WHY? SUMMITS

Updated: 12 March, 2025
for the latest programe update, please download agenda on conference website

June 5 - 6
2025

FUTURE OF PHARMACOVIGILANCE WORLD TOUR
WORLD DRUG SAFETY SUMMIT BASEL

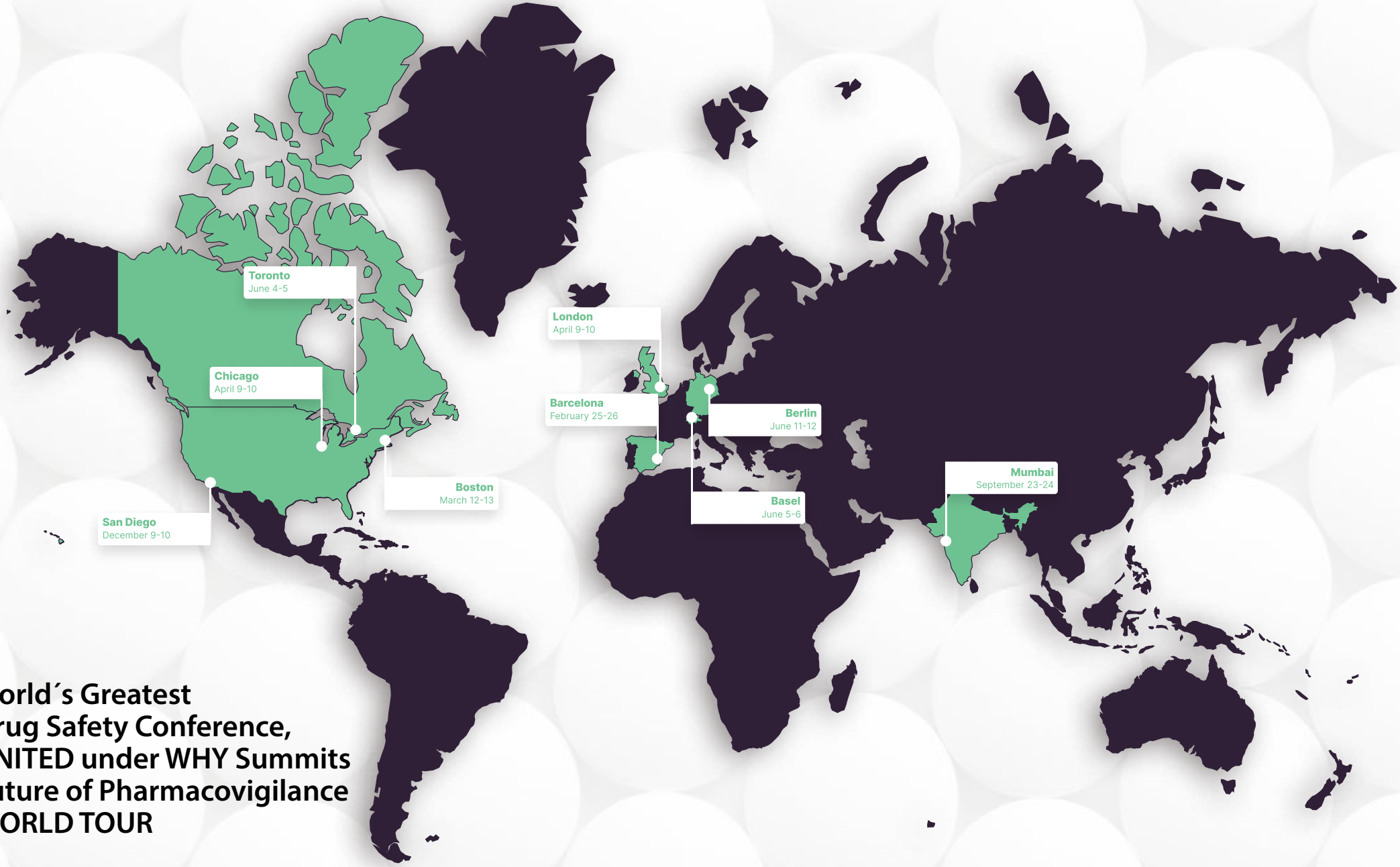
World's greatest minds in drug safety, pharmacovigilance, data analysis, reporting, government policy, and innovative technology.

