9th Annual European Drug Safety Pharma & Biotech Conference

November 29 - 30 2023, Basel, Switzerland

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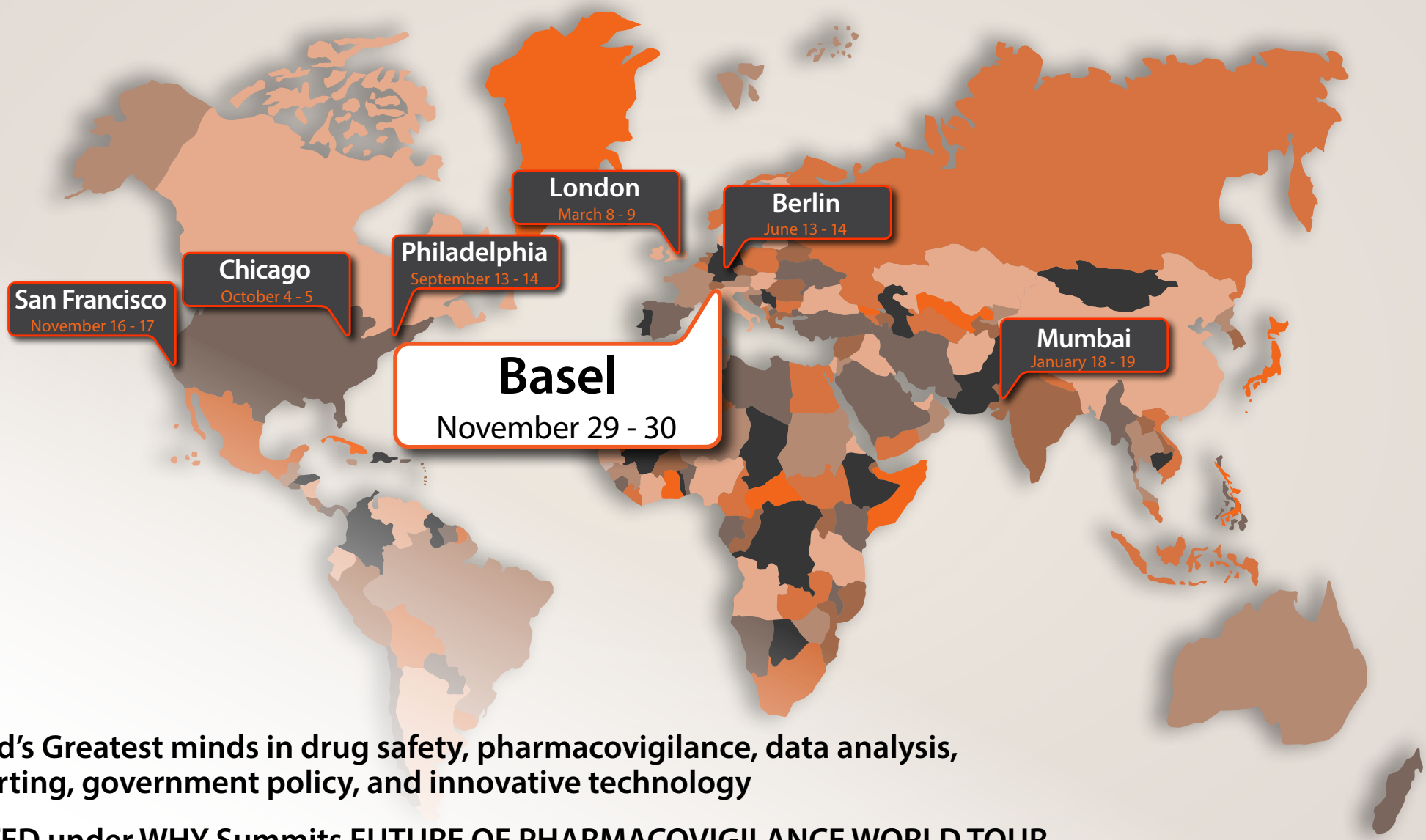
FoP Summits Worldwide



World's Greatest minds in drug safety, pharmacovigilance, data analysis, reporting, government policy, and innovative technology

UNITED under WHY Summits FUTURE OF PHARMACOVIGILANCE WORLD TOUR

What to expect?

