25th Pharmacovigilance 2021

#VIphv

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

22nd & 23rd September 2021, Virtual Conference (Time Zone - EST)

AGENDA AT A GLANCE

Key Speakers Include

MIRZA I. RAHMAN
Senior VP & Chief Global PV Officer
Otsuka Pharmaceutical Development & Commercialization

JULIE GIROD
Vice President, Global Head of Case Management & Medical Evaluation
Sanofi-Aventis

CARMIT STRAUSS
Global Safety Director (Benefit Risk Management Officer), Amgen

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

JUDY LI
Senior Director, Biostatistics Lead, San Diego Site, Bristol-Myers Squibb

MELVIN MUNSAKA
Senior Director, Head Safety Statistics
Abbvie

ARVIND BELLUR
Associate Vice President
Sanofi

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

KHAUDEJA BANO
Executive Medical Director, Combination Product Safety Head, Amgen

SHAUN COMFORT
Principal Scientific Enablement Director
Roche - Genentech

JAMES (JAY) DUHIG
Director, Patient Integration Pharmacovigilance & Patient Safety (PPS), Abbvie

GIHAN ATALLA
Vice President, Head of Global Drug Safety & Pharmacovigilance, Genmab

ABHISHEK PITTI
Associate Director, Global Drug Safety & Pharmacovigilance Physician, Genmab

MINA EBEID
Associate Director, Drug Safety & Pharmacovigilance Scientist, Genmab

FATEMEH NOURI E
Staff fellow
FDA

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

RENA PANDIT
Global Director & Global Patient Safety Head of PV Compliance and Training, Amgen

BEN LOCWIN
Executive SME
Black Diamond Networks

NANCY DUBOIS
Associate Director, Local Safety Officer, US Region, Alexion Pharmaceuticals

MICHAEL GLASER
Technology Innovation Director
GSK

Conceptualised By
Virtue Insight
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Associate Director, Pharmacovigilance and REMS, Lupin

KAL ELHOREGY
Director, Risk Evaluation and Mitigation Strategy (REMS) Programs, Amneal Pharmaceuticals

MOHAMED ABDILLAHI
Director, Risk management Product Lead
Pfizer

DIMITRIS ZAMPATIS
Scientific Director, Safety Strategy Lead
Healthcare Business of Merck

TEODORA DOHERTY
Global Medical Safety (GMS), Medical Safety Officer, Janssen Research & Development

JOHN SOLOMON
Head of Pharmacovigilance UK & Ireland
Sanofi

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation
Takeda Pharmaceuticals

MICHAEL BEAN
Senior Director, BioResearch Regulatory Compliance, Johnson & Johnson

TANJA PETERS
Head Global Patient Safety Neurology & Immunology, Merck KGaA

AYSE BAKER
Vice President of Regulatory Affairs
Almatica (Alvogen)

YUUNG YUUNG YAP
Assistant General Counsel, Global Legal Regulatory, Viatris

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

TEA BABIC
Director, PV Audits and Inspections
Teva Pharmaceuticals

ISRAEL GUTIERREZ
VP Drug Safety and Pharmacovigilance
Compugen

OYINKANSOLA ODEBO
Assistant Director, Drug Safety Clinical Research, Supernus Pharmaceuticals

DEEPA VENKATARAMAN
Head of Global Patient Safety and Pharmacovigilance, Summit Therapeutics

KATARINA ILIC
Senior Medical Director, Clinical Sciences
Takeda Pharmaceuticals

CHETAN SHATAPATHY
Executive Director, Head of ADC Patient Safety Oncology, AstraZeneca

KISHAN NANDHA
PVQA Manager & Lead Auditor
Astellas Pharmaceuticals

EMMANUEL PHAM
Former Vice-President Biometry
IPSEN

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Head- PV Process Excellence, Safety case Management, Novartis

KENNETH LIPETZ
Global Patient Safety Medical Business Advisor and Process Owner, Eli Lilly

ZULANE MALDONADO-CRUZ
Senior Drug Safety Specialist
Supernus Pharmaceuticals

NICOLE BAKER
CEO
Biologit

ARUN TIRUMALAI
Sr. Technical Consultant
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MARINA SUVAKOV
Global Head Safety Surveillance
Philip Morris

MARJAN DZEPAROSKI
RA and PV Manager
Bionika Pharmaceuticals

DEEPA ARORA
Director
CLINEXEL Life Sciences

SIVA KUMAR BUDDHA
Global Safety Physician Manager : Product Safety & Risk Management, Viatris

JIM BUCHANAN
President
Covilance

HEIDE CUNNING
US Pharmacovigilance Officer-Safety Services Operations, Janssen Pharmaceuticals

ALEXANDER ROUSSANOV
International Partner
Arnold & Porter

PASQUALE FEDELE
R&D Director
Blu Pantheon

BILL ARONSON
COO
Artificial Intelligence Research Group

ADI BEN-ARI
Founder & CEO
Applied Blockchain

KAVYA KADAM
Consultant Global Clinical Trials

Plus more COMING SOON.....

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AGENDA AT A GLANCE

OUR HISTORY : -

After the successful journey of a series of 24 Pharmacovigilance conferences, Virtue Insight is proud to announce its **25th Pharmacovigilance 2021**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade.** For the 2021 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.

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.

