectations, take advantage of recent digital advancements, and assure a long-term culture shift toward patient-centric trials. We risk losing this chance to reestablish patient confidence if we do not move quickly.

From October 2022, Proventa International will be gathering senior leaders from the pharmaceutical and biotech industries, to share practical guidance on how equity, inclusion, and diversity in clinical outsourcing, site selection strategies, and digital transformation can help deliver faster, and more cost-effective trials on time and on budget whilst maintaining resilience in patient integrity.

WHY SHOULD YOU ATTEND THIS MEETING?



To gain practical insight with Good Clinical Practice and Risk Based Quality Management strategies

Improve diversity through patient-centric approaches, decentralized trials and new digital technologies

Strengthen the overall global clinical operations to improve trial outcomes, and reduce costs of drug developments

Our unique closed door round-table discussion format is exclusively designed to engage 10-15 CxO, VP and director-level individuals from pharma, biotech and thought leaders from academia, to address and find solutions to industry challenges from a strategic perspective within the

Facilitated by expert thought leaders, you will have the option to select and attend the round-tables that provide valuable dialogue, addressing topical issues that is currently aligned with your work

Bespoke networking opportunities to help streamline your procurement processes, meaning the impetus for your peers attending is solely based around making business decisions at the highest level

SENIORITY OF ATTENDEES



Facilitator Faculty



Gayle Hamilton Director, RBQM, Digital Trial Management Suite IQVIA Technologies



Eric Klaver

Decentralized Clinical
Trial Regulatory
Director
IQVIA



Kate Godwin-Smith Director IQVIA Technologies



Allan Van Konynenburg Senior Director, Global Depot Network SanaClis



Zuzana Bat'ová Director of Regulatory Affairs SanaClis



Ash Rishi
CEO and Co-founder,
COUCH Health
Founder,
Demand Diversity
and COUCH Academy



Matt Marano
Chief Commercial
Officer
Rosa & Co.



Alex Guillen
Director of Sales Life Sciences and
Pharma Europe
Tive



Haider Alleg
Global Head of Digital
Ferring Pharma



Christian Biberger Head, Clinical Center of Excellence CSL Vifor



Michal Konstacky Senior Director, Clinical Development Luzsana Biotechnology



Domenico Merante VP Clinical Development Nephrology & Orphan Diseases CSL Vifor



Anja Urban Head of Clinical Operations DEU Immatics



Jean-Philippe Kunz Co-Founder Gnubiotics Sciences

HOW HAS OUR Strategy Meetings

Benefit The Life Science Industry



This was a very important insightful event and I have few takeaways messages/practices which I will be implementing on my current and future projects."

Jean-Pierre Metabanzoulou -Senior Director, CMC & RA, Acasti Pharma



This was a very informative, significantly interactive and highly educational event. "

Domenico Merante -VP Clinical Development, Sosei Heptares

WHO SHOULD ATTEND?

- Clinical Operations
- Clinical Project/ Program Leads
- Clinical Quality Assurance
- Clinical Research
- Clinical Outsourcing
- Data Management
- Data Management
- Vendor Management
- Medical/Scientific Officers
- Pharmacovigilance/Safety
- Medical Affairs
- Patient affairs

- Global study
- Site management/ selection
- Digital health
- TMF/eTMF
- Data monitoring
- Patient recruitment
- Patient engagement
- Clinical investigation
- Study optimisation
- Patient insights
- Clinical systems

Our Sponsors



Lead Sponsor



IQVIA (NYSE:IQV) is a leading global provider of advanced analytics, technology solutions and clinical research services to the life sciences industry dedicated to creating intelligent connections that deliver unique and actionable insights. With approximately 82,000 employees, IQVIA conducts operations in more than 100 countries. Learn more at www.igvia.com. www.igvia.com.

VISIT WEBSITE

Co-host Sponsors





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. SanaClis is a full-service Global CRO with a fully integrated clinical supply chain, thereby offering a comprehensive range of end-to-end services for clinical trials. SanaClis has vast experience of successfully running studies for various sized sponsors, ranging from virtual biotechs through to top ten pharma companies, both in terms of its CRO services and Clinical supply services. In addition to being a full service CRO, SanaClis is one of the very few service providers with an extensive range of in-house logistics and clinical supply capabilities. SanaClis has a portfolio of privately owned GMP and GDP certified storage and distribution depots, strategically located across the EU and Eur-Asia.

COUCH Health is a creative health engagement agency that has purpose at its heart and that is to make health human. That means we're challenging the norm to make health experiences more inclusive, equitable, accessible and empathetic. And we can only make this happen if we understand the real-life challenges that are at play. By connecting with people — the patients, caregivers, communities and healthcare professionals we're ensuring that we're making changes that matter.

What we do: Health engagement
 Health communications
 Health equity

Are you ready to start your next project? Let's talk. e. hello@couchhealth.agency | w. https://couchh

w. https://couchhealth.agency/

VISIT WEBSITE



VISIT WEBSITE

METRONOMIA M

Rosa & Co. was established in 2002 and is known worldwide for the creation of PhysioPD™ Research Platforms and Rosa Market Modeling. PhysioPD Research is a powerful component of modern drug development. It is a proven quantitative systems pharmacology (QSP) approach that complements the expertise and experience of clinicians, guides more effective experimental and trial design, and enables deeper understanding of empirical data. PhysioPD Research enables dramatically more effective learning about the connection of drug and disease mechanisms to relevant preclinical and clinical outcomes and supports more confident decisions at all stages in research and development.