Our 2023 flagship event concluding 2023 World Tour FUTURE OF PHARMACOVIGILANCE

- ✓ Meet crème de la crème of Drug Safety professionals from our 2023 world tour
- ✓ Learn about the most important issues addressed during the world tour
- ✓ Discuss the vision for 2024 and further
- ✓ Listen to the most crucial current topics selected & presented by industry leaders
- ✓ Enjoy education & networking focused event in a non-vendor-driven environment
- ✓ Create lasting work groups and friendships with the possibility to meet regularly on the next stops of our world tour

You will spend your time with

- ✓ Drug safety & Pharmacovigilance executives
- ✓ Heads of global safety programs
- ✓ QPPVs
- ✓ Benefit-Risk assessment management
- ✓ Medical affairs management
- ✓ Patient safety management
- ✓ Compliance specialists
- ✓ Post-market researchers
- ✓ PV auditors
- ✓ Regulatory affairs directors
- ✓ EMA professionals
- ✓ Compliance specialists
- ✓ Pharma IT management
- ✓ Safety consultants

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 [illegible]nce 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?

Creating contrast to loud, expo- style meetings with limited focus and personal touch, WHY SUMMITS World tour of Pharmacovigilance conferences brings another kind of experience.

Our Basel concentrated knowledge-focused meeting, is assembled in 8 blocks focusing on:

- ✓ New Paradigms in Drug Safety
- ✓ Advancements in Benefit-Risk assessment
- ✓ Elevating the status of the modern Drug Safety department
- ✓ Medical Affairs & Patient Engagement in Drug Safety
- ✓ What is new in signal detection automation
- ✓ Big data and digital transformation
- ✓ Drug Safety in consumer health
- ✓ Paneuropean compliance & culture change

2023 Speakers and Panelists

Petros Mavrogenis
Novartis
Head Vigilance Process Excellence

Finn B. Larsen
Sandoz
Head of Technology & Data Management, Patient Safety

Luvanka Hanxhari
Novartis
Global Risk Management Plan Lead

Felix Arellano
Roche
Global Head of Drug Safety

Santanu Mukhopadhyay
Vectura Fertin Pharma
Head of Medical Safety

Sabine Poltermann
BMS
Country Head Patient Safety

Dimitrios Zampatis
Novartis - CHAIRMAN
Global Program Safety Lead

Erika Barbarosie
Gilead
Associate director compliance

Ricarda Tiemeyer
Biogen
Head of Pharmacovigilance DACH

Marina Suvakov
Philip Morris International
Global head, product safety surveillance

Ján Škrle
Zentiva
Pharmacovigilance director

Marjan Dzeparoski
Bionika Pharmaceuticals
PV Manager & University lecturer

Henk Johan Streefkerk
Amarna Therapeutics
CEO

Lisa Stagi
Roche
Patient Safety Country Cluster Lead

Graeme Ladds
PharSafer
Director

Mark Waring
Pharmacovigilance Services
Industry consultant

Nikolina Nuic
Philip Morris International
Safety Database Manager

Fiorenza Gaudenzi
Novartis
Senior Global Program Safety Lead

Jost Leemhuis
Roche
Safety Science Partner

Dmytro Horilyk
Drug Cards
CEO

Agenda

19:30

WELCOME RECEPTION FOR EARLY ARRIVALS

Informal meeting in the Lobby of the hotel for all attendees coming to the conference the night before. A unique chance to network in tighter, relaxed circles and to register and receive your batch in advance.

