24th Pharmacovigilance 2021

#VIphv

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

24th & 25th Feb 2021, Virtual Conference – TimeZone – GMT

AGENDA AT A GLANCE

Key Speakers Include

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck (USA)

MICHAEL BEAN
Senior Director, Regulatory Compliance R&D
Johnson & Johnson

WIVINA DE WAELE
Director, Regional Safety Excellence EMEA. Global Drug Safety, Alexion Pharmaceuticals

KHAUDEJA BANO
Executive Medical Director, Combination Product Safety Head, Amgen (USA)

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation, Takeda

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

OYINKANSOLA ODEBO
Assistant Director, Drug Safety Clinical Research, Supernus Pharmaceuticals (USA)

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

TEA BABIC
Assoc. Dir – Audits and Inspections
Teva

DAVID J LEWIS
EU QPPV Head QPPV Office
Novartis

SHAUN COMFORT
Principal Scientific Enablement Director
Roche - Genentech

YUUNG YUUNG YAP
Senior International Regulatory Counsel, EU and International Regulatory Law, Pfizer

DAVID JEFFERYS
Sr. VP Regulatory
Eisai

VALENTINA MANCINI
Director PV, EU QPPV
Shionogi Europe

ROSALINA DOMIN
Senior Director, QA and Deviation Management Head, PV Quality, Sanofi

RAJ BHOGAL
Sr. Director, R&D Audits & Inspections
Jazz Pharmaceuticals

ANDREA OLIVA
Head of Pharmacovigilance, Italy
Viatris

JAYLAXMI NALAWADE
Associate Director - Pharmacovigilance & REMS, Lupin

FRANCK SCHWARTZ
QA Global Inspection, Intelligence Lead - Compliance & Regulatory Affairs Quality
Novartis

YVONNE NANCIU
Senior Manager Pharmacovigilance & Medical Information, Local QPPV, Abbvie

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RUDI SCHEERLINCK
PV Risk management - clinical studies
Galderma

CHETAN SHATAPATHY
Principal Pharamcovigilance Physician - Oncology R&D Unit, AstraZeneca

JOHN POUSTIE
Senior Director, Global Pharmacovigilance
Norgine

SUE REES
Pharmacovigilance Expert, (Former EU QPPV Executive Director, Global Safety, Amgen)

GAURI UTTURKAR
Senior Manager - Pharmacovigilance
Glenmark Pharmaceuticals

LISBETH TOFTE HEMMINGSEN
Director, Drug Safety Consult

NICOLE BAKER
Co-Founder
BioLogit

MARY LYNNE VAN POELGEEST
President , World Federation for Incontinent Patients - (WFIP)

Plus more COMING SOON.....

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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 - info.uk@virtueinsight.com

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AGENDA AT A GLANCE

OUR HISTORY

After the successful journey of a series of 23 Pharmacovigilance conferences, Virtue Insight is proud to announce its **24th Pharmacovigilance 2021**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade**. Considering the current pandemic situation, for the 2021st edition, the agenda includes a host of new and exciting features. Take a chance and make it count by attending this conference to network with your peers, exchange expertise and experiences, and arm yourself with the latest information to take your department to the next level.

The global pharmacovigilance market size was estimated at USD 4.87 billion in 2019 is expected to increase at a compound annual growth rate (CAGR) of 13.2% from 2020 to 2027. An increase in the prevalence of chronic diseases has led to an increase in drug consumption worldwide. Thereby demand for new drug development via extensive clinical trials has increased.

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 **24th Pharmacovigilance 2021**. I wish and pray that all our efforts will be beneficial to our industries and to our all at large.

CERTIFICATION

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

FOCUSES ON

- Overcoming this Pandemic Issues - Drug Safety Strategy for Pharmaceutical organisations
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Key factors driving the current global Pharmacovigilance (PV) market?
- Pharmacovigilance and assessment of drug safety reports during COVID 19
- What are the market opportunities, market risk and market overview of the (PV) market?
- PV Audit & Inspections – Keeping on the right side of Inspectors
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- Practical approaches - Quality, Safety & Signal Detection
- Medical devices – Increasing safety perspective
- Improving patient safety
- New Technologies in Pharmacovigilance (AI/ Machine Learning, IoT)
- Brexit Implications for the Pharmaceutical (pharmacovigilance) Industry
- RoW - Recent developments and future perspectives
- The developing regulatory framework in advanced and developing markets – EU, USA & ROW
- Be part of a major networking opportunity

