Future of Pharmacovigilance World Tour 2023

American Pharma and Biotech Advancements in Drug Safety Summit

September 13 - 14, 2023, Philadelphia, PA, United States

WHY? SUMMITS

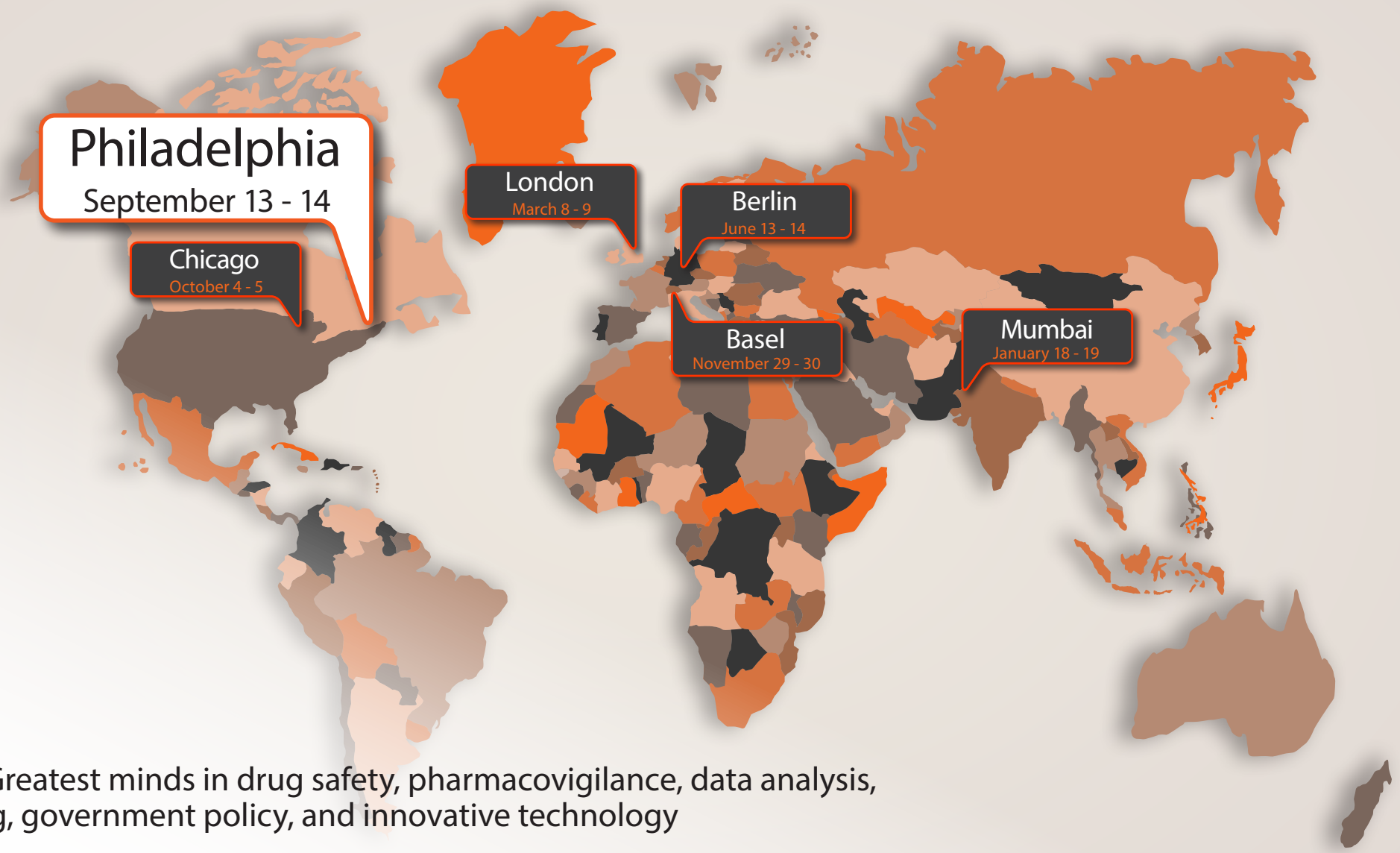
"ALWAYS BE CURIOUS"

Gold Sponsors

PREVAIL INFOWORKS

PharSafer®

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

Event format

Key topics

- ✓ PV in Emerging Economies
- ✓ Safety Risk Management
- ✓ PV and Outsourcing
- ✓ Data Management and Risk Management
- ✓ AI in Signal Detection
- ✓ Electronic Healthcare Data
- ✓ Patient Centricity
- ✓ Crisis Communication in medicines recall
- ✓ RPA and AI Implementation
- ✓ Predictive Drug Safety
- ✓ Audits & Inspections

... and more!