Day1

8:30 Morning Registration and early birds networking coffee

OPENING & NEW TRENDS IN DRUG SAFETY

9:00 **Official start of 9th Annual European Drug Safety Pharma & Biotech Conference with opening remarks of the chairmen duo.**

KEYNOTE PRESENTATION: NEW TRENDS IN PHARMACOVIGILANCE

- Social Media, Big data and the Internet of Things are going to impact new ways of working in Pharmacovigilance
- Innovation in Health Care will need new approaches on how to communicate on safety related topics and on how to collect data insights
- Pharmacovigilance will need to adopt to the changing environment in healthcare market and will need to build new skills and expertise

Ricarda Teimeyer, *Head of Pharmacovigilance DACH,* **Biogen**

9:30 **ICEBREAKING PANEL:** RETROSPECTIVE LOOK ON 2023: MILESTONES & DISRUPTIONS IN DRUG SAFETY

The main aim of the icebreaking panel is to make you feel comfortable to ask any question, express any opinion and gain confidence to become an active participant of the conversation. Why Summits panel discussions are not about politely knocking to each other and repeating rehearsed phrases. A vivid discussion among people with different opinions is crucial if new ideas and outcomes are supposed to emerge. The audience will receive shortly before the start of the panel a QR code to join the Sli.do platform, enabling you to ask any question or express opinion, either by your name or anonymously.

Ricarda Teimeyer, *Head of Pharmacovigilance DACH,* **Biogen**
Finn B. Larsen, *Head of Technology & Data Management, Patient Safety,* **Sandoz**
Jost Leemhius, *Patient safety partner,* **Roche**
Petros Mavrogenis, *Head Vigilance Process Excellence,* **Novartis**
Moderator:
Dimitrios Zampatis, *Global Program Safety Lead,* **Sandoz**

WHAT IS NEW IN SIGNAL DETECTION & AUTOMATION?

10:00 **RESERVED KEYNOTE:** THE GOOD, THE BAD AND THE UGLY – AUTOMATED SAFETY CASE PROCESSING

- Explore the current industry climate regarding ADR reporting and pharmacovigilance activities
- Understand the challenges associated with rising demands for traditional methods of reporting ADRs
- Acknowledge possible downturns and address any hesitations industry professionals may have towards implementing automated solutions
- Identify the benefits of implementing automation and innovative software solutions for ADR reporting and importance of adopting automation and innovative software solutions to streamline pharmacovigilance activities
- Assess how automation and innovative software solutions can improve patient safety and ensure greater levels of compliance with global regulatory requirements

Graeme Ladds, *Director,* **PharSafer**

10:30 Morning break: coffee and cake networking

11:00 **PANEL DISCUSSION:** SHARING EXPERIENCE WITH DIGITAL DISRUPTION AND DATA MANAGEMENT IN THE INDUSTRY. POINTING OUT DIFFERENCES IN BIG PHARMA, SME BIOTECH AND CONSUMER HEALTH COMPANY STRATEGIES

Petros Mavrogenis, *Head Vigilance Process Excellence,* **Novartis**
Marina Souvakov, *Global head, product safety surveillance,* **Philip Morris**
Hank Streefkerk, *CEO,* **Amarna Therapeutics**
Jost Leemhuis, *Safety Science Partner,* **Roche**

11:30 **COMPLEXITIES AND LEARNINGS IN PV SYSTEM TRANSFORMATION**

Finn B. Larsen, *Head of Technology & Data Management, Patient Safety,* **Sandoz**

12:00 Lunch break

13:00 **KEYNOTE:** SAFETY REAL WORLD EVIDENCE FOR TREATMENT DECISIONS

Jost Leemhuis, *Safety Science Partner,* **Roche**

Day1

13:30 **PANEL DISCUSSION:** SHARING EXPERIENCE WITH DIGITAL DISRUPTION AUTOMATION and A.I / M.L. IMPLEMENTATION IN SAFETY DEPARTMENTS.
Jost Leemhuis, *Safety Science Partner,* **Roche**
Graeme Ladds, *Director,* **PharSafer**
Dmytro Horilyk, *CEO,* **Drug Cards**
Finn B. Larsen, *Head of Technology & Data Management, Patient Safety,* **Sandoz**
Nikolina Nuic, *Safety Database Manager,* **Philip Morris International**
Moderator:
Dimitrios Zampatis, *Global Program Safety Lead,* **Sandoz**