Metronomia Clinical Research: Data. People. Excellence.For over 30 years, METRONOMIA has been the exceptional Data Science CRO partner for biostatistical services and consulting, clinical data management and medical writing. Our team of 100 highly skilled employees serve the needs of global biotech-, pharma-, and medical device customers with the highest degree of flexibility, reliability and quality.

Why Metronomia:

- roven track record: 650+ projects in all clinical development phases and major therapeutic areas
- Direct access to expert statisticians & data managers
- State-of-the-art knowledge, processes & technology Seamless integration with and extension of your team
- Enduring partnerships through outstanding customer satisfaction

VISIT WEBSITE

Global Sponsorship Opportunities

Proventa's end-to-end consulting division gather real-time business intelligence on the industry's needs, challenges, budgets and investment areas. We combine this information with your specific needs to enhance your business development strategy. With the wealth of intel we provide, Proventa guarantees tangible results for your business within twelve months of the event.

For Sponsorship Opportunites please contact:

SPONSORSHIP TEAM: info@proventainternational.com | +44 (0) 2070961222

How it Works?



Real insights are shared in conversations, not lectures. That's why our unique <u>roundtable</u> format guarantees real learning and ensures you only attend discussions that deliver value to you.

Join as many as four roundtable discussions, each with up to 20 other subject experts, networking with top-level peers in an informal, relaxed and sociable environment.

Simply follow the steps below to select your roundtable discussions and we'll create your own personalised agenda for the day:



EXPLORE THE FULL AGENDA

Select which roundtable discussions you would like to join. Our sessions are divided among 4 themed tracks for easy selection - you can choose to join any session you like.



COMPLETE YOUR SCHEDULING FORM

Select your preferred roundtable discussion for each time slot. We will send this form out via email a few weeks before the event - be sure to get your first choice by completing the form quickly.

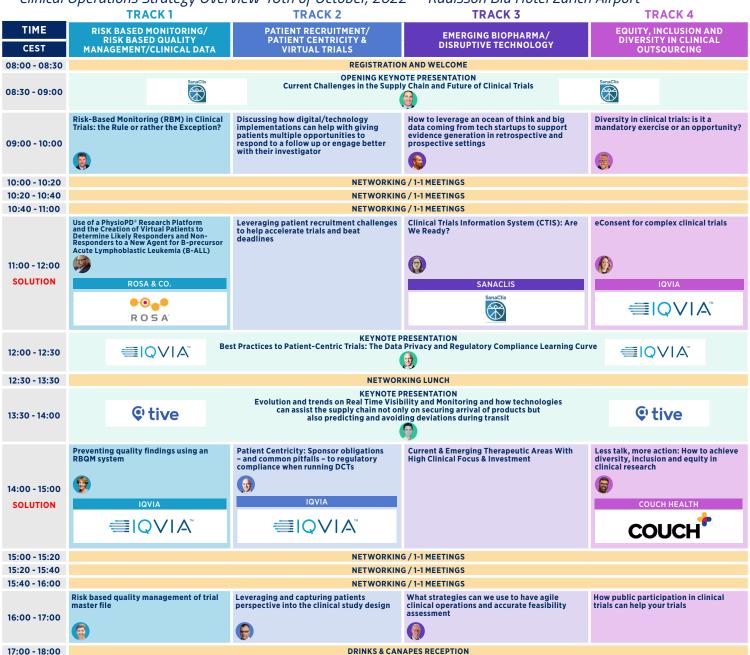


ENJOY YOUR PERSONALISED EXPERIENCE

Join your selected roundtable sessions on the day. We will give you your personalised agenda containing the time and room assignments of your chosen roundtable discussions so you won't miss it.

Agenda at a Glance

Clinical Operations Strategy Overview 10th of October, 2022 – Radisson Blu Hotel Zurich Airport









STRATEGY DINNER

The global pandemic has been a major disruptive force of change putting forth the critical role of data analytics; can Active Tracking replace Passive Tracking to achieve this goal today?

The global pandemic has been a major disruptive force of change while additional dynamics around data driven decision making bring pressures to adopt end to end visibility. These dynamics underline the mission-critical role of data capture and analytics to further improve effectiveness for all organizations in the supply chain. The question now is, what will it take to replace the older passive tracking manual intensive ecosystems within cold chain & bio-pharma to fully automated cloud based active tracking solutions without impacting the budget and operational overhead. And what is the relationship between technology, smart packaging, and the supply chain movers to adopt innovation at the speed of progress.

KEY TOPICS OF DISCUSSION

- (>) What is the definition of Active Tracking vs. Passive Tracking
- The impact today of Active Tracking and the intrinsic value it brings over current non-connected solutions
- The importance of collaboration between smart packaging, innovative technology, and the symbiotic relationship to cold chain distribution
- What does advanced analytics mean to your decision making and are you ready to integrate at governing level to transform monitoring
- The market says by 2025 50% of all global supply chain will be utilizing Active tracking in some capacity, do we agree 2025 is realistic sooner/later
- What will be the largest hurdle to overcome, budgets or change management

DATE

Monday. 10th October 2022

VENUE



Radisson Hotel Zurich Airport





KEY OPINION LEADERS



Jody Radoff - CRO, Adapt Ideations

An 18 year business development expert from leading global sales organizations across multiple industries brings his strategic leadership to Adapt Ideations. Jody has driven world class teams driving revenues into the 100's of million. As an honors graduate with a BA in Communications and Journalism from the University of Arizona, Jody is driven and through his strong work ethic is empowered to drive results through actions allowing business goals to be greatly achieved. As CRO, Jody is responsible for Adapt Ideations U.S. and EU expansion and providing oversight to global sales operations. Jody is dedicated to listening to our clients and connecting with them to assist them in reaching their company's goals & visions.