Why is this conference special?

We are trying to create a platform for opening new topics or troubling issues and create a safe space for a stimulating, inspiring, and fruitfull discussion about current trends and challenges in the field of Pharmacovigilance and drug safety.

What to expect?

- ✓ 2 day-long conference filled with the TOP industry speakers
- ✓ Interesting Keynotes, Case Studies, and Panel Discussions
- ✓ Workshops and Roundtables for a deeper dive into important topics
- ✓ Creative and inspiring platform for fruitfull discussion
- ✓ Sharing new ideas and building strong connections
- ✓ Fun and icebreaker social events every evening

Don´t miss this great opportunity to be part of this event, to connect with the specialist in the field and share your ideas and insights! !

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

Speakers and Panelists

PREVAIL INFOWORKS

Angela Overton

Pharmacovigilance Manager
Prevail InfoWorks

zoetis

Anthony Bailey

Director, Internal Audit
Zoetis

Jazz Pharmaceuticals

Dawn Mucci

Senior Manager, PV Alliance Management
Jazz Pharmaceuticals

Dennis Vargo

VMD FACP, pharmacovigilance consultant

PharSafer
Specialists in Global Clinical and Post Marketing Drug Safety

Graeme Ladds

CEO & Owner
Pharsafer

sanofi

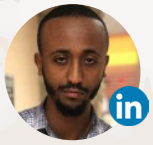
Julie Miller

Deputy Director, Audit and Inspection Readiness Manager, PV Quality - MCCQ
Sanofi

inozyme pharma

Kapil Bhutada

Senior Director, Quality and Compliance
Inozyme Pharma



Y-mAbs Therapeutics, Inc.

Kidus Mengistu

Pharmacovigilance Specialist
Y-mAbs Therapeutics

ARCUS BIOSCIENCES

Lina Ogbu
Medical Director Drug Safety & Pharmacovigilance,
Arcus biosciences

GSK

Michael Glaser
Safety Innovation Technology Director
GSK

Jazz Pharmaceuticals

Oleg Zvenigorodsky
Director, Medical Safety
Jazz Pharmaceuticals

almirall

Raidah Salem
Medical Affairs Manager
Almirall

ultragenyx pharmaceutical

Sandra Raff
Senior Director, Drug Safety and Pharmacovigilance
Ultragenyx Pharmaceuticals

blue spark

Sarah Bradley
Clinical Implementation Specialist
Blue Spark Technologies

novo nordisk®

Vanessa Roknic
Digital Transformation & Innovation Director
Novo Nordisk

Otsuka

Vincent D'Esposito
Associate Director, Pharmacovigilance Training
Otsuka Pharmaceutical Companies

Night before the event – MEET & GREET

Welcome to our event! We are so honored and grateful to have you with us! Come and join us for some drinks, where you will be able to do an early bird registration along with some rst hand networking! All the delegates will start arriving and we will all have a chance to get to know one another - the sooner the better. Drinks, conversations, hand shakes, smiles, hugs, whether with your old or new friends from the industry - everyone is welcome!

Day 1

9.00am **OPENING REMARKS & ICEBREAKER**

Start the conference on a positive note with warm welcoming remarks from our distinguished hosts. Dive into an engaging icebreaker activity designed to foster connections, spark conversations, and set the tone for a collaborative and productive event. Get ready to break the ice and kick off our conference with energy and enthusiasm!

Data Management & Signal Detection

9.30am **PANEL DISCUSSION:** Integrating Data Sources into a Comprehensive Signal Detection System

- Getting the best possible data
- Leveraging data beyond spontaneous reports
- Real world data or big data - What role do they play?
- Integrating social media in daily lives of PV scientists

Dennis Vargo, *MD FACP, pharmacovigilance consultant*
Oleg Zvenigorodsky, *Director, Medical Safety,* **Jazz Pharmaceuticals**

10.00am COFFEE & NETWORKING

10.30am **CASE STUDY:** Unintentional Adverse Event Generation from Market Research

Dawn Mucci, *Senior Manager, PV Alliance Management,* **Jazz Pharmaceuticals**

11.00am **RESERVED PRESENTATION: The Outcomes of the Integrated Safety from the Point of View of Clinical Teams Who Need to Dose Escalate and Meet Other Milestones Faster**

