27th Pharmacovigilance 2022

#VIphv

"Latest developments in pharmacovigilance, drug safety & risk management"

23rd & 24th February 2022, Virtual Conference (Time Zone – UK Time)

AGENDA AT A GLANCE

Key Speakers Include

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen (USA)

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation, Takeda Pharmaceuticals

FABIO DE GREGORIO
Vice President, Head of Drug Safety Europe
Shionogi Europe

MOHAMED ABDILLAHI
Director, Risk management Product Lead
Pfizer

WIVINA DE WAELE
Director EMEA, Global Drug Safety
Alexion Pharmaceuticals

RISHI CHOPRA
Senior Director, Head of International PV | Deputy EU UK QPPV, Biogen

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

JAMES WHITEHEAD
Director and Team Lead - Patient Safety Medical Devices & Digital Health, AstraZeneca

KLAUDIJA MARIJANOVIC BARAC
Sr. Director, Global Patient Safety & PV - TPC
Teva

MARIA MADDALENA LINO
Safety Risk Lead Director
Pfizer

PAV RISHIRAJ
Director – Pharmacovigilance (UK & Ireland) & ABPI PV Expert Chair, Ipsen

MOIN DON
CEO, PVCON Consulting, Lead S Asia Chapter ISoP,Member of Central Advisory Committee DIA

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety & PV, CSL Behring

RAJ BHOGAL
Senior Director, R&D Audits & Inspections
Jazz Pharmaceuticals

VALENTINA MANCINI
Director PV, EU QPPV
Shionogi

TEA BABIC
Director – PV Audits and Inspections
Teva

SHAANTANU DONDE
Head of Portfolio Management Team - Medical Affairs, Viatris

UWE GUDAT
Head of Medical Affairs & CSPV
Fresenius Kabi

RICARDA TIEMEYER
Country Head of PV (DACH)
Biogen

HOWARD SNOW
VP, Head of Pharmacovigilance
Hengrui Therapeutics

WALLY LANDSBERG
Vice President, Global Head of Medical Safety
Kyowa Kirin International

DNYANESHWAR SANAP
EU/UK QPPV, Head Regional PV and Global Compliance & Training, Glenmark

Conceptualised By

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Former Director & Head Pharmacovigilance Quality Assurance, Vifor Pharma

YVONNE NANCIU
Country Head Pharmacovigilance
Bayer

ALESSANDRO VAGHEGGINI
Associate Principal Biostatistician, Clinical SafetyStatistics, MSD (CH)

AMGAD SHEBL
Sr. Director, Global Safety Lead, Immunology Global Clinical Safety & PV, CSL Behring

RUDI SCHEERLINCK
Strategic Safety Lead
Merck Group

ALINA TUDOR
Senior Director, Pharmacovigilance
Kyowa Kirin International

PHILIP OLUWOLE
PFO PV Consulting

DIMITRIS ZAMPATIS
Head of Pharmacovigilance EMEA-EEA QPPV
Lupin

MINHAJ OBEIDULLAH
Head Compliance & Risk Management
Novartis

CHETAN SHATAPATHY
Executive Director, Head of Antibody-Drug Conjugates, Oncology Patient Safety
AstraZeneca

JEAN-KILGOUR CHRISTIE
Deputy EU QPPV
Novartis

DANIELA DI COSMO
Senior PV Manager, Global PV
Ferring Pharmaceuticals

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions

NICOLE BAKER
Co-Founder
BioLogit

MICHAEL RAMCHARAN
Managing Director
Reumat Consulting

MARINA SUVAKOV
Global Head Safety Surveillance
Philip Morris International

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

ALEXANDER ROUSSANOV
International Partner, Life Sciences and Privacy
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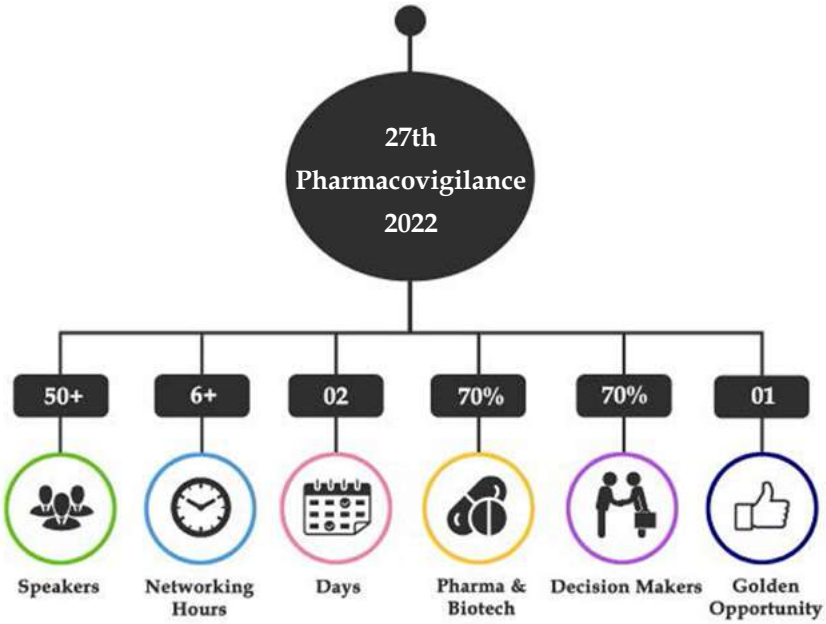
WHO ATTENDS?



