WHY? SUMMITS

9TH ANNUAL GLOBAL PHARMACOVIGILANCE & RWE Forum

Part of Pharmacovigilance World Tour

May 30 - 31, 2024

Hilton London Kensington,
179-199 Holland Park Ave, London W11 4UL, United Kingdom

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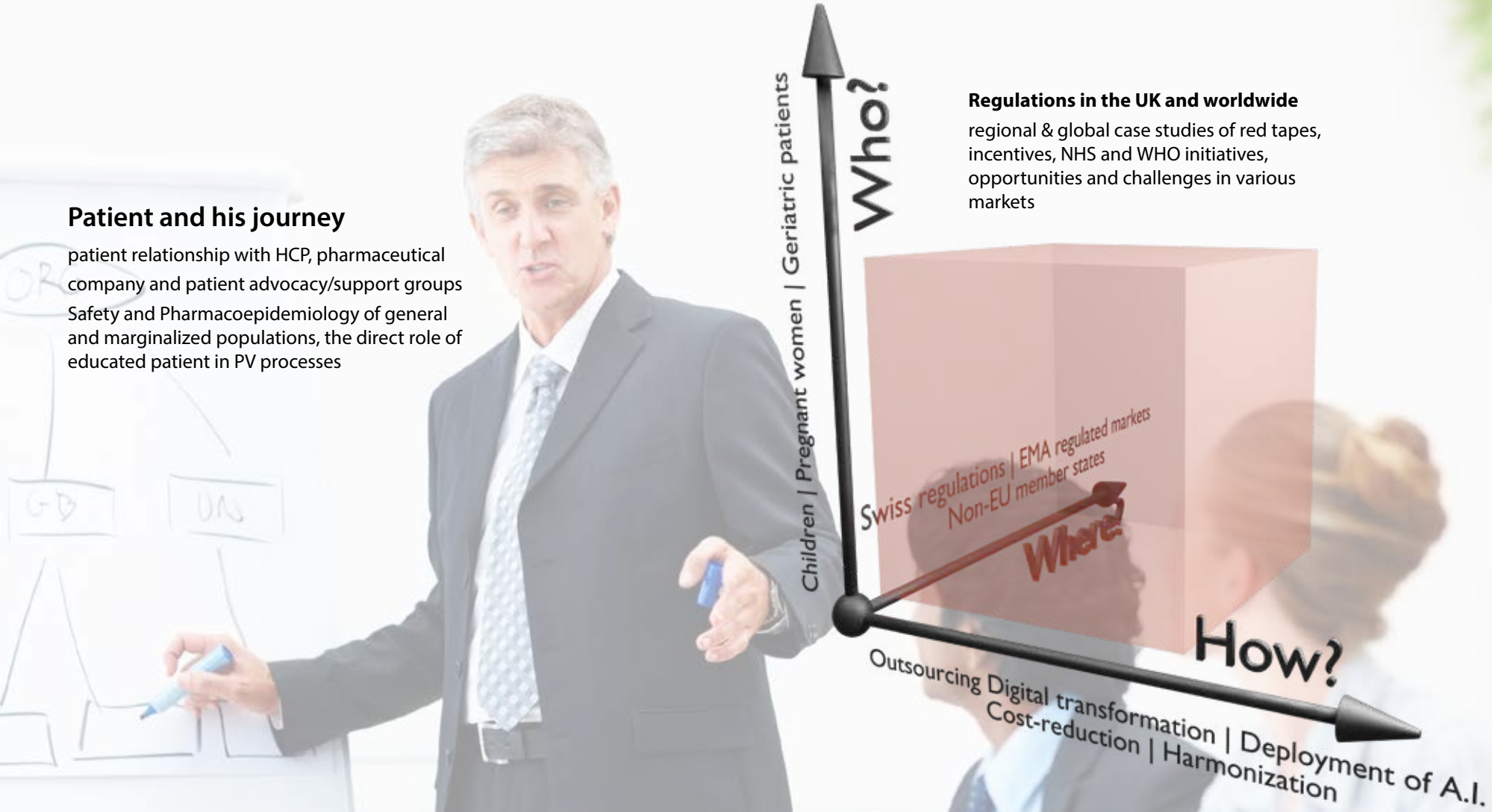
PHARMORA

Our conference is a story.
And such as our World, the story has 3 dimensions.



