Future of Pharmacovigilance World Tour 2023

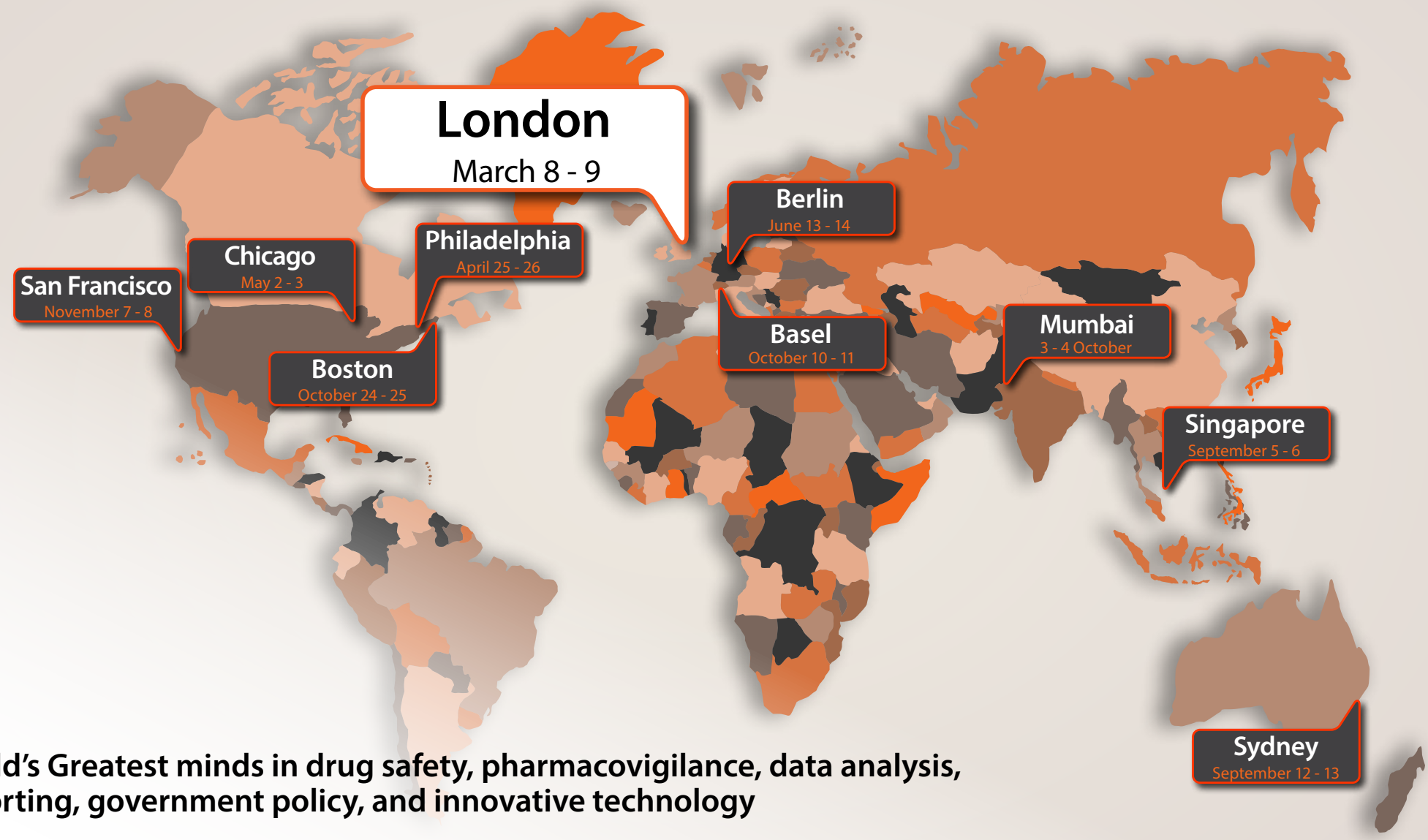
8th Annual Global Pharmacovigilance & RWE Forum - London