Prashanth Dharawath - CEO (Co-Founder), Adapt Ideations

With a degree in Aerospace Engineer from IIT Bombay, Powai (Mumbai, India), Prashanth is one of the co-founders of Adapt Ideations. Apart from heading the Asia Operations for Adapt Ideations, Prashanth has in-depth knowledge of Narrowband Internet of things technology, Industrial Robotics and Self-Driving vehicles. Aeromodelling and embedded systems design are his favorite hobbies.



Anirban Gupta - Director (Co-Founder), ANZ

Anirban has a strong background in IT & leadership roles across the FMCG and supply chain solutions sector. Anirban is a Harvard Business School alum having completed his executive MBA specialising in leadership and innovation. His experience and knowledge led him to form Adapt Ideations with Prashanth & Sai and has enabled Adapt Ideations to become what it is today.



Paul Della Villa – Director Digital Solutions Cold Chain Technologies (Global Leader of Cold Chain Packaging and Covid-19 Vaccine Packager), Cold Chain Technologies

 $Head \ of \ global \ new \ innovation \ solutions \ for \ Cold \ Chain \ Technologies. \ Paul \ is \ central \ to \ CCT's \ innovative \ packaging \ solutions \ to \ packaging \$ revolutionize cold chain management. An MBA graduate with 15+ Years of experience delivering quality results in the cold chain industry. Extensive experience in the international business arena specializing in new utilizing IOT and SAAS technologies to bring new products to market and developing business strategies around these technologies.

ABOUT ADAPT IDEATIONS

Adapt Ideations is a leading innovator of asset tracking and monitoring solutions designed for the global Cold Chain and Bio-Pharmaceutical industry. Their mission is to design and build tailored, vertically-integrated asset intelligence solutions for regulated industries to enable greater visibility, asset intelligence and compliance helping simplify everyday asset management through automated technology. With innovation at the forefront of their solutions, we tackle challenges that matter and we're doing it with diverse teams of amazing people all over the world. Adapt Ideations works with a range of clients globally in the U.S, Europe, Asia, ANZ, and the APAC region.

THE MEASURE OF EXCELLENCE®

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STRATEGY DINNER

"Smart PAT" (PAT = Process Analytical Technology).

Biopharmaceutical manufacturing is a notoriously complicated process. A major challenge in this process is the product itself - particularly for biologics manufacturing. Proteins are highly complex molecules with many closely related, but functionally different, variants., These realities can make analysis and control difficult. Traditional quality control methods are over-reliant on lab work for process sampling and analytics: often, labs, their location, capacity and the costs associated with them act as bottlenecks. Improving quality controlprocesses requires a true disruption of the traditional in-lab work with an advancement to smart quality control. Smart quality control shifts quality and performance monitoring to the shop floor to enable in-line monitoring, automated process control, and real-time release. This is achieved through harnessing cutting-edge technologies to realize increased cost-efficiencies throughout the supply chain.

Attendees will be able to address these issues and the innovations solving them, such as:

- New real-time measurement technologies that overcome the challenges of durability, specificity, and speed to measure PAT Critical Process Parameters and Key Performance Indicators during the process.
- Progressing digitalization to enable innovative process analytics (soft sensors), advanced process control (e.g. digital twin simulation), preventative maintenance, and asset management.



17:15-18:00 REGISTRATION, NETWORKING & COCKTAILS 18:30-19:00 WELCOME AND INTRODUCTION 19:00-20:00 ROUNDTABLE DISCUSSION Title: Smart, connected and controlled: The new bioprocesses. Speaker: Martin Mayer, Business Development Smart Engineering Services & Digitalization at

ZETA GmbH

- Digitalization and Smart Sensors for Bioprocesses
- Use of measurement data for process optimization and closed loop control in operations
- FDA take on ML / Advanced Process Control
- Learnings and outlook

20:00-20:45 DINNER

20:45-21:45 **ROUNDTABLE DISCUSSION**

Title: Of plasmids, proteins and viral vectors: (soft) sensors for the production of novel biopharmaceutical modalities.

Speaker: Prof. Dr. Thomas Villiger, Prof. of Bioprocess Technology at University of Applied Sciences Northwestern Switzerland (FHNW)

- Advantage of using simple and robust mechanisms over complicated mathematical models
- Applying soft sensor triggered fed-batch platform for plasmid and protein production
- Utilizing product quality control by biocapacity measurements in continuous cell culture
- · Discussing the capabilities and limitations of Raman spectroscopy

21:45-22:00 **CLOSING REMARKS AND COFFEE**

11[™] OCTOBER 2022 TUESDAY



Zurich Airport, 8058, Switzerland



Key Opinion Leaders



Prof. Dr. Thomas Villiger Prof. of Bioprocess Technology University of Applied Sciences Northwestern Switzerland (FHNW)

Thomas Villiger received his Msc and PhD in Chemical and Bioengineering from ETH Zurich. He gained more than a decade of industrial experience in bioprocess development and manufacturing at Merck, Novartis and Biogen. Since 2019, he is head of the Bioprocess Technology Laboratory at the University of Applied Sciences Northwestern Switzerland (FHNW) in Muttenz, Basel. His research focuses on upstream and downstream processes for antibodies, viral vectors, and other complex biologics, with particular emphasis on the application of process analytical technologies and data science tools to develop new manufacturing strategies, intensify processes, and control product quality.