Patient and his journey

patient relationship with HCP, pharmaceutical company and patient advocacy/support groups

Safety and Pharmacoepidemiology of general and marginalized populations, the direct role of educated patient in PV processes

Regulations in the UK and worldwide

regional & global case studies of red tapes, incentives, NHS and WHO initiatives, opportunities and challenges in various markets

Drug safety as business Disruption enabling your company to grow

What to expect?

Our audience

Professionals involved in:

- ✓ Drug safety & Pharmacovigilance executives
- ✓ Heads of global safety programs
- ✓ QPPVs
- ✓ Benefit-Risk assessment management
- ✓ Medical affairs management
- ✓ Patient safety management
- ✓ Compliance specialists
- ✓ UMC professionals
- ✓ Post-market researchers
- ✓ PV auditors
- ✓ Regulatory affair directors
- ✓ NHS professionals
- ✓ Compliance specialists
- ✓ Drug safety consultants
- ✓ Hospital management

Testimonies from previous participants

"Great dialogue on key issues. Everyone shared truthful insight and did not hold back, even on negative experiences."

Sameer Thapar, Assistant Professor & Advisor, Drug Safety and Pharmacovigilance, Rutgers University

"Loved it. It was very practical and provided valuable insight into practical methods that are actionable for patient safety."

Daniel Naranjo, Global Safety Lead, Global Patient Safety Evaluation, Takeda

"Unlike some other similar events, I found relevance in every session within your conference. The content was neither too simplistic nor too advanced. The participants and presenters provided a diverse view of the issues that are present for most in this industry."

Christine Clearwater, Manager, Safety Operations and Vendor Management, Baxter, Global Patient Safety

ALLWAYS ASK WHY?

Join us for the 9th Annual Drug Safety & RWE Forum, returning after a successful year to the vibrant city of London with the arrival of Spring. Our conference weaves a narrative of personal experiences, connecting exceptional individuals who have chosen this path to deliver essential medicines, protect the vulnerable, and enhance the health of millions worldwide.

Key Discussion Points Data Management in Pharmacovigilance: Explore the pressing issues surrounding data management in Pharmacovigilance, given the ever-evolving landscape. Real-World Evidence (RWE): Understand the significance of RWE and its impact on Pharmacovigilance and drug safety practices. Regulatory Challenges: Delve into the challenges posed by evolving regulations in the pharmaceutical industry. Efficiency in Pharmacovigilance Departments: Learn strategies for optimizing PV departments in the wake of significant market layoffs last year. Discover best practices for enhancing efficiency while working within tighter budgets. Engaging Workshops: As a special offering this year, participants can expect two complimentary workshops to enrich their conference experience. Our conference provides a unique opportunity to actively engage with experts who are at the forefront of the pharmaceutical industry. We will delve into topics such as integrating disruptive technologies into PV processes:

- ✓ Sharing experiences in the safety of novel immunotherapies
- ✓ Consequences of growing population of geriatric patients – inclusive patient safety
- ✓ RWE management strategies
- ✓ A.I. / M.L. & Automation toolbox 2024
- ✓ Power of Intradepartmental and external collaborations in data management
- ✓ Consequences of centralization of PV processes
- ✓ Challenges of communication with HCPs in UK - opportunities for meaningful impact
- ✓ Harmonization and auditing – inviting QA to the table

Meet our knowledgeable speakers

Rishi Chopra
Executive Director, Head of International Pharmacovigilance
CSL Behring

John Solomon
Head of Pharmacovigilance - UK & Ireland
Sanofi

Nick Nikberg
Senior Patient Safety Specialist
Astrazeneca

Ranjana Khana
Global Director GVP QA
Beigene

Robert Massouh
Head of Risk Management and Benefit/ Risk Evaluation
GSK

Vijay Kara
Safety and Quantitative Innovation Director
GSK

Alexandru Barbarosie
EU/UK QPPV & Global Safety Lead
Amryt Pharma

Amit Jadhav
Director Global Patient Safety
Regeneron

Karen Cheng
Principal Director Pharmacovigilance and Pharmaceutical Medicine
Phlox PVMed Consultancy