WHY? SUMMITS

March 8 - 9 2023

"ALWAYS BE CURIOUS"

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

Speakers and Panelists

Dimitrios Zampatis
Novartis
Chairman
Global Program Safety Lead

Mark Duman
Chairman
Chief patient officer

Michael von Forstner
Biogen
Global head of clinical safety & PV

Lionel Van Holle
UCB
Safety surveillance lead

Philip Eichorn
Amryt Pharma
Global Head of Drug Safety

Emanuel Lohrman
Otsuka Pharmaceuticals
Lead safety physician

Stephanie Tcherny-Lessenot
Sanofi
Global Head of benefit-risk evaluation

Priya Singhal
Biogen
Executive VP – head of development

Azza Elgharably
Astrazeneca
Associate director patient safety

Henk Johan Streefkerk
Cell Prothera
Chief Medical Officer

Petar Gjorgiev
Pfizer
Safety Risk Lead & Medical Director

Sue Rees
PV lecturer
Pharmacovigilance trainer

Zina Sadeq
Amicus therapeutics
Director regional Pharmacovigilance

Nicole Baker
Biologit
CEO

Ricarda Tiemeyer
Biogen
Head of Pharmacovigilance DACH

Rohan Mane
Pfizer
Director of Safety Risk management

Leonardo Pereira
Roche
Safety Director

Shikta Das
Astrazeneca
Principal Scientist

Samuel Wallis
Celgene
Senior director & deputy QPPV

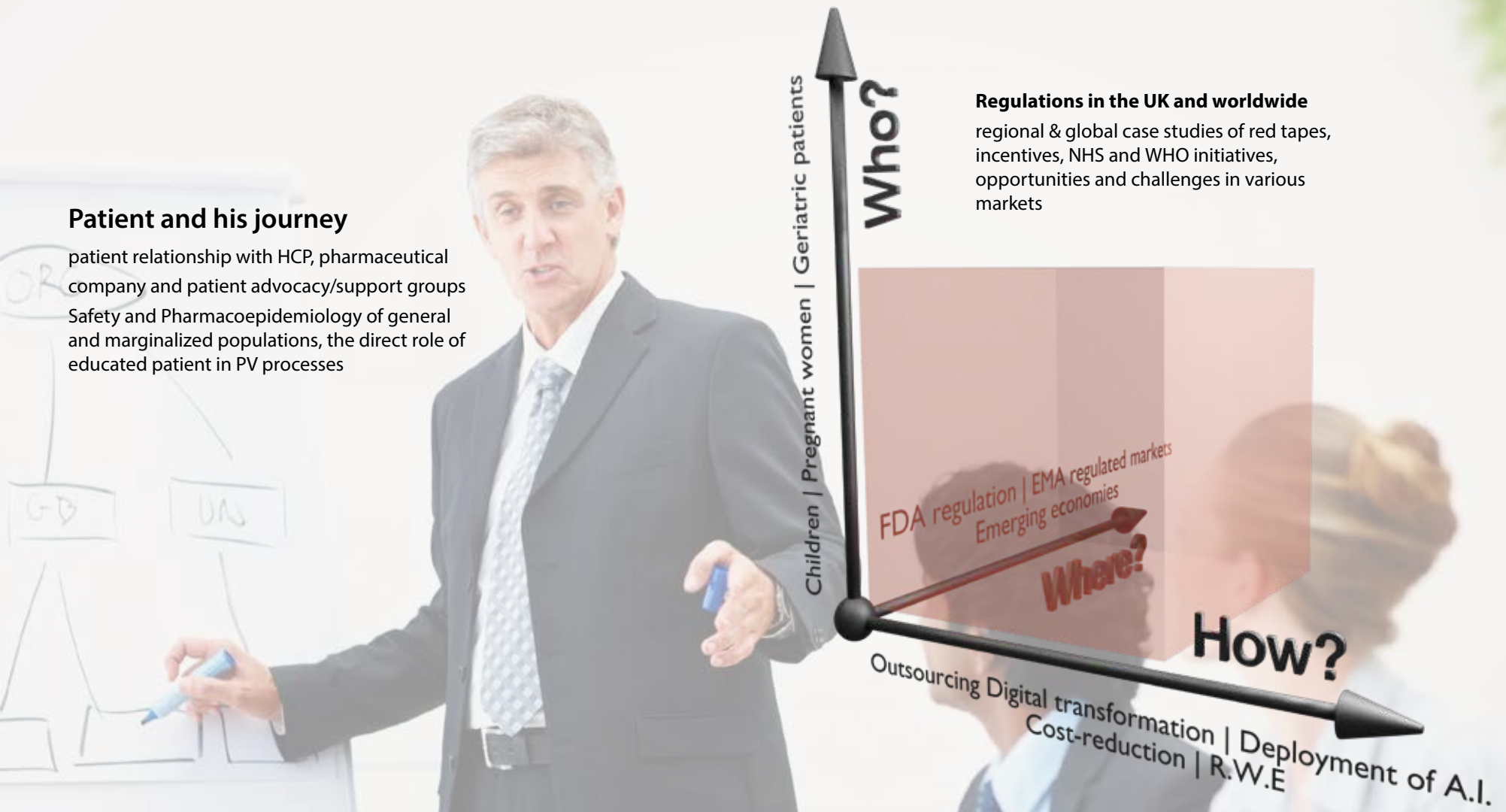
Robert Adams
Reckitt
Global Safety Physician