Gold Sponsor: ALWIS

Silver Sponsor: IQVIA TECHNOLOGIES, HERAX Life Science, biologit

Authorities joining the summit: swissmedic

2025 Pharmacovigilance Summits Worldwide



World´s Greatest Drug Safety Conference, UNITED under WHY Summits Future of Pharmacovigilance WORLD TOUR

Future of Pharmacovigilance

Our most prestigious European event, concluding 2024 World Tour

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 of meeting regularly on the next stops of our world tour

Always 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:

Real world implementation of Patient-centric Drug Safety strategies

Low-end digital disruptions in PV: improving lives while cutting costs

Advancements in Benefit-Risk assessment and aRMMs

Post Trial Access and Clinical Safety

Multidepartment collaboration towards better safety and commercial outcomes

Regulatory Affairs in Drug Safety

Innovative approach in signal detection & reporting automation

Role of Pharmacovigilance in data-driven pharmaceutical business

Comprehensive compliance updates in European Pharmaceutical Safety

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

"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

"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

Industry Pioneers Attending From

Meet the first onboarded speakers to 2024 edition:

In the Chair

Erika Barbarosie
Associate Director - Compliance
Gilead

Shaloo Pandhi
Global Head Patient safety
Sandoz

Sanjeev Srivastav
Signal Management Lead
BionTech

Michael von Forstner
Head of Safety Science
SOBI

Sibel Guerler
Head Strategy & Safety Evolution
BMS

Nicolas Perez
Data Scientist
SwissMedic

Julien Castera
Senior Director, Global Risk Management & Safety Surveillance
Incyte

Petros Mavrogenis
Head Vigilance Process Excellence
Novartis

Yvonne Nanciu
Pharmacovigilance Country Head
Bayer

Luvanka Hanxhari
Global RMP Lead & Deputy of Head RMP Office
Novartis

Santanu Mukhopadhyay
Head of Global Patient Safety
Merck

Adriano Galati
Digital Safety Director Pharmacovigilance & Scientific Development
Roche

Alejandra Padovani
Medical Safety Director Gene Therapy
Uniqure

Dimitrios Zampatis
Global Program Safety Lead
Sandoz

Sabine Poltermann
Country Head Patient Safety
BMS

Lisa Stagi
Patient Safety Country Cluser Lead
Roche

Minhaj Obeidullah
Head of Compliance & Risk Management
Novartis

Antje Baumgarten
Senior Global System Auditor
Bayer HealthCare

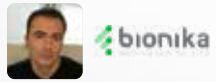
Gurpreet Singh
Vice president Integrated Safety
IQVIA

Marija Simic Koumoutsaris
Director Medical Safety
Sandoz

Jost Leemhuis
Safety Science partner & Global Business Lead
Roche

Elena Radu
Senior Global Drug Safety Physician
Basilea Pharmaceuticals

Juergen Dietrich
Senior Data Lead Scientist
Bayer



Marjan Dzeparoski
PV Manager & University lecturer
Bionika

Agenda

Day1

8:30 MORNING REGISTRATION AND EARLY BIRDS NETWORKING COFFEE

SUMMIT OPENING & STRATEGIC ROLE OF PV

9:00 OFFICIAL START OF WORLD DRUG SAFETY SUMMIT WITH OPENING REMARKS OF THE CHAIRMAN

KEYNOTE: STRATEGIC ROLE OF PHARMACOVIGILANCE IN DATA-DRIVEN PHARMACEUTICAL INDUSTRY
Opening keynote highlighting the critical role of pharmacovigilance in leveraging data, namely RWE & RWD to drive innovation and ensure drug safety in the pharmaceutical industry.
Michael Forstner, *Head of Safety Science,* **SOBI**

9:30 **RESERVED PRESENTATION:** FUTURE OF PHARMACOVIGILANCE
Gurpreet Singh, *Vice president Integrated Safety,* **IQVIA**

10:00 **OPENING TOWNHALL DISCUSSION:** CONSEQUENCES OF MAJOR RESTRUCTURING IN EUROPEAN PHARMA ON DRUG SAFETY DEPARTMENTS
Opening summit panel discussion will focus on the impacts of significant restructuring in the European pharmaceutical sector on drug safety departments and strategies to maintain safety standards. Challenges of working global while not losing local touch.

10:30 MORNING BREAK: COFFEE, CAKE & NETWORKING

19:30
EVENING BEFORE SUMMIT - MEET & GREET
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.

EXPLORING CLINICAL SAFETY AND POST-TRIAL ACCESS

11:00 **KEYNOTE:** POST TRIAL ACCESS (PTA) PROGRAMS AND PATIENT SAFETY
- current regulations on PTA
- implementation challenges
- safety standards
- signal, risk and benefit-risk assessment with PTA.