Angela Overton, *Pharmacovigilance Manager,* **Prevail**
Dr. Gerald Klein, *Principal,* **MedSurgPI**

Safety Risk Management

11.30am **PANEL DISCUSSION:** New Directions in Benefit Risk Assessments and Risk Management

- Determine the best way to work across organizational and geographical boundaries to develop and implement effective strategies for managing risk
- Develop a structured approach to benefit-risk assessments

Dennis Vargo, *MD FACP, pharmacovigilance consultant*
Kapil Bhutada, *Senior Director, Quality and Compliance,* **Inozyme Pharma**

12.00pm LUNCH BREAK

1.00pm **CASE STUDY:** Risk Measurement Tools and Methods Assessing Effectiveness of Risk Management Plans

- Development of optimal risk management strategy, what risks to mitigate with routine vs additional risk minimisation measures
- How to develop risk minimisation measures that are adequate, balanced, and feasible, and do not create an undue burden to the healthcare system
- How to implement and evaluate risk minimisation measures globally
- Recognizing that the evaluation of the effectiveness of risk minimisation measures is an evolving area of medical sciences with a need for further development of methods and harmonized approaches
- How to identify primary tools for measuring effectiveness of risk minimisation, criteria for when (and how deeply) to assess effectiveness of risk minimisation measures and how to define what constitutes success in risk minimisation
- Recent examples of risk management effectiveness

Kapil Bhutada, *Senior Director, Quality and Compliance,* **Inozyme Pharma**

Audits & Inspection

1.30pm **CASE STUDY:** Impact of the COVID-19 Pandemic on Pharmacovigilance Audits & Inspections

The COVID-19 pandemic impacted the way Pharmacovigilance (PV) audits and inspections are conducted. This has required flexibility on the part of audit and inspection readiness teams and the development of new ways of working. This case study will present how the pandemic impacted the conduct of PV audits and inspections, as well as other types of audits and inspections where PV may be a contributor (GMP, GCP, MDSAP, etc).

Julie Miller, *Deputy Director, Audit and Inspection Readiness Manager, PV Quality - MCCQ,* **Sanofi**

2.00pm **PANEL DISCUSSION:** Navigating Audits and Inspections in Pharmacovigilance

- Gain insights into effective strategies for audit and inspection readiness.
- Share practical tips on document management, staff training, and communication strategies.
- Delve into the key stages of an audit or inspection, from the initial notification to the final report.
- Discuss common challenges and success stories in managing on-site inspections and remote assessments.

Julie Miller, *Deputy Director, Audit and Inspection Readiness Manager, PV Quality - MCCQ,* **Sanofi**
Anthony Bailey, *Director, Internal Audit,* **Zoetis**

Day 1

2.30pm COFFEE & NETWORKING

Roundtables (60min)

Choose one of these interactive activities to fully engage and to work closely with other participants to share your insightful ideas! All roundtable discussion topics are to run simultaneously TWICE IN A ROW

3.00pm **ROUNDTABLE 1:** To Outsource or not to Outsource

- Case studies of successful long-term outsourcing
- In-house solutions as a source of real-life learning
- Steering internal team and external team towards common goal
- IT support of drug safety department: factors influencing successful cooperations

Anthony Bailey, *Director, Internal Audit,* **Zoetis**

3.00pm **ROUNDTABLE 2:** Benefit-Risk Assessment Challenges

- Which automation & risk measurement software improves processes and positively impacts benefit-risk assessment workflows?
- What is the role of a patient?

Kapil Bhutada, *Senior Director, Quality and Compliance,* **Inozyme Pharma**

4.30pm THAT´S A WRAP!
Closing Remarks and Informal Open Floor Discussion

Day 2

Proactive PV approaches and business challenges

9.00am **NETWORKING DISCUSSION:** Engaging Q&A Session on Key Industry Topics

Join us for an interactive icebreaker session at our conference, where we delve into the current state of things and explore future possibilities. Our Q&A session is designed to spark insightful conversations and exchange valuable insights. Here, you'll have the opportunity to discuss topics such as workplace improvements, professional learning, pharmacovigilance processes, patient safety challenges, and the most influential books that have shaped your perspective. This engaging activity will not only foster connections but also ignite innovative thinking as we navigate the path forward together.