Tiberius Pereira
Patients for Patient Safety
Patient safety advocate

Erika Barbarosie
Gilead
Associate director compliance

Ivanna Rosendal
Ascendis Pharma
Senior Director
IT Business Partner

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



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

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

Drug safety as business Disruption enabling your company to grow

Our Audience:

Professionals involved in:

- Pharmaceutical executives
- QPPVs
- Benefit-Risk assessment management
- Medical affairs management
- Patient support & groups representatives
- Compliance specialists
- UMC professionals
- Post-market researchers
- PV auditors
- EMA professionals
- Compliance specialists
- Startup founders
- Drug safety consultants
- Hospital management

Company breakdown:

25% Industry consultants, Academia & Solutions and Software providers

75% Big & SME Pharma and Biotech companies

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

Our conference program, our story to tell the world

Our 8th Global Pharmacovigilance and RWE Forum in the capital of the United Kingdom, the country with a great history of scientific inventions and innovation in the pharmaceutical and biotech industry is not just another common pharmaceutical industry meeting. This is a conference which tells a STORY. One personal experience followed by another, a storyline of exceptional people who happen to choose to improve, build, explore and help with transforming the difficult world of Real World Data and Pharmacovigilance and other Drug safety related professions as their way to bring needed medicines and protect those who are the most vulnerable, and to improve the health of millions of people on our planet.

Why Summits offer not only a chance to hear but to actively join experts discussing current issues in this ever-evolving industry. The best practice case studies on how to integrate new, disruptive technology into the rather rigid processes of PV organization and how it evolves to stay compliant. But how to do this with the more and more restrictive budget? How to prioritize, what methodologies to use for advanced therapies? What is the next evolution step in signal detection noise clearance? Are A.I.-based tools to become our colleagues, helpmates, or our replacement?

Real World Evidence (RWE) is a rather big elephant in the room. While there is currently not a single biopharmaceutical player who does not recognize its value, is there anyone with a fully established technological platform, enabling leverage on those data from both developmental AND commercial perspective?

Regardless of the problem, each company, department, and project starts with people. But how to build a winning cross-functional team and what kind of workforce is necessary for a drug safety department of the future? What kind of skills to expect from millennials and gen-z entering the industry and why do we need veterans in the industry as well? Challenges with innovations, outsourcing, everchanging regulatory landscape, harmonization, educating other departments on how to use RWE data, and engaging the more and more aware public.

Pharmacovigilance services simply cannot lag behind changing landscape of new advanced therapies, such as regenerative medicine, CAR-T cell therapy, and other kinds of gene therapies. The same way it is impossible to overlook growing impact of Digital Theraputics (DTx) and growing patient awareness and involvement in pharmacovigilance processes.