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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AGENDA AT A GLANCE

DAY ONE - 24th February 2021

09:20 – Welcome Address & Virtual Conference Platform Instructions

MARKET TRENDS & WAY FORWARD

09:30 – Overcoming this Pandemic Issues - Drug Safety Strategy for Pharmaceutical organisations

- Pharmacovigilance - Emerging Markets
- Pharmacovigilance: What comes next for the industry?
- Key factors driving the global Pharmacovigilance (PV) market?
- Does the shift towards emerging markets pose a risk to drug safety and biased data reports?

10:10 - 'IMI ConcePTION: Building an ecosystem for generating, and providing evidence on the safety of medicines in pregnancy & breastfeeding'

Every woman has the right to safe & effective use of medicines, based on scientific evidence, especially when she is making a decision for two. But the current situation is unsatisfactory, because:

- Scientific evidence of the use of medicines in pregnancy and during breastfeeding is lacking, incomplete or unavail able in the public domain
- No harmonised infrastructure exists;
- There is fragmentation and inconsistencies regarding advice and knowledge
- The situation is not sustainable
- IMI ConcePTION aims to address these problems

DAVID J LEWIS
EU QPPV Head QPPV Office
Novartis

10:50 – Solution Provider Presentation

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11:10 – Morning Coffee/Tea & Discussion

11:30 – Keynote Panel Discussion: Improvising the PV ecosystem for betterment

- During the pandemic - Complications associated with Pharmacovigilance (PV) procedures.
- What are the market opportunities, market risk and market overview of the Pharmacovigilance (PV) market?
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Pharmacy practice and its guidelines
- Importance of Proper communication - Sponsor – Site – CRO & Patients
- Possible impacts of Brexit

Moderator:

Panellists:

JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi

SUMIT MUNJAL
Global Director, PV & EU Region Medical Advisor - Lead Oncology Portfolio, Takeda

ANDREA OLIVA
Head of Pharmacovigilance, Italy
Viatris

YVONNE NANCIU
Senior Manager Pharmacovigilance & Medical Information, Local QPPV, Abbvie

12:20 – Solution Provider Presentation

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12:40 – Networking luncheon

REGULATORY OVERVIEW & UPDATE

13:50 – Panel Discussion – PV - Regulatory Updates

- Impact of the pandemic
- Key current changes and their impact on current PV
- Impact of Brexit – Regulatory aspect
- Future Legislation: Pharmacovigilance – Industry Vision
- PV System Legislation Updates

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DAY ONE - 24th February 2021

- Outsourcing – Key areas to look out while outsourcing
- Enhancing communication between regulators, regional authorities and patients

Moderator:

Panellists:

DAVID JEFFERYS
Sr. VP Regulatory
Eisai

MICHAEL BEAN
Senior Director, Regulatory Compliance R&D
Johnson & Johnson

YUUNG YUUNG YAP
Senior International Regulatory Counsel, EU and International Regulatory Law, Pfizer

14:40 – Drug Safety and Pharmacovigilance processes: Ensuring a smooth and accurate workflow

OYINKANSOLA ODEBO
Assistant Director, Drug Safety Clinical Research
Supernus Pharmaceuticals (USA)

15:10 - Afternoon Tea/Coffee

15:30 - How to ensure quality of PV deliverables

- What quality checks are really needed?
- Key Metrics and KPIs
- Proactive Quality Management
- Relationship with PV stakeholders

ROSALINA DOMIN
Senior Director, QA and Deviation Management Head, PV Quality, Sanofi

DATA COLLECTION – MANAGEMENT

16:00 – Panel Discussion - PV Audit & Inspections – Keeping on the right side of Inspectors

- Key international legislation and guidelines covering PV Quality Management, including PV audits and PV in spections
- Creating and maintaining a risk based PV audit algorithm – and a corresponding audit program
- Design and implement appropriate and effective corrective and preventive actions
- Always prepared for a regulatory PV inspection
- Data management is a key principle of pharmacovigilance
- Risk based selection criteria for auditing
- Relationship to other GxPs

Moderator:

VALENTINA MANCINI
Director PV, EU QPPV
Shionogi Europe

Panellists:

TEA BABIC
Assoc. Dir – Audits and Inspections
Teva

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

JAYLAXMI NALAWADE
Associate Director - Pharmacovigilance & REMS
Lupin

FRANCK SCHWARTZ
QA Global Inspection, Intelligence Lead - Compliance & Regulatory Affairs Quality Novartis

LISBETH TOFTE HEMMINGSEN
Director, Drug Safety Consult

16:50 - End of the conference

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DAY TWO - 25th February 2021

IMPACT OF TECHNOLOGY

09:40 – Future Pharmacovigilance Systems: Adoption of emerging technologies

- Artificial intelligence/Machine learning in Pharmacovigilance
- Can PV keep up with the pace of innovation?
- Are stakeholders and PV systems ready to embrace AI?
- Information technology in pharmacovigilance
- Decision process

10:20 – Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration

JOHN POUSTIE
Senior Director, Global Pharmacovigilance
Norgine

10:50 – Solution Provider Presentation

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11:10 – Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:30 – Keynote Panel Discussion : Patient Centric - Pharmacovigilance & Patient Safety

- Driving patient centricity into your PV plans
- Challenges for safety reporting activities due to the COVID-19 pandemic
- Pharmacovigilance as a tool for safety and monitoring
- Pharmacovigilance and assessment of drug safety reports during COVID 19
- Patient-Perspectives in Benefit-Risk Assessments
- Adapting operations to changing conditions
- Leveraging technology to transform patient safety
- Next generation pharmacovigilance for enhanced patient safety

Moderator:

Panellists:

WIVINA DE WAELE
Director, Regional Safety Excellence EMEA.Global Drug Safety, Alexion Pharmaceuticals

MARY LYNNE VAN POELGEEST
President
World Federation for Incontinent Patients - (WFIP)

SUE REES
Pharmacovigilance Expert, (Former EU QPPV Executive Director, Global Safety, Amgen**)**

NICOLE BAKER
Co-Founder
BioLogit

12:20 – Solution Provider Presentation

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12:40 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:50 – Panel Discussion – PV – Risk Management & Planning

- Global approach to good pharmacovigilance and risk management
- Risk management in the lifecycle of a drug
- How effective is your risk management?
- Implementation and maintenance of RMP's – Overcoming its challenges
- Risk management in different jurisdictions
- Benefit/Risk ratio: the common denominator
- Research and development improvement

Moderator:

Panellists:

GAURI UTTURKAR
Senior Manager - Pharmacovigilance
Glenmark Pharmaceuticals

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DAY TWO - 25th February 2021

CHETAN SHATAPATHY
Principal Pharamcovigilance Physician - Oncology R&D Unit, AstraZeneca

RUDI SCHEERLINCK
PV Risk management - clinical studies
Galderma

QUALITY - SAFETY – SIGNAL DETECTION

14:40 – A PV Organization's Transformational Journey Towards Combination Product Safety

- Discuss the changing environment of post marketing safety and factors driving the change
- Key challenges and recommended best practices for the PV organizational transformation
- How has the role of PV and the definition of Safety and Risk evolved to support Combination product safety

KHAUDEJA BANO
Executive Medical Director, Combination Product Safety Head, Amgen (USA)

15:20 - Afternoon Tea/Coffee

15:40 – Safety Evaluation in Master Protocols

- Aggregate safety assessment planning and monitoring
- Statistical considerations in multi-cohort and multi-arm studies
- Safety evaluation with statistical multiplicity considerations

WILLIAM WANG
Executive Director
Merck (USA)

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

16:20 - How Good Are You? Documenting and Analyzing Human Causality Performance in PV

- How to perform comparative analysis of causality assessments of Drug-Event-Pairs
- Common metrics and results for Human Expert causality assessments from the medical literature
- Future directions - simple steps to improving causality assessments

SHAUN COMFORT
Principal Scientific Enablement Director
Roche - Genentech

16:50 - End of the conference

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REGISTER ONLINE :

Link : https://www.virtueinsight.com/pharma/24th-Pharmacovigilance-2021--Virtual-Conference/products/

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

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First Name

Surname

Company

Position

Address

Pincode

Telephone

Fax

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(Choose one of the following payment options)

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CERTIFICATION

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

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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.

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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.

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