Michael von Forstner
Head of Safety Science
Sobi

Vijay Singh
Associate Director & Surveillance Lead
UCB

Pav Rishiraj
Director, Head of Pharmacovigilance
Ipsen

Petar Gjorgiev
Global Safety Lead
Regeneron

Meet our knowledgeable speakers

Arun Ravindran
Patient Safety Physician
UCB

Pratiksha Dokhe
Patient Safety Physician
UCB

Rohan Mane
Director of Safety Risk management
Pfizer

Erika Barbarosie
Associate director compliance
Gilead

Marianne Mounir
Senior Global Auditor
Bayer

Elizabeth Smalley
Vice President
TriNetX

Sue Rees
PV lecturer
University of Hertfordshire

Gurpreet Singh
Vice President, Managing Director Integrated Safety
IQVIA

Daniel Hawcutt
Director of Research
Alder Hey Children's Hospital

Nicole Baker
CEO
Biologit

Andreas Webber
Vice President
TriNetX

Updesh Dosanjh
Next generation technology
IQVIA

John O'Brien
Principal Scientist
Pharmora Limited

Day1

OPENING & RWE, SIGNAL DETECTION & DATA MANAGEMENT IN PV

8:45 Morning Registration and early birds networking coffee

9:00 OPENING OF 9TH ANNUAL GLOBAL DRUG SAFETY FORUM BY THE CHAIRMEN DUO WITH

OPENING PRESENTATION: HARNESSING REAL-WORLD DATA AND REAL-WORLD EVIDENCE IN PHARMACOVIGILANCE

- Implementing RWD/RWE in daily PV
- Regulatory grade RWE for BR decision making
- Integration of RWD and AI/ML to improve outcomes

Michael von Forstner, *Head of Safety Science,* **Sobi**

9:30 **RESERVED CASE STUDY:** USE CASES FOR A.I. IN SAFETY & HOW TO MAKE IT SUCCESSFUL
Updesh Dosanjh, *Next generation technology,* **IQVIA**

10:00 **OPENING PANEL DISCUSSION:** RWD & RWE IN PV AND THE TECHNOLOGIES TO ENABLE VALUE

- Explore the role of a global RWD network combined with advanced technologies like LLM and Blockchain.
- Global Data Landscape: Navigating Changes and Challenges A.I. driven Digital Transformation in Pharmacovigilance
- Harnessing Technology for Safety Monitoring Collaborative Approaches to Pharmacovigilance Strengthening Industry Partnerships Preparing for the Future
- Anticipating and Addressing Emerging Risks

Michael von Forstner, *Head of Safety Science,* **Sobi**
Nicole Baker, *CEO,* **Biologit**
Elizabeth Smalley, *Vice President,* **TriNetX**
Updesh Dosanjh, *Next generation technology,* **IQVIA**

10:30 Morning break: Coffee and cake networking

11:00 **CASE STUDY:** SIGNAL DETECTION IN ORPHAN DISEASES
Alexandru Barbarosie, *EU/UK QPPV & Global Safety Lead,* **Amryt Pharma**

11:30 **PANEL DISCUSSION:** ADVANCEMENTS & CHALLENGES IN SIGNAL DETECTION
Alexandru Barbarosie, *EU/UK QPPV & Global Safety Lead,* **Amryt Pharma**
Vijay Singh, *Associate Director & Surveillance Lead,* **UCB**
Arun Ravindran, *Patient Safety Physician,* **UCB**
Arun Ravindran, *Patient Safety Physician,* **UCB**
John O'Brien, *Principal Scientist,* **Pharmora Limited**