Our conference will be chaired by the dynamic duo of industry veterans to ensure a smooth and also entertaining experience. Furthermore, it will feature numerous assisted formal and informal networking, matchmaking, and breakout sessions to create those critical business friendships that will bring fruitful cooperation and fill that missing piece in our common mission to improve drug safety and quality of life for all.

Day 1

8.30am Morning Registration and early birds networking coffee

INNOVATION & SIGNAL DETECTION SESSION

9.00am **Opening of 8th Annual Global Drug Safety Forum by the chairmen duo with opening presentation: Global trends Signal detection management & RWE**
Dimitris Zampatis, *Global Program Safety Lead,* **Patient Safety BioPharma, Novartis**

9.30am **ICEBREAKING PANEL DISCUSSION:** TRENDS & PAIN POINTS OF MODERN PHARMACOVIGILANCE
The role of our icebreaking panel is to make you feel comfortable to ask any question, express any opinion, and even protest when necessary! 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. Discussing improvements in pharmacovigilance practices across different countries is a great topic to start with, who is the best player in this complicated game?
Philip Eichorn, *Global Head of Drug Safety,* **Amryt Pharma**
Henk Johan Streefkerk, *Chief Medical & Safety Officer,* **Cell Prothera**
Ivanna Mikhailovna Rosendal, *Senior Director & IT Business partner,* **Ascendis Pharma**
Zina Sadeq, *Director regional Pharmacovigilance,* **Amicus therapeutics**

10.00am **KEYNOTE:** WHAT ARE THE LOW-HANGING FRUITS IN PHARMACOVIGILANCE & WHERE ARTIFICIAL INTELLIGENCE COULD EASILY BE ADOPTED?
Within the pharmaceutical industry alone, clinical/drug safety activities cost over $21 billion annually, a figure that continues to rise as the number of approved medicinal products/vaccines and volume of real-world data grows. With so much information available and the need to better understand and prevent adverse events and minimise risks, the industry feels the need to automate repetitive tasks and keep core activities in the capable hands of healthcare professionals responsible for pharmacovigilance. We are going to focus on medical literature monitoring and how artificial intelligence models developed with pharmacovigilance professionals can help tackling the issue of increasingly high volumes of data
Nicole Baker, *CEO,* **Biologit**

10.30am Morning break: Coffee and cake networking

11.00am **CASE STUDY:** HYBRID APPROACH FOR SIGNAL DETECTION & MANAGEMENT SYSTEMS
UCB is using an off-the-shelf signal detection & management system but added on top of it an in-house open-source analytics and visualization system. Lionel will describe the rationale behind it, how it went and what perspectives it offers
Lionel van Holle, *Safety Surveillance lead,* **UCB**

11.30am **A PANEL DISCUSSION:** SIGNAL DETECTION ADVANCEMENTS IN LARGE AND SMALL BIOPHARMA
Lionell van Holle, *Safety Surveillance lead,* **UCB**
Dimitrios Zampatis, *Global Program Safety Lead, Patient Safety BioPharma,* **Novartis**
Zina Sadeq, *Director Regional Pharmacovigilance,* **Amicus therapeutics**

12.00pm LUNCH BREAK

CURRENT ISSUES SESSION

13.00pm **KEYNOTE:** AGGREGATE REPORTS AND ASSESSMENTS- RECENT APPROACHES
Prashant Kathuria, *Global Safety Lead contractor,* **NHS foundation UK**

13.30pm **PANEL DISCUSSION:** DATA FLOWS IN RWE & DRUG SAFETY: DATA-BASED FUTURE OF THE INDUSTRY
Ivanna Mikhailovna Rosendal, *Senior Director & IT Business partner,* **Ascendis Pharma**
Petar Gjorgajev, *Safety risk Lead & Medical Director,* **Pfizer**
Philip Eichorn, *Global Head of Drug Safety,* **Amryt Pharma**