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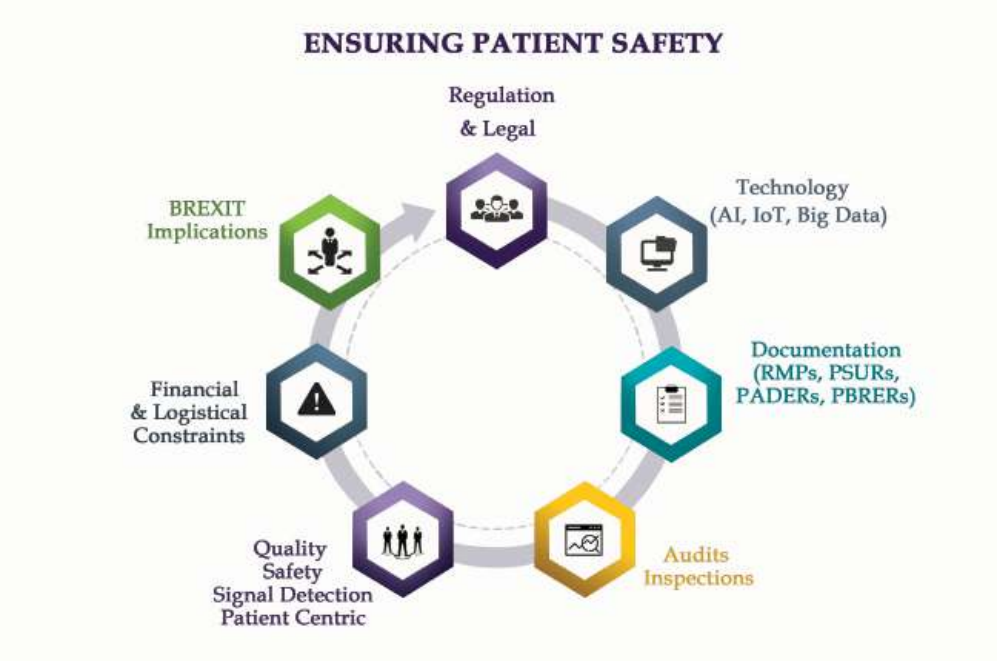
OUR HISTORY

After the successful journey of a series of 26 Pharmacovigilance conferences, Virtue Insight is proud to announce its **27th Pharmacovigilance 2022**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade**. For the 2022 edition, the agenda includes a host of new and exciting features focusing on how the industry should evolve especially after the pandemic. Take a chance and make it count by attending our event to network with your peers, exchange expertise and experiences, and arm yourself with the latest information to take your department to the next level.

As per current market situation, the global pharmacovigilance market was approximately USD 3.87 billion in 2018 and is expected to generate around USD 8.33 billion by 2025, at a CAGR of around 11.6% between 2019 and 2025. This event will bring together top pharmaceutical, biotechnology and regulatory representatives under one roof that will address the key issues of the industry. Get more from the event, with a broader scope bringing the whole communications value chain together. Enjoy and make the best out of our dedicated networking drinks time, meet the leading international vendors showcasing the products of tomorrow in the co-located exhibition.

It gives me great pleasure in welcoming all of you to the Virtue Insight's 27th Pharmacovigilance 2022. I wish and pray that all our efforts will be beneficial to our industries and to our all at large.

MAJOR FOCUS ON



WHO SHOULD ATTEND

CEO's, CTO's, CIO's, Presidents, VPs, Directors, Heads, Managers, Scientific Advisors, Consultants of:

Pharmacovigilance, Pharmacoepidemiology, Pharmacogenomics, Drug/Product Safety, Drug Development, Information and Clinical, Data Management, Clinical Pharmacology, Clinical Safety, Periodical safety update Reports, Risk Management, Research & Development, Quality Assurance, Patient Safety, Signal Detection, Safety Surveillance, Outcomes Research, Data Analysis, Epidemiology, Medical Affairs, Regulatory Affairs and Compliance, Information technology, Sales and Marketing

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DAY ONE - 23rd February 2022

09:30 - Welcome Address & Virtual Conference Platform Instructions

SAFETY

09:40 - Implementation of the new EU Clinical Trial rules - and the impacts on safety departments