Martin Mayer Business Dev Smart Engineering Services & **ZETA GmbH**

Martin Mayer studied industrial engineering and business at the Technical University Graz. During his career a wide variety of senior roles from business development, research and development responsibility to general management challenged his skills within more than 15 years of interesting international work.

Within that time he was responsible for a number of projects in chemical industry, Pulp and Paper as well in biotech/biopharma industry mainly in the field of digitization, data management, data analytics and model based optimization (DoE). Within the last years the growing awareness for digitalization topics within the pharma industry in combination with the harmonization activities (ICH Q8-012) have formed excellent boundary conditions for the establishment of new products and services, not only in the manufacturing sector, but especially in the field of R&D (Data Management in R&D, advanced control strategies for conti processes,...). Within ZETA he is responsible for business development in the field of Smart Engineering Services and Digitalization. Martin Mayer is member of the Steering Committee for the Plug&Produce activities within the ISPE Pharma 4.0 program.



STRATEGY DINNER

Seamless global strategy for NCE development and API supply chain by optimizing technology, providing collective expertise, and reducing the delivery time and cost - an unmet need

The "heart of drug development" is to employ innovative technologies and collaborations across the globe, to assemble a powerful Drug Development Engine to accelerate candidates from drug discovery, PRD, scale-up through commercialization. The best way to increase the valuation of drug discovery and development pipeline and company's portfolio is to accelerate their milestones, reduce costs while maintaining quality. Today's CDMO industry is lacking a unique collective expertise in one place, utilizing ground-breaking technologies for the synthesis of architecturally complex molecules that can intercept any molecule, at any stage of development. Ultimately the know-how of phase appropriate execution, 'shaving' months off the development cycle time and a "one stop shop" of delivery of entire CMC management is an unmet need.







Radisson Blu Hotel Zurich Airport

AGENDA	
17:00 - 18:00	Registration, Networking & Cocktails
18:00 - 18:15	Welcome & Introductions Swapan Bhattacharya, Managing Director, TCG Lifesciences Pvt. Ltd. Sanjoy Kumar Mahanty, Ph.D, Vice President & Head of Business Development-NA, TCG Lifesciences Pvt. Ltd.
18:15 - 19:15	Roundtable Discussion on: Big Pharma training with Biotech mentality to "Accelerate Molecules to Medicines" Solving complicated CMC problems for NCEs adopting "First Time Right" techniques for First in Human studies Reducing timelines by utilizing optimized "Drug Development Engine" Leveraging innovative technologies embedded in Process Research and Development for API Utilization of dynamic cost structure model Tapping global resource pool US management oversight operation 24 hr/day for solving problems and deliveries Smooth tech transfer for API in a global setting Implementing collective expertise of globally based scientists, scientific project managers and engagement with client-based approach Maintaining transparency and IP protection Joseph D. Armstrong, III, Ph.D, COO, TCG GreenChem, Inc. (NJ & VA, USA)
19:15 - 20:30	Dinner
20:30 - 21:30	Roundtable Discussion: Continue the topic Big-Pharma training with Biotech mentality to "Accelerate Molecules to Medicines" Subho Roy, Ph.D, Vice President - Business Head, Clinivent Research Pvt. Ltd, A 100% subsidiary of TCG Lifesciences
21:30 - 22:00	Closing Remarks, Coffee & Cognacs Vishal Rajput, Ph.D, Vice President, Business Development, TCG Lifesciences Pvt. Ltd. Dr. Gopal Sirasani, Associate Vice President, TCG GreenChem
VEV ORINION LEADERS	

KEY OPINION LEADERS



Swapan Bhattacharya - Managing Director, TCG Lifesciences Pvt. Ltd.

Swapan Bhattacharya is the Managing Director of TGE Lifesciences (TCGLS) and is responsible for the executive leadership and overall management of the company. He co-founded TCGLs in 2011 and has taken the Company to a global leadership position in the research services space, it is also a key member of the Governing Council of the TCG for FCE ducation and Research in Science and Technology, a not considered and responsible multiple centre of the Company to a global leadership objective in the tree for the field of the TCG for an under the tree for the field of the Total for the field in the tree for the field of the TCG for an under the tree for the field of the TCG for an under the tree for the field of the tree for the t



Sanjoy Kumar Mahanty, Ph.D - Vice President & Head of Business Development-NA, TCG Lifesciences Pvt. Ltd. Dr. Sanjoy Kumar Mahanty is part of the core business development, account management, marketing & sales team in the USA. Dr. Mahanty has twenty-five years of expertise in scientific research, and extensive leadership experience in drug discovery & development process. Dr. Mahanty has been associated with TCG Lifesciences for over eight years. He has been highly successful in penetrating CRO/CDMD markets globally, and proven track-record in establishing the new business, and maintaining existing clients. He holds a bachelor's degree from Utkal University, and a master's of sciences (MSC) & PhD degree in Biochemistry from Jawahartal. Nehru University, New Delhi, India. Dr. Mahanty completed his Post-Doctoral Research Experience from Harvard Medical School, Boston, and University of North Carolina, Chapel Hill, USA. He has eighteen co-authored peer reviewed publications including one in the highly reputed journal CELL, one book chapter, and ten shared



Joseph D. Armstrong, III, Ph.D - COO, TCG GreenChem, Inc. (NJ & VA, USA)

Disapin D. Armistrong, III, PTI.D – COU, TOS Of BEILDIERII, IIII... (IN) & VA, USA)

Dr. Armstrong is a high energy scientific and executive leader with 28 years of experience at Merck & Co., Inc. in Process Research, Formulation Development and Project
Management with deep knowledge and experience of all drug discovery and development processes to support IND to NDA filings. As the Merck Preclinical Integration Lead
(Process R&D, Formulation R&D, DMPK, Safety Assessment, and Clinical Supplies) for the merger with Schering Plough, created a multidisciplinary organization that leveraged
development knowledge to accelerate identification of Preclinical Candidates and their rapid entry into the clinic and beyond. He led the cross-functional team that filed the drug
Januvia¹⁰¹ for the treatment of type II diabetes in less than 4 years by executing new green and sustainable technologies and strategies. He led the Process R&D Team that
discovered the novel asymmetric hydrogenation process for the preparation of Stagliptin, the active ingredient in Januvia¹⁰¹. This team received the Thomas Edison award, the
EU IChemE Aztra-Zeneca Award for Green Chemistry and Engineering and the US Presidential Green Chemistry Challenge Award.