9.30am **PANEL DISCUSSION:** Transparency and Patient Engagement - Proactive Pharmacovigilance Approaches

- Do we correctly communicate the risks of medicines and vaccines to the general public? Focus on making patients' aware of all adverse reactions and on communicating risk minimization measures.
- Pharmacovigilance approaches and patient centric innovations.
- Use of technology for Patient Engagement.
- Active engagement and capacity building with patient communities and healthcare professional bodies to support impact research

Sarah Bradley, *Clinical Implementation Specialist,* **Blue Spark Technologies**
Raidah Salem, *Medical Affairs Manager,* **Almirall**

10.00am COFFEE & NETWORKING

Robotic Process Automation and AI Implementation: From Science Fiction to Business Facts

10.30am **PANEL DISCUSSION:** Artificial Intelligence (AI) and Robotic Process Automation (RPA) Applications in Pharmacovigilance

- RPA and AI implementation in audit, inspection and reporting in product safety and PV area
- Myths and realities of emerging technologies: RPA, AI, Machine Learning
- How to efficiently handle the increasing regulatory burden using RPA/AI techniques
- How to leverage AI and advanced data analytics for effective PV strategies
- Success strategies to adopt and pitfalls to avoid in implementing emerging technologies

Michael Glaser, *Safety Innovation Technology Director,* **GSK**
Oleg Zvenigorodsky, *Director, Medical Safety,* **Jazz Pharmaceuticals**

11.00am **RESERVED PRESENTATION: Automated Safety Case Processing – Are We There Yet?**

- Explore the current industry climate regarding ADR reporting and pharmacovigilance activities
- Understand the challenges associated with rising demands for traditional methods of reporting ADRs
- 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
- Acknowledge how automation and innovative software solutions can improve patient safety and ensure greater levels of compliance with global regulatory requirements

Graeme Ladds, *CEO & Owner,* **PharSafer**

11.30am **CASE STUDY:** Best practises from pharmacovigilance training – how to implement successful training program into your company

Vincent D'Esposito, *Associate Director, Pharmacovigilance Training,* **Otsuka Pharmaceutical Companies**

12.00pm LUNCH BREAK

Day 2

PV safety & strategies

1.00pm **KEYNOTE FOLLOWED BY A PANEL DISCUSSION:** Proactive and Innovative Pharmacovigilance Approaches

- Advances in social media listening
- Evaluating predictive drug safety technologies
- The power of patient communities
- Exploring computational and mathematical models with aspects of applicability

Presenter:
Raidah Salem, *Medical Affairs Manager,* **Almirall**
Panelists:
Dennis Vargo, *MD FACP, pharmacovigilance consultant*
Anthony Bailey, *Director, Internal Audit,* **Zoetis**
Raidah Salem, *Medical Affairs Manager,* **Almirall**

2.00pm COFFEE & NETWORKING

ROUNDTABLES (60min)

Choose one of these interactive activities to fully engage and to work closely with other participants to share your insightful ideas! All roundtable discussion topics are to run simultaneously TWICE IN A ROW

2.30pm **ROUND TABLE 1:** 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

Michael Glaser, *Safety Innovation Technology Director,* **GSK**

2.30pm **ROUND TABLE 2:** Pharmacovigilance Training

Vincent D'Esposito, *Associate Director, Pharmacovigilance Training,* **Otsuka Pharmaceutical Companies**

3.30pm THAT´S A WRAP!
Closing Remarks and Informal Open Floor Discussion

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 November 29 - 30 Basel, Switzerland
10th Annual European Drug Safety Pharma & Biotech Conference

5 January 18 - 19 Mumbai, India
Global Drug Safety & PV Outsourcing Summit

6 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.