2.00pm **KEYNOTE:** LOOKING AT IMPORTANCE OF PATIENT EXPERIENCE AS ELEVATING FACTOR FOR QUALITY & SAFETY
Mark Duman, *Patient Experience Officer*

2.30pm **KEYNOTE:** ROAD TO SUCCESS IN QPPV ENVIRONMENT- CHALLENGES OF DRUG SAFETY JOBS IN MULTILEVEL ORGANIZATIONS. SOFT SKILLS SURVIVAL KIT
Sue Rees, *Senior Pharmacovigilance lecturer & former QPPV,* **University of Hertfordshire**

3.00 pm NETWORKING BREAK

3.30pm **PANEL DISCUSSION:** PATIENT INVOLVEMENT IN DRUG SAFETY- WHY PHARMA NEEDS TO CHANGE?
Mark Duman, *Patient Experience Officer*
Tiberius Pereira, *Patient safety advocate,* **Patients for Patient Safety**
Stéphanie-Tcherny Lessenot, *Global Head of benefit-risk evaluation,* **Sanofi**
Hillary Thomas, *partner in healthcare,* **PA consulting**

4.00pm **OPEN ROUNDTABLE DISCUSSION:** COMING BACK TO MOST IMPORTANT TOPICS OF THE DAY 1 & ANSWERING ALL REMINING SLI.DO QUESTIONS

Day 2

BENEFIT-RISK ASSESSMENT SESSION

9:00 am **CASE STUDY:** MEASURING THE EFFECTIVENESS OF RISK MINIMISATION MEASURES (RMM) IN THE EU
Rohan Mane, *Director of Safety Risk management,* **Pfizer**

9.30am **KEYNOTE:** ADVANCEMENTS IN PATIENT CENTRICITY IN BENEFIT-RISK EVALUATION
The presentation will embrace recent changes in the regulatory landscape as well as improved use of patient experience data for Benefit-Risk assessment.
As we are heading 2023 "post covid" era of healthcare, new trends and perspectives for the future in benefit-risk assessment will be thoroughly discussed
Stéphanie-Tcherny Lessenot, *Global Head of benefit-risk evaluation,* **Sanofi**

10.00am **PANEL DISCUSSION:** BENEFIT-RISK ASSESSMENT TOOLS & APPROACHES
The industry of Drug Safety solutions is currently exhibiting a growth rate (CAGR) of 6.60% in the next 5 years. Listening to the voice of pharmaceutical Benefit-risk assessment managers, which automation & risk measurement software improves processes and positively impacts benefit-risk assessment workflows? What is the role of a patient?
Moderator: Pryia Singhal, Executive VP, Biogen
Stéphanie-Tcherny Lessenot, *Global Head of benefit-risk evaluation,* **Sanofi**
Petar Gjorgajev, *Safety risk Lead & Medical Director,* **Pfizer**
Emanuel Lohrman, *Lead Safety Physician,* **Otsuka Pharmaceuticals**
Rohan Mane, *Director of Safety Risk management,* **Pfizer**

10.30am NETWORKING BREAK

11:00 **KEYNOTE:** BENEFIT-RISK ASSESSMENT CHALLENGES
Emanuel Lohrman, *Lead Safety Physician,* **Otsuka Pharmaceuticals**

REGULATION & COMPLIANCE SESSION

11.30am **KEYNOTE:** DRUG SAFETY IN ONCOLOGY: CONSEQUENCES OF ACCELERATED ASSESSMENT IN EMA REGULATED MARKETS AND UK
In Europe, accelerated assessments in oncology are on a steep rise, but only 43% of molecules will ultimately receive regular approval! Is patient safety in a majority of those drugs compromised? What are the best practices for mitigating such risks?
Leonardo Pereira, *Clinical Safety Director,* **Roche**

12.00pm LUNCH BREAK

1.00pm **CASE STUDY:** ADR SELECTION FOR YOUR FIRST RISK MANAGEMENT PLAN
Henk Johan Streefkerk, *Chief Medical & Safety Officer,* **Cell Prothera**