12:00 LUNCH BREAK

13:00 **KEYNOTE:** LITERATURE MONITORING: INTEGRATING GLOBAL AND LOCAL
Description: The traditional method of literature surveillance involves separate searches and processes for global and local literature screening, often associated with manual and time-consuming work. Here we discuss trends in literature monitoring including the growing volume of data across the world and cost pressures that creating further challenges. Learn about new approaches to enable a unified global and local search in one place, and the benefits of automation and AI in transforming literature monitoring in PV.
Nicole Baker, *CEO,* **Biologit**

13:30 **KEYNOTE:** FUTURE OF PHARMACOVIGILANCE - WHERE ARE WE GOING?
Pav Rishiraj, *Director, Head of Pharmacovigilance,* **Ipsen**

14:00 **PANEL DISCUSSION:** LEADERSHIP AND FUTURE OF CAREERS IN PHARMACOVIGILANCE
Pav Rishiraj, *Director, Head of Pharmacovigilance,* **Ipsen**
John Solomon, *Head of Pharmacovigilance - UK & Ireland,* **Sanofi**
Gurpreet Singh, *Vice President, Managing Director Integrated Safety,* **IQVIA**
Rishi Chopra, *Executive Director, Head of International Pharmacovigilance,* **CSL Behring**

Day1

INNOVATIVE APPROACHES IN PHARMACOVIGILANCE

14:30 **KEYNOTE:** EMBRACING THE DAWN OF DIGITAL PILL IN PHARMA FROM PERSPECTIVES OF SAFETY
Karen Cheng, *Principal Director Pharmacovigilance and Pharmaceutical Medicine,* **Phlox PV Med Consultancy**

15:00 NETWORKING BREAK

15:30 **CASE STUDY:** INNOVATION IN VACCINE SAFETY: HVCM (HUMAN VIRAL CHALLENGE MODEL) AS A CORNERSTONE OF NEW VACCINE DEVELOPMENT FROM CLINICAL PV PERSPECTIVE
Pratiksha Dokhe, *Patient Safety Physician,* **UCB**

16:00 **CASE STUDY:** Additional risk Minimization measures
Amid Jadhav, *Global Director Patient Safety,* **Regeneron**

16:30 **ROUNDTABLE DISCUSSION:** Updates in Safety: Oncology, Patient support in rare diseases, Communication & open questions
We would kindly ask all participants to submit theirs questions during the day1 to sli.do and we will discuss them during the roundtable after initial topics.
Andreas Webber, *VP,* **TriNetX**
Claire McMENAMIN, *Global Pharmacovigilance & Patient Safety Scientist*

17:00 WHY SUMMITS CONFERENCE RECEPTION – COCKTAIL PARTY SPONSORED BY TRINETX
Join Us for the Cocktail Reception at the Annual Drug Safety & RWE Forum! Dear Attendee, As the first day of the Annual Drug Safety & Real-World Evidence (RWE) Forum draws to a close, we invite you to unwind and connect with fellow attendees at our exclusive Cocktail Reception. Hosted by esteemed solution provider TrinetX, this evening promises engaging conversations, networking opportunities, and delightful refreshments in a relaxed atmosphere.

Day2

COMPLIANCE & SAFETY INSPECTIONS SESSION

9:00 **CASE STUDY:** BEST PRACTICE LEARNING ON PSMF (Pharmacovigilance Systems Master File)
Sue Rees, *PV lecturer,* **University of Hertfordshire**

9:30 **KEYNOTE FOLLOWED BY CASE STUDY:** UNVEILING THE GOOD, THE BAD AND THE DATA-FUL IN GVP INSPECTIONS
Erika Barbarosie, *Associate Director Compliance,* **Gilead**

10:00 **PANEL DISCUSSION:** UPDATES ON COMPLIANCE AUDITING & REGULATIONS
Ranjana Khana, *Global Director GVP QA,* **Beigene**
Erika Barbarosie, *Associate Director Compliance,* **Gilead**
Sue Rees, *PV lecturer,* **University of Hertfordshire**

10:40 NETWORKING BREAK

11:00 **CASE STUDY:** AUDITING OF SPECIAL PROGRAMS IN PHARMACOVIGILANCE
Ranjana Khana, *Global Director GVP QA,* **Beigene**