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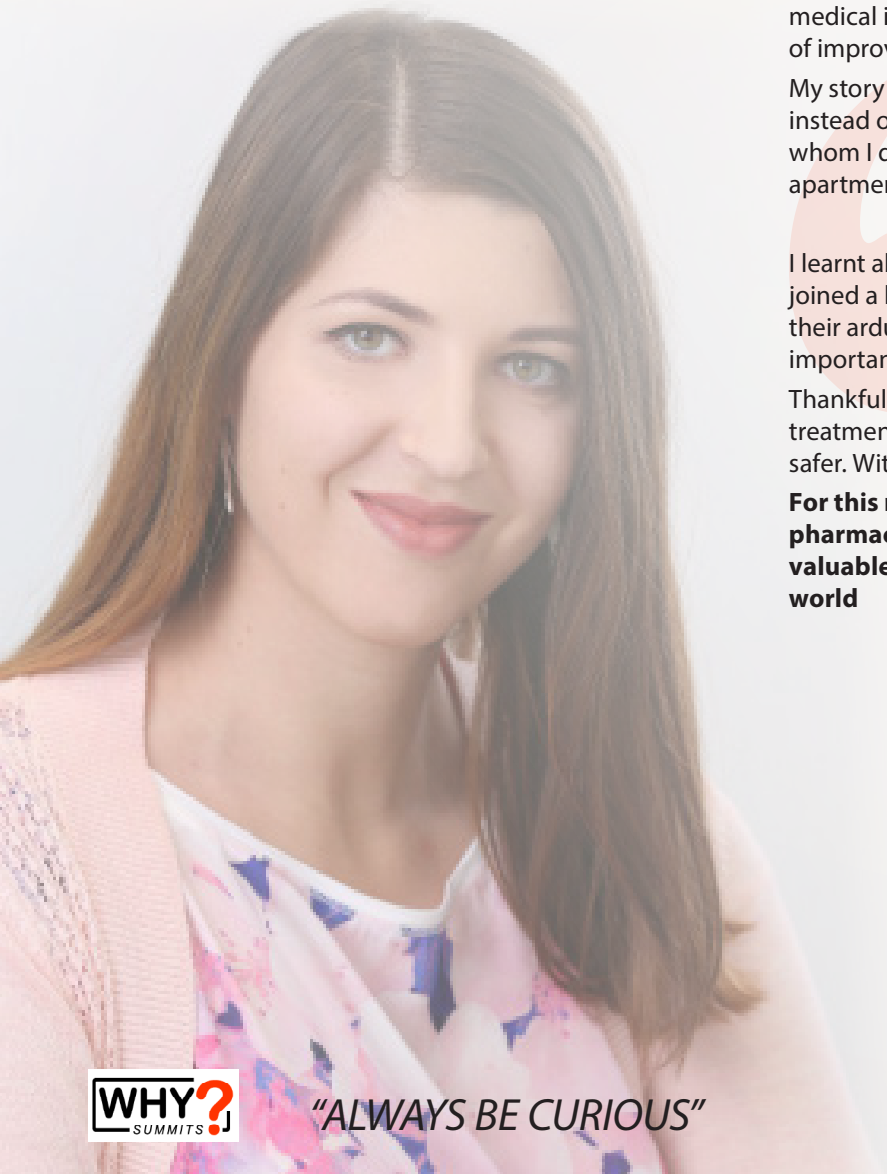
WHY have we decided to create the World Tour of pharmaceutical summits focused on drug safety?



Pharmacovigilance started about 170 years ago, at that time it was just letters written by clinicians to publishers of important and famous scientific journals, whilst today we have modern and ultra-structured electronic registries. The medical industry is evolving rapidly but pharmacovigilance can still be considered a young science with many possibilities of improvement. Let me show you a personal example:

My story begins long before my birth. I come from a family, where, unlike in other families, it was wished to have a daughter instead of a son. We carry in our blood hemophilia genes (bleeding disorder), that are only harmful to boys. My grandfather, whom I do not even remember, suffered from a severe stage of hemophilia, thus he was not able to move or leave his apartment. The treatment of this disease was not very efficient back then. Nor safe. He died when I was just 2 years old.

I learnt about our family history when I turned 15. Since then I devoted myself to studying the disease as much as I could. I joined a hemophilia summer camp as a kid´s animator. It was both joyful to see their enthusiasm, and heart-breaking to see their arduous treatment – getting a shot of medication intravenously every two days. This experience made me realize how important it is to control the quality of treatment.

Thankfully, the treatment has improved marvelously in the past decade (latest news claim it to be enough to get the treatment once in 2 years, not in 2 days!) It makes me, and many others, relieved knowing my children's treatment will be safer. With rapidly improving drug and device safety I am really looking forward to seeing the world my children will live in.

For this reason – to contribute to making the world a safer place, we decided to create a network of pharmacovigilance professionals to help them in their journey and provide them with space to share their valuable ideas and reach their common goal – creating the safest drugs and devices to help patients all over the world

Simona

Future of Pharmacovigilance World Tour 2023

Simona Starinska

simona.starinska@whysummits.com

Balazs Kovacs

balazs@whysummits.com

NEXT STOPS:

BASEL, SWITZERLAND
NOV 2023

LONDON, UK
MAR 2024

PHILADELPHIA, PA, USA
SEP 2024