1.30pm **CASE STUDY:** SURVIVING PHARMACOVIGILANCE AUDIT: SURVIVAL KIT FOR A SMALL BIOTECH COMPANY
A pharmacovigilance audit is one of the most important and stressful periods for pharmaceutical organizations. When facilitated by a vendor, a significant stress burden might fall, while other problems emerge. As the presence of vendor in the process significantly raises the costs of internal audit, time management and sufficient preparedness become a priority. What really to expect? How do deal with usual problems while cooperating with audit team and vendor?
Zina Sadeq, *Director regional Pharmacovigilance,* **Amicus therapeutics**

2.00pm **KEYNOTE:** LOOKING AT COMPLIANCE: WRITING SOLID SOP
Writing Standard Operating Procedures (SOPs) can initially seem daunting, but it's a vital skill for any company looking to streamline its processes and maximize efficiency. SOPs are the backbone of any well-oiled organization, providing a clear and concise set of instructions for employees to follow. Discover the art of writing Standard Operating and how to strike a balance between thoroughness and simplicity and take your business to the next level!
Erika Barbarossie, *Associated director compliance,* **Gilead Sciences**

2.30pm **Life cycle management of pharmacovigilance agreements**
As a Marketing Authorization Holder, your company must be sure to have a reliable partner who will watch your back over any hindrance and mistake, that will cost you a lot of time and resources, once the day of judgment will come. How does cooperation look like from the beginning to the end?
Azza Elgharably, *Associate director Patient safety,* **Astrazeneca**

3.00pm NETWORKING BREAK

Day 2

3.30pm **PANEL DISCUSSION:** FUTURE OF TALENT IN THE DRUG SAFETY DEPARTMENT

Impacts of pandemic disruption on work routine of drug safety professionals

- Change of teams structure due to automation
- Attrition rates in pharma and their consequences
- Generation Z entering the workforce
- Obsolescence of current skillset
- Employee education: what is the healthy amount?

PR of the pharma industry, what can we improve in the field of industry attractiveness for future workforce?

Philip Eichorn, *Global Head of Drug Safety,* **Amryt Pharma**
Zina Sadeq, *Director regional Pharmacovigilance,* **Amicus therapeutics**
Nicole Baker, *CEO,* **Biologit**

4:00pm **CLOSING PANEL DISCUSSION OF SUMMIT:** MAJOR TAKEAWAYS FROM OUR 2-DAY JOURNEY

As in other events and aspects of our life, a proper closure is important for our minds to move on.

After a staggering amount of information and ideas being discussed in the last two days, it is healthy to summarise key takeaways, make useful notes, make a final exchange of ideas, harvest some business cards, and make both short & long-term goals. In a more informal and open atmosphere, our team along with the chairman and speakers will facilitate this pleasant, yet crucial experience.

Chairman will introduce the most pressing questions voted by the audience via Sli.do, which were raised during the 2-day conference. The conference will end as an interactive discussion

2023 Future of Pharmacovigilance World at a Glance

1. March 8 - 9 London, UK
   9th Global Pharmacovigilance Forum
2. April 25 - 26 Philadelphia, PA, United States
   American Pharma and Biotech Advancements in Drug Safety Summit
3. May 2 - 3 Chicago, IL, United States
   American Medical Device Safety Management Conference
4. June 13 - 14 Berlin, Germany
   European Medical Device Safety & Innovation Conference
5. September 5 - 6 Singapore
   APAC Drug Safety Pharma & Biotech Summit
6. September 12 - 13 Sydney, Australia
   Australian Risk management & Drug safety innovation Summit
7. October 3 - 4 Mumbai, India
   Global Drug Safety & PV Outsourcing Summit
8. October 10 - 11 Basel, Switzerland
   10th Annual European Drug Safety Pharma & Biotech Conference
9. October 24 - 25 Boston, MA, United States
   Global Pharma & Biotech Drug Safety Conference
10. November 7 - 8 San Francisco, CA, United States
    17th American Drug Safety Biotech & Pharma Conference

Sponsorship

Exhibiting:

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2022 PPM 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.

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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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