HOWARD SNOW
VP, Head of Pharmacovigilance
Hengrui Therapeutics

10:20 - How to tailor safety surveillance for new and well established products: our experience

- What to do when the portfolio contains both new and well-established products
- Our approach and our experience
- What's next

DANIELA DI COSMO
Senior PV Manager, Global PV
Ferring Pharmaceuticals

11:00 – Morning Coffee/Tea

11:20 – Keynote Panel Discussion: Improving the PV ecosystem for advancement – Rising back from the pandemic

- Lessons learnt from the pandemic
- Possible impacts of Brexit
- Staying ahead in the race - Update on PV in EU, USA & RoW - Current trends for PV and new and future guidelines
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Best practices & the way forward

Moderator:

WALLY LANDSBERG
Vice President, Global Head of Medical Safety
Kyowa Kirin International

Panellists:

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation
Takeda Pharmaceuticals

YVONNE NANCIU
Country Head Pharmacovigilance
Bayer

WIVINA DE WAELE
Director EMEA, Global Drug Safety
Alexion Pharmaceuticals

VALENTINA MANCINI
Director PV, EU QPPV
Shionogi

PHILIP OLUWOLE
PFO PV Consulting

12:10 – Pharmacovigilance - Emerging Markets - What comes next for the industry especially post this pandemic?

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions

12:40 – Networking luncheon

QUALITY - SAFETY – SIGNAL DETECTION

13:40 – Panel Discussion – Quality, Safety & Signal Detection – Peep into the future

- Best practice in signal detection and management across product life cycle
- Developing a global safety intelligence process
- Quality assurance and compliance
- Exploring patient support and marketing research programs from a safety perspective
- How should we approach?
- Statistical signal detection as a routine pharmacovigilance practice
- Latest updates and hot topics

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AGENDA AT A GLANCE

DAY ONE - 23rd February 2022

Moderator:

MICHAEL RAMCHARAN
Managing Director
Reumat Consulting

Panellists:

CHETAN SHATAPATHY
Executive Director, Head of Antibody-Drug Conjugates Oncology Patient Safety, AstraZeneca

DIMITRIS ZAMPATIS
Head of Pharmacovigilance EMEA-EEA QPPV
Lupin

JEAN-KILGOUR CHRISTIE
Deputy EU QPPV
Novartis

MARIA MADDALENA LINO
Safety Risk Lead Director
Pfizer

MARINA SUVAKOV
Global Head Safety Surveillance
Philip Morris International

DANIELA DI COSMO
Senior PV Manager, Global PV
Ferring Pharmaceuticals

14:30 – A new probabilistic tool for causality assessment in signal detection

- Principles and background
- Description and performance (accuracy, sensitivity/ specificity)
- Application and perspectives

FABIO DE GREGORIO
Vice President, Head of Drug Safety Europe
Shionogi Europe

15:00 – Back to the future: bigger or better in PV?

- Data volume versus data quality
- Heterogeneity and plurality and the conclusions we can draw
- Beyond Drug Event Combinations: Bringing the patient back into the picture

UWE GUDAT
Head of Medical Affairs & CSPV
Fresenius Kabi

15:30 - Afternoon Tea/Coffee

15:50 – Subgroup issues in safety evaluation

- Bias due to post-stratification
- Reduced sample sizes and related statistical issues
- Multiplicity issues

ALESSANDRO VAGHEGGINI
Associate Principal Biostatistician, Clinical Safety Statistics, MSD (CH)

16:30 - What are the challenges of Global and Local Medical Literature Monitoring? Can we improve it?

- Large volume of articles, can AI help?
- Local Literature content, too much or too little?
- Costs: is open access data an option?

NICOLE BAKER
Co-Founder
BioLogit

17:00 - End of Day One Conference

FOR DELEGATE REGISTRATIONS:-

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - delegate.uk@virtueinsight.com

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DAY TWO - 24th February 2022

PV FOR 2022

09:40 – Pharmacovigilance in 2022

- Future horizons and efficiencies in data acquisition, evaluation and risk management
- Future-proofing Safety Systems
- Where are we?
- Boldly Shaping the Future

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance, CSL Behring

10:20 – Global Safety impacts due to combination products

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen (USA)

11:00 – Morning Coffee/Tea

PATIENT SAFETY

11:20 – Keynote Panel Discussion: Prioritising Patients - Reshaping patient safety

- Developing COVID treatment in the midst of the pandemic: Protecting patients and pharmacovigilance compliance in extraordinary circumstances
- Driving patient centricity into your PV plans
- Pharmacovigilance as a tool for safety and monitoring
- Patient-Perspectives in benefit-risk assessments
- A review of general issues and the specific challenges with patients
- Next generation pharmacovigilance for enhanced patient safety

Moderator:

MIRCEA CIUCA
Global Therapeutic Area Head - Global Clinical Safety and Pharmacovigilance, CSL Behring

Panellists:

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen (USA)

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

JAMES WHITEHEAD
Director and Team Lead - Patient Safety Medical Devices & Digital Health, AstraZeneca

SHAANTANU DONDE
Head of Portfolio Management Team - Medical Affairs
Viatris

12:10 - The globalization of medicines: how to ensure global risk management strategies and ensure safe use by patients worldwide

- The globalization of regulation paving the way to implementation of transnational risk management strategies
- How the practice of medicine and the healthcare provider-patient interactions have transformed across the globe, allowing for better access to global safety data, to be used when developing risk management plans
- One RMP to fit all or all to fit within one RMP: core RMP and how to make good use of this internal tool

ALINA TUDOR
Senior Director, Pharmacovigilance
Kyowa Kirin International

12:40 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:30 – Panel Discussion – Risk Management Plan and Pharmacovigilance System - New Paradigm

- Implementation of complex risk minimisation measures
- Challenges and overcoming problems in Pharmaceutical product life cycle management

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DAY TWO - 24th February 2022

- Managing risks / Administrating risks – Right way in handling situations
- Tailored approaches towards benefit-risk evaluations
- Implementation and maintenance of RMP's
- Risk management in different jurisdictions
- New approaches to managing benefit-risk

Moderator:

AMGAD SHEBL
Sr. Director, Global Safety Lead, Immunology Global Clinical Safety & PV, CSL Behring

Panellists:

RUDI SCHEERLINCK
Strategic Safety Lead
Merck Group

MOHAMED ABDILLAHI
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Country Head of PV (DACH)
Biogen

MINHAJ OBEIDULLAH
Head Compliance & Risk Management
Novartis

SANDY EISEN
Chief Medical Officer
Frontline Pharma Consulting

ENSURING COMPLIANCE

14:20 – Remote audits and inspections

- Logistical issues
- How to prepare and what to expect
- Differences from onsite

TEA BABIC
Director – PV Audits and Inspections
Teva

15:00 - Afternoon Tea/Coffee

15:20 – Panel Discussion - Pharmacovigilance Audits: Keeping on the right side of inspectors

- Managing Pharmacovigilance Audits and Inspections
- Data Quality Management and Analysis
- PV Inspection readiness: What to expect? How ready can we be?
- Risk based selection criteria for auditing
- Methodologies, scope and oversight

Moderator:

RAJ BHOGAL
Senior Director, R&D Audits & Inspections
Jazz Pharmaceuticals

Panellists:

TEA BABIC
Director – PV Audits and Inspections
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MOIN DON
CEO, PVCON Consulting, **Lead S Asia Chapter,** ISoP
Member of Central Advisory Committee, DIA

DNYANESHWAR SANAP
EU/UK QPPV, Head Regional PV and Global Compliance & Training, Glenmark

RANJANA KHANNA
Former Director & Head Pharmacovigilance Quality Assurance, Vifor Pharma

REGULATION OVERVIEW & UPDATE

16:10 – Panel Discussion: PV - Regulatory Updates

- PV System Legislation Updates
- Key current changes and their impact on current PV
- Brexit – Regulatory aspect
- Future Legislation: Pharmacovigilance – Industry Vision
- Enhancing communication between regulators, regional authorities and patients

Moderator:

RISHI CHOPRA
Senior Director, Head of International PV | Deputy EU UK QPPV, Biogen

DAY TWO - 24th February 2022

Panellists:

PAV RISHIRAJ
Director – Pharmacovigilance (UK & Ireland) & ABPI PV Expert Chair, Ipsen

KLAUDIJA MARIJANOVIC BARAC
Sr. Director, Global Patient Safety & PV - TPC
Teva

ALEXANDER ROUSSANOV
International Partner, Life Sciences and Privacy
Arnold & Porter

17:00 - 17:10 – End of the conference

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Sponsorship or exhibition is the best way to speed network with decision makers. The world leader speakers in our conferences attract niche delegates from all over the world. This would be a wonderful opportunity to reach the right audience and save money and time on all your other advertising gimmicks. To give you an advertising edge we constantly update the industry pioneers via emails/news letter about the event and advertise the event via different forms of media.

Sponsorship Enquires - sponsor.uk@virtueinsight.com

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REGISTER ONLINE :

Link : https://www.virtueinsight.com/pharma/27th-Pharmacovigilance-2022-Virtual-Conference/products/

For Multiple Bookings - Photocopy this form and send it to info.uk@virtueinsight.com

Delegate Details:

Title Mr ☐ Mrs ☐ Ms ☐ Dr ☐

First Name

Surname

Company

Position

Address

Pincode

Telephone

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TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of £200

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Video : If you cannot attend the conference, you can still purchase the Video of the virtual conferences for £300.

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will reschedule the event.