Subho Roy, Ph.D - Vice President - Business Head, Clinivent Research Pvt. Ltd, A 100% subsidiary of TCG Lifesciences Dr. Subha Roy Joined the group in 2002 and has been one of the key leadership members responsible for the growth of the company. He holds a Ph.D degree from Indian Institute of Chemical Technology, working with Dr. A.V.Rama Rao, on synthesis of natural products of biological importance and subsequently spent few years at the University of Kansas, Lawrence, USA, working with Dr. Gunda Georg for his post-doctoral studies. He has more than 20 years of Industrial experience of progressing small molecules coming out of R&D through various phases of development and taking them all the way to commercialization. He is a specialist in new process development, optimization and various other aspects of CMC. Dr. Roy has several publications to his credit and holds several European and US patents. He has played a key role in conceptualizing and designing of the manufacturing facility, "Clinivent Research Pvt. Ltd.", a 100% subsidiary of TCG Lifesciences, which has successfully compilered US FDA inspection.



Vishal Rajput, Ph.D - Vice President, Business Development, TCG Lifesciences Pvt. Ltd.

NISHA RAJPUL, PILD - VICE PLESIGERIL, DUSINESS DEVECUPINENT, TO LIESCHEES PLUC.

Dr. Vishal Rajput holds Masters in Chemistry from IT Roorkee, he is a Ph.D in Medicinal Chemistry from CDRI Lucknow, and a Post Doctorate from Lund University, Sweden and University of Alberta, Canada. He also holds PG diploma in patent Law from NALSAR Law University, Hyderabad. He is a seasoned techno-commercial professional with experience in Pharma/Life science Industries spans across Business Development (DM), API-Sales, Project and Portfolio Management and in RAD from top-tier pharma and biotech companies like Syngene Intl Ltd. Merck and Sigma-Aldrich etc. His last assignment was with Shilpa Medicare Ltd. as Head of Global CDMO Business- Drug Substance and Drug Product. He also has cross value chain expertise and Business Development experience covering discovery, development and manufacturing services for small and large molecules (ADC, NCE, Carbohydrates, Polymer and peptide) API for global Innovator and Generic companies.



Dr. Gopal Sirasani - Associate Vice President, TCG GreenChem

Dr. Gopal Sirasani is the Associate Vice President of TCG GreenChem. He is responsible for key account management, marketing, and sales operations. He has been highly successful in establishing new business collaborations between biotech companies and TCG GreenChem/TCG Lifesciences. Dr. Sirasani is heavily involved in tracking the customer projects for CMC development, in terms of route scouling, process development, scale-up operations and GGMP/non-GMP campaigns to deliver for preclinical and clinical needs of the clients. Dr. Sirasani received his bachelor's in Chemical Technology, Masters in Drugs and Pharmaceuticals, Ph.D. in Synthetic Organic Chemistry at Temple University, Philadelphia, and Post-Doctoral training at Harvard University. In total, he has 18 years of academic and industrial experience.

At TCG, we address these needs with a proven strategy utilizing the following inherent strengths:

- Top tier and experienced people from big-Pharma
 Large PRD group working across the globe
 Trust-based client relations and depth of engagement spanning two decades
 World class facilities and infrastructure

We deliver integrated end-to-end solutions to the global life sciences' industries.



IN PARTNERSHIP WITH:





Why Book Your V.I.P Seat Now?

- Be amongst 10-15 Industry thought leaders from a mix of large Pharmaceutical Institutions ensuring you are given ample opportunity to
- 🎺 Wine, dine and network with industry leaders who face common challenges in 60-minute roundtable discussions that enable you to share ideas and
- Facilitated by expert moderators, these sessions provide a valuable dialogue with peers on current challenges and topical issues.
- No media, marketing or press, just solve your key strategic challenges for the next 3-9 months.















OPENING KEYNOTE PRESENTATION



(\) 8:30 - 9:00 CEST

Current Challenges in the Supply Chain and Future of Clinical Trials

- What should be applied to future supply chain strategies
- What mistakes should be avoided



Allan Van Konynenburg Senior Director, Global Depot Network





ABOUT THE SPEAKER

Allan van Konynenburg has more than two decades of experience in Business Development and Operations in the pharmaceutical arena, specifically in specialty logistics and supply chain. He brings with him a wealth of knowledge and experience across the pharmaceutical ecosystem, extending to Warehousing, Fulfilment, Distribution, CTSM, Logistics, Directto-patient, and Cell & Gene therapy. Allan is responsible for SanaClis vendor relationships, identification of specialized Clinical Trial Depots, formalization of business relationship with current and new vendors and establishing and negotiation of unified pricing models. His knowledge and experience play a key role in managing innovative approaches to existing and new business challenges and work with teams across SanaClis to deliver customer-centric products and services that support SanaClis' mission statement.