RISK MANAGEMENT & BENEFIT-RISK ASSESSMENT SESSION

11:30 **EXPERIENCE SHARING IN COMPLEX RISK MANAGEMENT**
Arun Ravindran, *Patient Safety Physician,* **UCB**

12:00 LUNCH BREAK

13:00 **PANEL DISCUSSION:** ADVANCEMENTS AND CHALLENGES IN BENEFIT-RISK ASSESSMENT
Robert Massouh, *Head of Risk Management and Benefit/Risk Evaluation,* **GSK**
Rohan Mane, *Director of Safety Risk Management,* **Pfizer**
Petar Gjorgiev, **Regeneron**
Nick Nickberg, *Senior Patient Safety Specialist,* **AstraZeneca**

13:30 **COMMUNICATION IN PHARMACOVIGILANCE – CHALLENGES IN RISK MANAGEMENT**
Nick Nickberg, *Senior Patient Safety Specialist,* **Astrazeneca**

14:00 NETWORKING BREAK

14:30 **EDUCATIONAL ROUNDTABLE:** BEST PRACTICES IN RISK MANAGEMENT
Karen Cheng, *Principal Director Pharmacovigilance and Pharmaceutical Medicine,* **Phlox PVMed Consultancy**

15:00 **OPEN PLENARY DISCUSSION:** SHARING EXPERIENCES IN HCPs APPROACH: COLLABORATION WITH FIELD FORCE, OUTSOURCING OF COMMUNICATION SERVICES, UTILIZING DIGITAL TOOLS
Nick Nickberg, *Senior Patient Safety Specialist,* **Astrazeneca**
Gurpreet Singh, *Vice President, Managing Director Integrated Safety,* **IQVIA**
John Solomon, *Head of Pharmacovigilance - UK & Ireland,* **Sanofi**
Rishi Chopra, *Executive Director, Head of International Pharmacovigilance,* **CSL Behring**

Conference chair summarizing two days of the conference, answering all questions from the audience, finished by free networking.

Sponsorship

Exhibiting

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2023 FoP SUMMIT WORLD is a popular sponsorship option with great value for solution providers.

Sponsorship includes

- Selected Summit Three Access Passes
- Exhibition space
- Helping to prearrange face to face meetings with selected participants

Dinner Sponsorship

2023 FoP SUMMIT WORLD TOUR will host a series of dinners These dinners bring together thoughtfully selected groups of 15-20 peers from established pharma, biotech, healthcare, and medtech companies. The dines start with a 30-minute networking reception followed by a 60-minute seated dinner, with the option for participants to remain afterward to continue networking.

- Selected Summit Three Access Passes
- 30-minute reception, and 60 minute seated dinner