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

11:30 **PANEL DISCUSSION:** BRIDGING INSIGHTS: SYNERGIZING POST-MARKET PHARMACOVIGILANCE AND CLINICAL SAFETY
Enhancing communication between pharmacovigilance and clinical safety teams. Sharing best practices and experiences. Integrating data for improved safety profiles. Exploring regulatory alignment challenges.

12:00 LUNCH BREAK

TOUCHING BASE ON ADVANTAGES OF PATIENT-CENTRIC PV

13:00 **KEYNOTE:** ADVANCEMENTS IN VACCINE SAFETY: LANDSCAPE FOR PERSONALISED VACCINE
Evaluating the current state of patient and safety-centric practices in major pharmaceutical companies. Identifying opportunities for enhancing patient engagement and safety protocols in rapidly advancing landscape of personalized vaccines.
Sanjeev Srivastav, *Signal Management Lead,* **BioNTech**

13:30 **RESERVED CASE STUDY:** TECHNOLOGY CREATING NEW BRIDGES BETWEEN PATIENTS, HCPS AND MARKET AUTHORISATION HOLDER
Showcasing how innovative technologies are connecting patients, healthcare providers, and market authorization holders. Highlighting successful implementations and their impact on patient safety and communication.

Day1

14:00 **PANEL DISCUSSION:** NAVIGATING COMPLEXITIES IN DATA MANAGEMENT - TECHNOLOGY, REEDUCATION, IMPLEMENTATION

Panel of senior speakers will address the challenges of managing complex data in pharmacovigilance with a focus on technology, education, and implementation strategies. Discussing practical solutions and best practices from industry leading companies and tech providers.

14:30 COFFEE & CAKE BREAK

15:00 **CASE STUDY:** LOW-END DIGITAL DISRUPTIONS IN PV: IMPROVING LIVES WHILE CUTTING COSTS

So-called low-end digital disruption sumps up innovations are transforming pharmacovigilance in era of ever decreasing budgets. Simple real world use case demonstration on ways these disruptions enhance patient outcomes while reducing operational costs.

Luvanka Hanxhari, *Global RMP Lead & Deputy of Head RMP Office,* **Novartis**

15:30 **PANEL DISCUSSION:** EDUCATION OF SAFETY PROFESSIONALS AND FUTURE OF PV JOBS– DEMAND FOR DATA-ORIENTED AND AGILE MINDSET

The ever-evolving educational requirements for pharmacovigilance professionals in a rapidly changing landscape. This panel will focus on the growing demand for data-oriented skills and an agile mindset, addressing how educational institutions and industry training programs can adapt. Insights will be shared on how to prepare the next generation of safety professionals to meet future challenges and opportunities in the field.

16:00 **KEYNOTE:** LEARNING AMONG DEPARTMENTS: UTILIZATION OF MARKETING, FIELD FORCE, OMNICHANNEL AND SOCIAL MEDIA IN DAILY LIFE OF PV PROFESSIONAL

Keynote examining how pharmacovigilance professionals can leverage marketing, field force, omnichannel strategies, and social media. Highlighting practical applications and benefits in daily operations.

16.30 **PANEL DISCUSSION:** SHARING EXPERIENCE AMONG PHARMACEUTICAL STAKEHOLDERS – PATIENT EXPERIENCE AS A CUSTOMER EXPERIENCE

In the final panel of the day explore how pharmaceutical stakeholders can use patient data and real-world field experiences to enhance customer satisfaction and safety. Focus will be into integrating patient feedback into pharmacovigilance practices, as well as experience sharing from field work in PV.

Day2

ARTIFICIAL INTELLIGENCE, SIGNAL DETECTION & AUTOMATION

9:00 **KEYNOTE:** AI IN PATIENT SAFETY – AN HONEST APPRAISAL
Examining the role of artificial intelligence in filtering valuable signals from the overwhelming influx of pharmacovigilance data. Highlighting practical applications and benefits of AI in improving drug safety monitoring and decision-making processes, and provide honest review of current application in large pharmaceutical companies.
Sibel Guerler, *Head Strategy & Safety Evolution,* **BMS**

9:30 **RESERVED KEYNOTE:** VENDOR MANAGEMENT IN SIGNAL DETECTION: REAL WORLD LEARNING ON EFFICIENT COOPERATION FOR OUTSOURCING SIGNAL MANAGEMENT
Discussing effective strategies for managing vendors in the signal detection process. Sharing real-world experiences and best practices for outsourcing signal management to enhance efficiency and collaboration.