ELEVATING THE ROLE OF DRUG SAFETY DEPARTMENT

14:00 **KEYNOTE:** SWEAT OF DRUG SAFETY DEPARTMENT: DOES REPEATED FOLLOW-UP IMPROVE THE QUALITY OF SAFETY DATA? BALANCING EFFORT AND REWARD
Petros Mavrogenis, *Head Vigilance Process Excellence,* **Novartis**

14:30 Coffee & Cake break

15:00 **PANEL DISCUSSION:** ROLE OF MODERN DRUG SAFETY DEPARTMENT IN PHARMACEUTICAL COMPANY- THE IMPORTANCE OF INTERDEPARTMENTAL COLLABORATION & PROVIDING BUSINESS VALUE
Dimitrios Zampatis, *Global Program Safety Lead,* **Sandoz**
Felix Arenallo, *Global Head of Drug Safety,* **Roche**
Ricarda Teimeyer, *Head of Pharmacovigilance DACH,* **Biogen**
Jost Leemhuis, *Safety Science Partner,* **Roche**
Moderator:
Petros Mavrogenis, *Head Vigilance Process Excellence,* **Novartis**

PATIENT INVOLVEMENT IN PHARMACOVIGILANCE

15:30 **KEYNOTE:** ELEVATING PATIENT VOICE IN PHARMACOVIGILANCE
Lisa Stagi, *Patient Safety Country Cluster Lead,* **Roche**

16:00 **PANEL DISCUSSION:** FUTURE OF COLLABORATION BETWEEN DRUG SAFETY & MEDICAL DEPARTMENT – improving patient safety, adherence and satisfaction through data
Lisa Stagi, *Patient Safety Country Cluster Lead,* **Roche**
Dimitrios Zampatis, *Global Program Safety Lead,* **Sandoz**
Dmytro Horilyk, *CEO,* **Drug Cards**
Moderator:
Petros Mavrogenis, *Head Vigilance Process Excellence,* **Novartis**

17:00 OFFICIAL WHY SUMMITS COCKTAIL RECEPTION – GRAB A DRINK AND FINISH THE DAY WITH INFORMAL NETWORKING PARTY

Day2

ADVANCEMENTS IN BENEFIT-RISK ASSESSMENT

8:30 **KEYNOTE:** BENEFIT-RISK MANAGEMENT IN ADVANCED THERAPIES- FOCUS ON GENE THERAPY
Hank Streefkerk, *CEO,* **Amarna Therapeutics**

9:00 **KEYNOTE:** RISK MANAGEMENT AND EFFECTIVENESS OF ARMMS
- Risk categorization
- Handling of Risk Minimization measures
- How to measure effectiveness of aRMMs
- RMP for Biosimilars, Biologics

Dimitrios Zampatis, *Global Program Safety Lead,* **Sandoz**

9:30 **RESERVED PRESENTATION:** DEVELOPMENT OF RISK MANAGEMENT PLANS: INCREASING EFFICIENCY AND IMPROVING QUALITY.
Which challenges and pitfalls do organizations commonly encounter when developing RMPs?
- How can we systematically identify and assess relevant topics during RMP development and determine which risk management measures to propose?
- What approaches can help produce RMPs more efficiently, and with better quality?

Mark Waring, *Industry consultant,* **Mark Waring Pharmacovigilance Services**

10:00 Networking break

DIGITAL TRANSFORMATION- NEW APPROACHES TO COLLABORATION

10:30 **KEYNOTE:** DIGITAL APPROACH TO COMMUNICATION WITH HCPS – ARE PHYSICIANS AND INDUSTRY READY?
Luvanka Hanxhari, *Global Risk Management Plan Lead,* **Novartis**

11:00 **CASE STUDY:** CHALLENGES AND ADVANTAGES OF SELECTING LOCAL VENDOR FOR PHARMACOVIGILANCE ACTIVITIES
Ján Škrle, *Pharmacovigilance director,* **Zentiva**