END OF OPENING KEYNOTE

KEYNOTE PRESENTATION



(1) 12:00 - 12:30 CEST

Best Practices to Patient-Centric Trials: The Data Privacy and Regulatory Compliance Learning Curve

So much discussion within the clinical trials industry is around "Patient Centricity" but what's left out of these discussions are the impacts of regulatory and data privacy compliance on patient centricity. The pandemic may have accelerated sponsors embracing decentralized clinical trials faster than originally intended, demonstrating real benefits to patients, sites, and sponsors. For all the benefits DCT technology bring, it presents additional complexities related to patient data privacy and regulatory compliance adherence that are critical for continued success and global expansion while staying aligned to patient centric principles.

- Build trials and protocols that meet regulatory and legal frameworks that follow data privacy laws and Good Clinical Practice (GCP) standards
- Understand how regulatory and privacy laws improve patient centricity
- Foster a relationship with sites and give sponsors confidence that their CRO can uphold the trust of participants that is so crucial to patient centricity



Eric Klaver Decentralized Clinical Trial Regulatory Director

ABOUT THE SPEAKER

Eric Klaver brings almost 30 years of clinical research experience to IQVIA in roles varying from data management to post-trial access. His focus has been on compliance in clinical trials. through training and auditing. Eric has trained clinical research staff literally around the world and has audited, supported audits and inspections on an international stage as well. Currently, Eric focuses on the continued compliance of the IQVIA DCT strategy and platform.

END OF KEYNOTE

AFTERNOON KEYNOTE PRESENTATION

(1) 13:30 - 14:00 CEST

Evolution and trends on Real Time Visibility and Monitoring and how technologies can assist the supply chain not only on securing arrival of products but also predicting and avoiding deviations during transit





Alex Guillen Director of Sales - Life Sciences and Pharma Europe

ABOUT THE SPEAKER

Alex Guillen is an established executive with a proven record in global business and market development, with well-rounded experience in multicultural sales management and brand building. Alex has extensive experience and expertise in cold chain; as SME - Life Science and Pharma at Tive, Alex leads sales and business development within the company's rapid-growth Life Science division. Previously, Guillen served as a Board Member and leader of Corporate Strategy at SWITRACE S.A, a developer of temperature and humidity data loggers compliant to the Pharma and Biotech industries. Alex's extensive experience also includes serving as Global Cold Chain Director of Fisher Clinical Services, CEO of Escort Cold Chain Solutions SA, and Director for Commercial Operations for Novartis Vaccines.

END OF AFTERNOON KEYNOTE





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Intimate format events where senior leadership discuss the biggest challenges facing the industry.





TRACK 1: RISKED BASED MONITORING/RISK BASED QUALITY MANAGEMENT/CLINICAL DATA

A mix of risk assessments, analytical capabilities, and cutting-edge technology is required to provide an effective risk-based monitoring risk-mitigation methods and how we can accelerate patient safety to



ROUNDTABLE 1:

Risk-Based Monitoring (RBM) in Clinical Trials: the Rule or rather the Exception?

- 10 years after the first Regulatory Guidances: to what extent and how is RBM applied nowadays?
- Have used systems and technologies proved to be satisfying and robust?
- Which Return on Investment (ROI) did RBM bring finally?



ABOUT THE SPEAKER

Christian Biberger, PhD, is Head of Clinical Center of Excellence at CSL Vifor (previously Vifor Pharma), and is based in Glattbrugg, Switzerland. In this role, his key focus is to ensure Vifor's clinical development processes and systems are state-of-the-art and enable the teams to deliver efficiently, in full compliance with regulations and, last not least, with a patient-centric mindset, Christian's development tenure spans more than 25 years. During that time, he has held various management and leadership positions in both pharma and the CRO industry. His development experience comprises studies in all phases as well as numerous



SOLUTION FOCUS ROUNDTABLE 2:

Use of a PhysioPD® Research Platform and the Creation of Virtual Patients to Determine Likely Responders and Non-Responders to a New Agent for B-precursor Acute Lymphoblastic Leukemia (B-ALL)

- How can a Systems Pharmacology Model identify factors that contribute to making individual patients responders or non-responders to a new therapy?
- How can the Model identify recommended dosing strategies to improve the llikelihood of response to the new therapy?
- What is the benefit of creating Virtual Patients to help answer these questions?



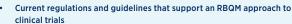


ABOUT THE SPEAKER

Mr. Matt Marano has over 30 years of experience in the life sciences industry, both as a researcher and as a sales and business development professional. Prior to joining Rosa in 2017, Mr. Marano held worldwide business development leadership roles at SolveBio, a developer of actionable information assets that drive precision medicine, and Gen9 (now part of Ginkgo Bioworks), a leading synthetic biology solutions provider. Prior to Gen9. Mr. Marano created and expanded the global commercial presence for a number of industry-leading life sciences firms, including Archimedes Inc. (acquired by Evidera), BioTroye's RapidFire business unit (now part of Agilent Technologies Inc.), Ardais Corporation, and Molecular Dynamics. Mr. Marano began his career as a bench scientist at BASF Bioresearch Corporation (now part of AbbVie), and was a member of the development team for Humira®, one of a class of medications called biological response modifiers. Mr. Marano received his BS in Biology from Providence College, and completed graduate-level course work in Molecular Biology at Providence College and Harvard University Extension

(\) 14:00 - 15:00 CEST

SOLUTION FOCUS ROUNDTABLE 3: Preventing quality findings using an RBQM system



- Unpacking common audit findings in clinical trials
- Ensuring regulatory compliance and audit readiness using RBQM technology



Gavle Hamilton Director, RBQM, Digital Trial Management Suite



ABOUT THE SPEAKER

Gayle Hamilton is an experienced Risk-Based Monitoring project advisor and project lead with a strong background in clinical operations and project management. She has supported study trial teams and IT development in RBQM implementation across all phases and therapeutic areas, driving the development of processes, tools, and systems. Gayle is also experienced in assuring high-quality business performance of clinical operations within global projects.