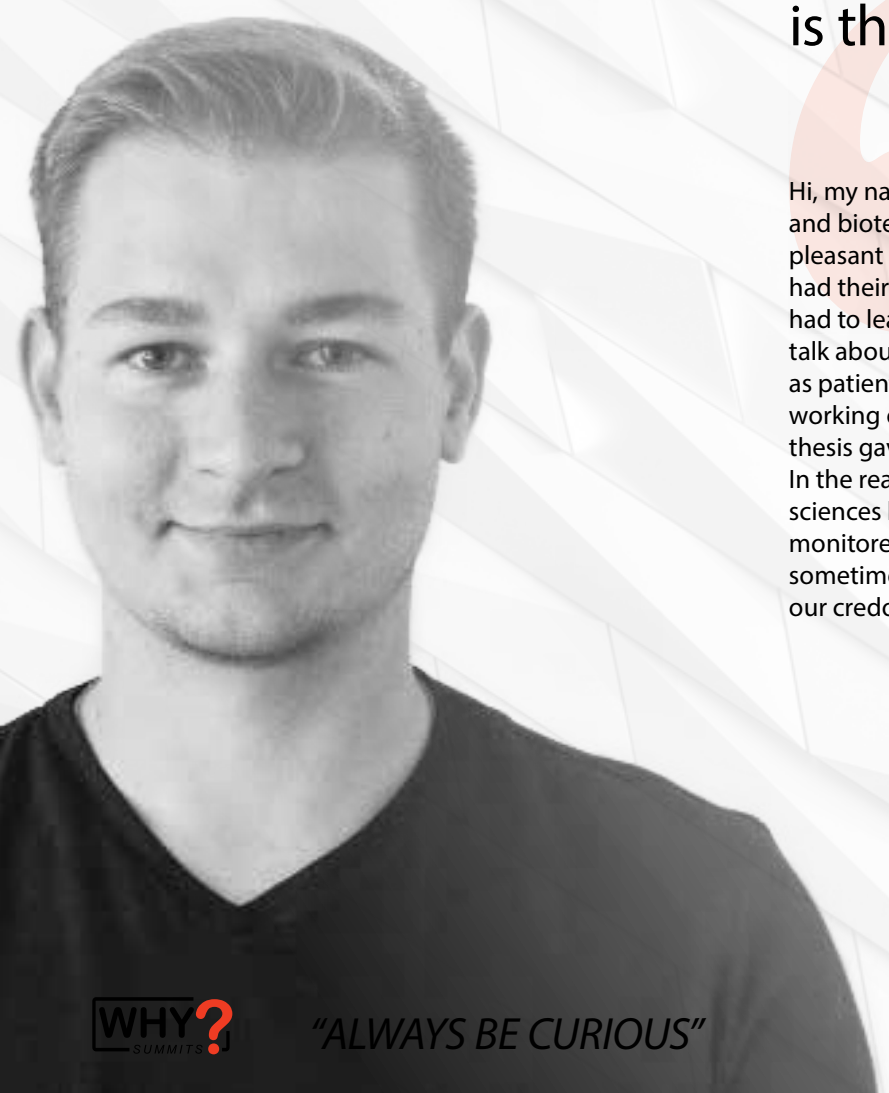
Speaking

Limited speaking opportunities are available for our sponsoring partners to demonstrate the expertise of their organization. Be sure to ask about these early so we can ensure your presentation flows seamlessly with the overall content. Speaking sponsorships has several options – keynote presentations, case study presentations, expert presentations, panel discussions, workshops, or roundtable leadership. Speaking opportunities are available for experts in the field of Drug safety specialists, QPPVs, Safety Heads, C-level pharmaceutical and biotech executives, hospital management, clinicians, epidemiologists, pharmacologists, Project and Portfolio Management, Contract Management, Consultancy, CROs, Data Management, Artificial Intelligence, Robotics and Digital Innovation experts

Additional sponsorship opportunities are available for those who wish to further customize their involvement.

WHY have we decided to create the World Tour of pharmaceutical summits focused on drug safety?

Challenging regulations, disruptive innovations, constant change, false signals, and myriads of data... is the struggle worth it?



Hi, my name is Thomas and I am a scientific consultant at Whysummits, responsible for the company's pharmaceutical and biotechnology divisions. My calling to work in the pharmaceutical industry came to me very early, although not in pleasant circumstances. Being born into the Lynch family, many of my dearest family members, which meant a world to me, had their lives burdened or taken by cancer induced by this hereditary condition. I did not understand as a kid, why they had to leave, but I was determined to figure it out. Why there was no efficient prevention and screening, why did nobody talk about it, why there was a stigma, and why there was no support group and nobody to lead them on their journey as patients? Later on, studying life sciences with a focus on molecular biology provided me with profound answers, and working on new methods for cancer detection using liquid biopsy and epigenetic marks on DNA as my master's and Ph.D. thesis gave me a wonderful opportunity to add my grain to improve future cancer diagnostics. But I wanted to do more. In the real world, so much of scientific work leads to a dead end, and great ideas, discoveries, and improvements in life sciences have to be always supported by a strong commercial plan, to be able to reach the patient, and afterward closely monitored to ensure its safety and efficiency. For this to happen, the crucial thing is that the right industry professionals, sometimes from the same, sometimes from totally different environments meet and collaborate. In Why Summits, this is our credo, our goal, and with years of experience also proven fact.

Let's connect!

Thomas

Contact us

SPEAKING:

Tomas Rendek

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ATTENDING AND SPONSORING:

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