10:00 **PANEL DISCUSSION:** AI AT THE HELM: CHARTING THE COURSE FOR PHARMACOVIGILANCE'S FUTURE – CROSS INDUSTRY LEARNING
Focusing on how AI is shaping the future of pharmacovigilance through cross-industry insights. Panelists will discuss the implementation of AI technologies and their potential to revolutionize drug safety practices.

10:30 NETWORKING COFFEE & CAKE BREAK

PIONEERING RISK MANAGEMENT PLANS and aRMMs

11:00 **CASE STUDY:** SHARING EXPERIENCE IN RMP STRATEGIES DEVELOPMENT
Presenting a detailed case study on creating risk management plans, Highlighting the challenges and solutions in ensuring patient safety for cutting-edge treatments.
Julien Castera, *Senior Director, Global Risk Management & Safety Surveillance,* **Incyte**

11:30 **PANEL DISCUSSION:** NAVIGATING UNCERTAINTY: INNOVATIONS AND INSIGHTS IN RISK MANAGEMENT PLANS AND ADVANCED RISK MINIMIZATION MEASURES (ARMMS)
Discussing the latest innovations and insights in risk management plans and advanced risk minimization measures. Panelists will share their experiences in addressing uncertainties and improving patient safety.

12:00 LUNCH BREAK

COMPLIANCE IN PV & REGULATORY AFFAIRS

13:00 **KEYNOTE:** NAVIGATING REGULATORY INTELLIGENCE CHALLENGES FOR SMALL PHARMA
Providing strategies for navigating complex regulatory landscapes in pharmacovigilance. Emphasizing best practices for maintaining compliance and ensuring effective safety monitoring in context of small and early stage pharmaceutical players.

13:30 **CASE STUDY:** GVP INSPECIONS SURVIVAL KIT: UNVEILING THE GOOD, THE BAD AND THE DATA-FUL
Erika Barbarosie, *Associate Director Compliance,* **Gilead**

14:00 **PANEL DISCUSSION:** ADDRESSING COMPLIANCE CHALLENGES IN GLOBAL PHARMACOVIGILANCE: A REGULATORY PERSPECTIVE
Examining the compliance challenges faced by global pharmacovigilance teams from a regulatory standpoint. Panelists will discuss strategies for overcoming these challenges and ensuring consistent safety practices worldwide.

14:30 NETWORKING COFFEE BREAK

COMMUNICATION OF SAFETY INFORMATION – CREATE A VOICE TO SAVE LIVES

15:00 **KEYNOTE:** THE POWER OF COMMUNICATION: EFFECTIVELY TRANSLATING PHARMACOVIGILANCE DATA INTO ACTIONABLE INFORMATION
Highlighting the importance of effective communication in pharmacovigilance. Discussing methods to translate complex data into clear, actionable information that can improve patient safety and regulatory compliance.

15:30 **TOWNHALL DISCUSSION:** BUILDING TRUST THOUGH PV: BUILDING STAKEHOLDER RELATIONSHIPS AND PROMOTING TRANSPARENCY THROUGH SAFETY COMMUNICATIONS
Focusing on the importance of engaging stakeholders through transparent safety communications. Sharing approaches to build trust and enhance collaboration among all parties involved in drug safety.

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 networking and discussion setting goals for 2025 PV World Tour

2025 World tour at a glance

1. 25 - 26 February, BARCELONA
   European Drug Safety & PV Outsourcing Summit
2. 12 - 13 March, BOSTON
   American Drug Safety Summit 2025 - East coast
3. 9 - 10 April, LONDON
   10th Global Pharmacovigilance & RWE FORUM
4. 9 - 10 April, CHICAGO
   2nd Annual American MedTech Summit
5. 4 - 5 June, TORONTO
   Canadian Pharmacovigilance Management & Compliance Conference
6. 5 - 6 June, Basel
   2nd Annual World Drug Safety Summit
7. 11 - 12 June, BERLIN
   2nd Annual European MedTech Summit
8. 23 - 24 September, MUMBAI
   2nd Annual Global Drug Safety & PV Outsourcing Summit
9. 9 - 10 December, SAN DIEGO
   American Drug Safety Summit 2025 - Westcoast

Our Partners

Sponsorship

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

Exhibiting

With a large and senior audience and decision makers, thoroughly selected, exhibiting at any Summit at 2024 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

2024 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

Contact us

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