(16:00 - 17:00 CEST

ROUNDTABLE 4:

Risk based quality management of trial master file

- Gap and risk analysis on a paper TMF
- KPI calculation on a paper TMF
- Implementation of risk based approach and quality control in a paper and electronic TMF



Anja Urban Head of Clinical Operations DEU **Immatics**

ABOUT THE SPEAKER

Anja Urban, Director Clinical Operations at Immatics Biotechnologies GmbH has been working all her professional life in the medical field and started her career in clinical research in 2002. She started off at a niche provider for Medical Imaging and moved to a global international CRO before joining Immatics Biotechnologies GmbH in 2021. Anja has worked in a number of different positions in clinical research on which she gained a high level understanding of ICH-GCP and hands-on experiences in all operational aspects of clinical trials in all phases and a number of indications including Oncology.

END OF TRACK 1



TRACK 2: PATIENT RECRUITMENT/ **PATIENT CENTRICITY & VIRTUAL TRIALS**

pitfalls, and exploring effective patient recruitment plans that leverage the latest tools, technologies and analytical approaches to deploy into having a



SOLUTION FOCUS ROUNDTABLE 3: Patient Centricity: Sponsor obligations - and common pitfalls - to regulatory compliance when running DCTs

- Implementing DCTs is a costly exercise. Is it worth the investments?
- A one-size-fits-all does not work for every DCT. Looking with a fresh eye at the endpoints to use in decentralised trials helps incorporate a more tailored approach
- Let's not throw tech at sites and participants without supporting them in how to use it



Eric Klaver Decentralized Clinical Trial Regulatory Director



IQVIA

ABOUT THE SPEAKER

Eric Klaver brings almost 30 years of clinical research experience to IQVIA in roles varying from data management to post-trial access. His focus has been on compliance in clinical trials, through training and auditing. Eric has trained clinical research staff literally around the world and has audited, supported audits and inspections on an international stage as well. Currently, Eric focuses on the continued compliance of the IQVIA DCT strategy and platform



(1) 16:00 - 17:00 CEST

ROUNDTABLE 4:

Leveraging and capturing patients perspective into the clinical study design

- Patients input needs to be captured from clinical setting and clinical practice
- How to better capture this input into a clinical study desig



Domenico Merante VP Clinical Development Nephrology & Orphan Diseases Vifor Pharma

ABOUT THE SPEAKER

Domenico Merante graduated in Medicine at University of Pisa/Italy in 1988. He specialized at the same University in 1993 and practiced at the main Pisa city hospital of St. Chiara whilst specializing in endocrinology and diabetes. His practice experience is 20+ years, including working as emergency doctor for 12 years in the NHS in Italy. During the compulsory military service, he also worked for three years as Medical Officer and subsequently as Chief Medical Officer of a ship unit named "Ammiraglio Magnaghi" in the Italian Navy. Domenico focus is on diabetic neuropathy, neuropathic pain and diabetic wound treatments. In addition to his medical practice experience, so far Domenico has developed 26 years' experience in global clinical development, half of which spent with Japanese organizations (Daiichi Sankyo, Shionogi and Sosei Heptares) within the pharmaceutical and biotechnology environment. The other half of his career was with Lab. Guidotti, Novo Nordisk, Eli Lilly and GSK in Italy and in the UK. In this context, Domenico has worked in global clinical development programs (phase 1,2 and 3) in pain area, infectious diseases, type 1 & 2 diabetes and diabetic complications (including painful diabetic neuropathy), severe hypertension, metabolic and endocrine area. To date Domenico has produced 103 publications as main or co-author among full papers, abstracts and oral presentations.

END OF TRACK 2







TRACK 3: **EMERGING BIOPHARMA/ DISRUPTIVE TECHNOLOGY**

This track will highlight important discussions to help you stay ahead of the curve and retain a competitive advantage in the industry by examining major trends that will emerge and impact the future of clinical operations.

9:00 - 10:00 CEST

ROUNDTABLE 1:

How to leverage an ocean of think and big data coming from tech startups to support evidence generation in retrospective and prospective settings

- Startups need the industry for clinical evidence generation
- Data is the new oil: why think + big data is the right combo for generating value to healthcare systems
- Governance and new operating models for unleashing collaboration, in tightly regulated environment



Haider Alleg Global Head of Digital Ferring Pharma

ABOUT THE SPEAKER

Haider Alleg is an entrepreneur, who blends commercial and marketing innovation into brands. He is specialized in business transformation and product launches within regulated industries such as pharmaceuticals. Developing a natural obsession for creating new customer experiences, Haider disrupts the way global organizations adopt emerging marketing and technology trends.



(1) 11:00 - 12:00 CEST



SOLUTION FOCUS ROUNDTABLE 2: Clinical Trials Information System (CTIS): Are We Ready?

CTIS is the online system for the regulatory submission, authorization and supervision of clinical trials in the EU and the European Economic Area. It is a single-entry point for all clinical trial data. As of 31st January next year, the use of the CTIS will be mandatory for all initial submissions and with just under 4 months to go 'live' the guestion lies in are we truly ready?