11:30 **PANEL DISCUSSION:** ROLE OF PHARMACEUTICAL INDUSTRY AS EDUCATOR: RESPONSIBILITY IN REACHING HEALTHCARE PROVIDERS, PATIENTS AND AUTHORITIES
Luvanka Hanxhari, *Global Risk Management Plan Lead,* **Novartis**
Sabine Poltermann, *Country Head Patient Safety,* **Bristol Mayers Squibb**
Erika Barbarosie, *Associate Director – Compliance,* **Gilead**
Ján Škrle, *Pharmacovigilance director,* **Zentiva**
Marjan Dzeparoski, *PV Manager & University lecturer,* **Bionika Pharmaceuticals**
Moderator:
Erika Barbarosie, *Associate Director – Compliance,* **Gilead**

12:00 Lunch break

COMPLIANCE & CULTURE CHANGE IN PHARMA

13:00 **KEYNOTE:** ROLE OF MEDICAL SAFETY IN THE DUE DILIGENCE PROCESSES
During the appraisal of a pharmaceutical business, a prospective buyer's evaluation is crucial as to ensure a successful deal. How is patient safety involved? Does it play a marginal, or (hint!) a strategic role? This lecture, with pragmatic suggestions, will provide the answer to the above questions.
Fiorenza Gaudenzi, *Senior Global Program Safety Lead,* **Novartis**

13:30 **CASE STUDY:** THE PITFALLS OF THE EU PSMF
Pharmacovigilance System Master File is a critical document and concept related to the regulatory requirements for monitoring and ensuring the safety of pharmaceutical products on the market. The PSMF is typically required in the European Union and serves as a comprehensive overview of a marketing authorization holder's pharmacovigilance system. How much pain can possible mistakes, mishaps, and inaccurate wording cause to pharmaceutical companies and is it possible to avoid it?
Erika Barbarosie, *Associate Director – Compliance,* **Gilead**

14:00 **KEYNOTE:** CHALLENGES AND CHANGES OF PROCESS CENTRALIZATION: CONSEQUENCES FOR LOCAL DRUG SAFETY TEAMS
Sabine Poltermann, *Country Head Patient Safety,* **Bristol Mayers Squibb**

14:30 Networking break

15:00 **KEYNOTE:** A KEY TO BUILDING MATURE DEPARTMENT FOCUSED ON NOVEL THERAPEUTIC APPROACHES: INHALATION THERAPEUTICS
Keynote presentation discussing the safety aspects of inhaled drug delivery and the role of safety in various stages of inhaled therapeutic development
Santanu Mukhopadhyay, *Head of Medical Safety,* **Vectura Fertin Pharma**