- Discussing the impact of the new system on business, procedures, SOPs,
- Weighing the benefits and challenges of CTIS
- Sharing firsthand experiences: registration of the company in OMS, access to CTIS, CTA submission, RFIs, public and non-public documents



Zuzana Baťová Director of Regulatory Affairs SanaClis

SANACLIS



Zuzana Batova brings years of regulatory experience and has a highly successful track record. Most notably, she was the Executive Director of the National Competent Authority in Slovakia (State Institute for Drug Control). For over 5 years, Zuzana was responsible for the final decision making in the field of human pharmacy such as granting marketing authorization, authorization of clinical trials and drug recall. She also represented the agency on national and international level (V4 Presidency, SK Presidency and EMA Management Board). Prior to that, Zuzana was heading the Drug Registration Department at the State Institute for Drug Control and took charge of the activities associated with the marketing authorization of human medical products, ensuring that approved medicines meet appropriate standards of quality, safety and efficacy coming from the ICH, EMA and WHO quidelines.

(16:00 - 17:00 CEST

ROUNDTABLE 4:

What strategies can we use to have agile clinical operations and accurate feasibility assessment

- How can brands integrate digital technologies into their processes to transform trials?
- Which type of study are subject to 2.0 approach like?
- What new protocols should we put in place to improve digital recruitment channels, virtual visits, and eConsent forms?
- What are the most essential metrics to examine when evaluating new options?



Jean-Philippe Kunz Co-Founder **Gnubiotics Sciences**

ABOUT THE SPEAKER

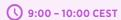
Jean Philippe is a serial Entrepreneur with international experiences in strategy and business development for added value products, having leadership credentials in bridging brands with their markets to make an edge for sustainable growth. Partner at Kainioo Group SA and co-founder of GNUbiotics Sciences. Swiss biotech start-up with mission to improve health by unlocking the benefit of the microbiome.

END OF TRACK 3



TRACK 4: EQUALITY, INCLUSION, AND DIVERSITY IN CLINICAL OUTSOURCING

The healthcare industry has seen a tremendous development of outsourcing operations after the COVID-19 outbreak. Many businesses are looking for a reason to modify their present tactics in order to achieve significant returns on their investments and better cooperation. Here we will be highlighting the importance of using different strategies to increase engagements, and what's stopping businesses from achieving diversity goals.



ROUNDTABLE 1: Diversity in clinical trials: is it a mandatory exercise or an opportunity?

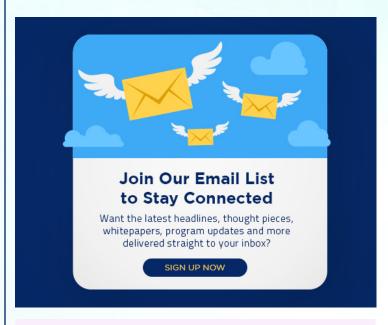
- How do you engage with patient organizations in diversity?
- Diversity and Asian patients in clinical trials
- What was the reason that diversity was not a part of the trials sooner?



ABOUT THE SPEAKER

Dr. Michal Konstacky, is currently employed at Luzsana Biotechnology, since June 2021, holding the title of Senior Medical Director for Innovative Medicines Clinical Development. Previously, Michal held global medical positions at Roche, Takeda, Aegerion or Almirall in Switzerland, UK, Spain, Sweden. Michal completed a Master of Business Administration - MBA • General management degree from City University of Seattle, he holds MD and PhD titles from Charles University in Prague and he also studied international business law at Salford Uni (UK) and negotiation at Harvard Business School. Michal is author of two published books: Nejezte hříbatal and The Predictive Value of Fortune Cookies and advisor to the Czech Senate, Ministry of Education and former advisor to the Ministry of Foreign Affairs. Since 2009 Michal has lived in Switzerland and currently he is the president of Sokol Zuerich Club (founded in 1867).





(1) 11:00 - 12:00 CEST

SOLUTION FOCUS ROUNDTABLE 2: eConsent for complex clinical trials



- basket)
 Create a more patient-friendly consent experience in complex therapeutic areas (e.g., oncology, pediatrics, emergency medicine)
- Support sites to accurately execute complex consenting workflows









(\) 14:00 - 15:00 CEST

SOLUTION FOCUS ROUNDTABLE 3:

Less talk, more action: How to achieve diversity, inclusion and equity in clinical research

- What is diversity? Learn what diversity in the context of clinical research means and why it matters
- Understand what the barriers are to diversity in clinical research
- Get practical tips so you can implement actionable strategies to ensure your studies are more diverse



Ash Rishi CEO and Co-founder, COUCH Health Founder, Demand Diversity and COUCH Academy





ABOUT THE SPEAKER

What I believe in:

I've been in this industry long enough to understand how things work, but not quite long enough to see the change I want to see in the industry. My expertise is in communicating with diverse groups, from patients, communities to medical stakeholders. As a leader of an independent team, I make sure I bring together that magic sauce that serves to elevate the industry with a team that can drive action. I believe in social justice and this starts with the basic human right of all... access to

Why we need COUCH Health Academy?

The industry needs to unlearn some of their practices, it's no longer enough to continue conducting research as we do. We need to have the patient in mind when designing research and creating solutions, we also need to understand who the patients are, what backgrounds they have, where they work, and how their beliefs and culture influence their decisions. Patient groups need to learn how to diversify their communications. Community groups need support on how to work with the industry and healthcare professionals need to learn how to make their practices more inclusive. I believe COUCH Academy is here to bridge this gap.

END OF TRACK 4







END OF Clinical Operations Strategy Meeting Europe 2022

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