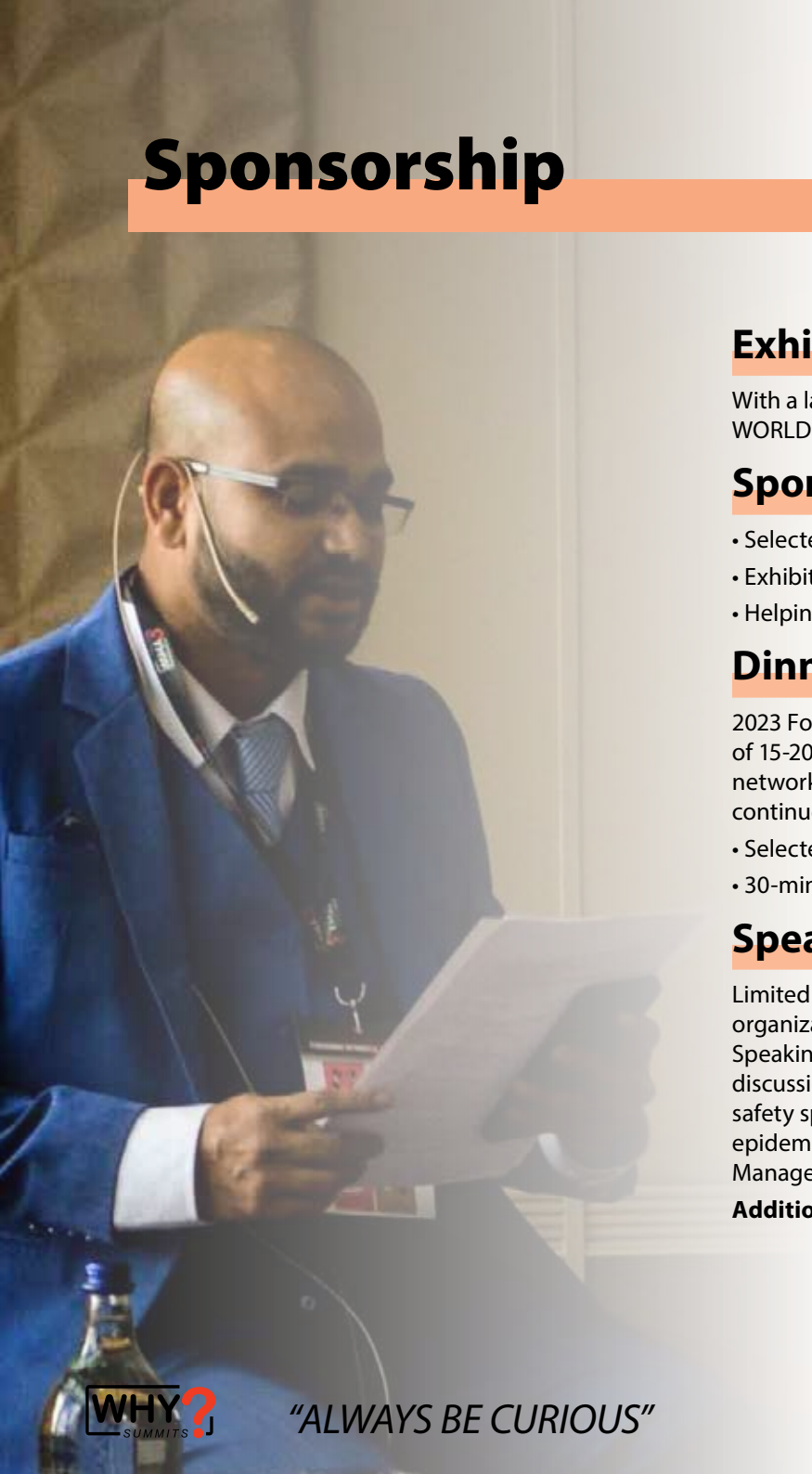
15:30 **CLOSING PANEL DISCUSSION:** CULTURE CHANGE IN PHARMA: LEADERSHIP & SKILLSET FOR DRUG SAFETY DEPARTMENT OF THE FUTURE
Santanu Mukhopadhyay, *Head of Medical Safety,* **Vectura Fertin Pharma**
Sabine Poltermann, *Country Head Patient Safety,* **Bristol Mayers Squibb**
Henk Streefkerk, *CEO,* **Amarna Therapeutics**
Fiorenza Gaudenzi, *Senior Global Program Safety Lead,* **Novartis**
Finn B. Larsen, *Head of Technology & Data Management, Patient Safety,* **Sandoz**
Moderator:
Erika Barbarosie, *Associate Director – Compliance,* **Gilead**

16:00 **SUMMIT WRAP-UP:** Major takeaways from the last two days
An open plenary discussion, with chairmen introducing the most interesting & unanswered questions raised via Sli.do during the 2-day event. The conference will end as a free interactive discussion setting goals for 2024 PV world tour

2023 Future of Pharmacovigilance World at a Glance

1. March 8 - 9 London, UK
   8th Global Pharmacovigilance Forum
2. June 13 - 14 Berlin, Germany
   European Medical Device Safety & Complaince Conference
3. September 13 - 14 Philadelphia, PA, United States
   American Pharma and Biotech Advancements in Drug Safety Summit
4. October 4 - 5 Chicago, IL, United States
   American Medical Device Safety Management Conference
5. November 16 - 17 San Francisco, CA, United States
   17th American Drug Safety Biotech & Pharma Conference
6. November 29 - 30 Basel, Switzerland
   10th Annual European Drug Safety Pharma & Biotech Conference
7. January 18 - 19 Mumbai, India
   Global Drug Safety & PV Outsourcing Summit
8. spring 2024 London, UK
   9th Global Pharmacovigilance Forum

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

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