It gives me great pleasure in welcoming all of you to the Virtue Insight's **25th 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

- Market analysis – Pharmacovigilance in 2022 - future horizons and efficiencies
- Impacts of PV on Covid-19
- Regulations, Legal Implications for the pharmacovigilance Industry
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- New Technologies in Pharmacovigilance (AI/ Machine Learning, IoT, Blockchain & Big Data)
- PV Audit & Inspections – Knowing what is to be done
- Never let a crisis go to waste: Practicing Pharmacovigilance Post-Pandemic!
- RWE & RWD
- PV – Risk Management and Planning - REMS
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- Quality, Safety and Signal Detection - Future of 2020
- Medical devices – Increasing safety perspective
- Case studies from various countries on the PV frameworks around the world
- Patient centric approach to help improve patient safety
- 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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DAY ONE - 22nd September 2021

09:20 – Welcome address and Virtual conference platform introduction

PHARMACOVIGILANCE IN THE FUTURE

09:30 – Keynote Address - Never let a crisis go to waste: Practicing Pharmacovigilance Post-Pandemic!

- Securing the safety and well-being of your employees
- Putting the lessons learnt during this pandemic into practice
- Implementing new structures and processes to get the desired outcomes
- Effectively using innovative informatics – different communication platforms, automation, artificial intelligence, cloud computing & databases, etc.
- Enhancing patient safety, compliance and cost-effectiveness by ensuring global business continuity

MIRZA I. RAHMAN
Senior VP & Chief Global PV Officer
Otsuka Pharmaceutical Development & Commercialization

IMPACT OF TECHNOLOGY

10:10 – Panel Discussion - PharmaTech – AI, IoT, Blockchain, Digital Transformation in Pharma - The Way Forward

- AI, IoT and Blockchain - Benefits, challenges & future directions
- The Acceleration of Digitalisation in Pharma in 2020
- How Pharma companies capitalize on technology?
- Implementation Challenges - Preparing for a smooth transition
- Pitfall and Learnings
- Vigilance in the era of digital media
- Building trust and openness with technology

Moderator:

DEEPA VENKATARAMAN
Head of Global Patient Safety and Pharmacovigilance
Summit Therapeutics

Panellists:

MICHAEL GLASER
Technology Innovation Director
GSK

ISRAEL GUTIERREZ
VP Drug Safety and Pharmacovigilance
Compugen

BILL ARONSON
COO
Artificial Intelligence Research Group

ADI BEN-ARI
Founder & CEO
Applied Blockchain

EMMANUEL PHAM
Former Vice-President Biometry
IPSEN

PASQUALE FEDELE
R&D Director
Blu Pantheon

11:00 – Morning Coffee/Tea & Discussion

QUALITY - SAFETY – SIGNAL DETECTION

11:20 – Panel Discussion – Quality, Safety & Signal Detection

- Strategies for best practice in Signal Detection
- Exploring patient support and marketing research programs from a safety perspective
- How should we approach?
- Using technology to enhance interactive connection with patients
- Statistical signal detection as a routine pharmacovigilance practice
- Latest updates and hot topics

Moderator:

BEN LOCWIN
Executive SME
Black Diamond Networks

Panellists:

CHETAN SHATAPATHY
Executive Director, Head of ADC Patient Safety Oncology
AstraZeneca

HEIDE CUNNING
US Pharmacovigilance Officer-Safety Services Operations
Janssen Pharmaceuticals

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AGENDA AT A GLANCE

DAY ONE - 22nd September 2021

DIMITRIS ZAMPATIS
Scientific Director, Safety Strategy Lead
Healthcare Business of Merck

FATEMEH NOURI E
Staff fellow
FDA

SIVA KUMAR BUDDHA
Global Safety Physician Manager : Product Safety & Risk Management, Viatris

ZULANE MALDONADO-CRUZ
Senior Drug Safety Specialist
Supernus Pharmaceuticals

12:10 – Solution Provider Presentation

For sponsorship opportunities please contact
info.uk@virtueinsight.com

12:30 – Networking luncheon

13:30 - AI for Safety and Safety for AI?

- AI solutions for PV activities (case processing, literature screening, signal detection etc)
- PV activities for AI utilized in healthcare sector (patient safety, cybersecurity, regulatory landscape).

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

14:00 – Keynote Panel Discussion: Optimising the PV ecosystem for betterment

- Pharmacovigilance in the US: What comes next for the industry?
- Impact of Covid-19 PHE on the PV activities
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Pharmacy practice and its guidelines
- Future Drivers for Pharmacovigilance
- New ways to generate evidence including real world evidence
- Proper communication - Sponsor – Site – CRO & Patients
- Best practices

Moderator:

DEEPA ARORA
Director
CLINEXEL Life Sciences

Panellists:

KHAUDEJA BANO
Executive Medical Director Combination Product Safety Head, Amgen

JULIE GIROD
Vice President, Global Head of Case Management & Medical Evaluation, Sanofi-Aventis

TEODORA DOHERTY
Global Medical Safety (GMS), Medical Safety Officer
Janssen Research & Development

MARINA SUVAKOV
Global Head Safety Surveillance
Philip Morris

PAVAN BADALE
Head- PV Process Excellence, Safety case Management
Novartis

14:50 – ICSR Automation: Benefits of AI and Case Quality

- Use of AI in ICSR processing
- Benefits in operations and quality

ARVIND BELLUR
Associate Vice President
Sanofi

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

15:30 - Afternoon Tea/Coffee

DAY ONE - 22nd September 2021

15:50 - Discussion on Post PMSR implementation Impact to Safety

KHAUDEJA BANO
Executive Medical Director, Combination Product Safety Head, Amgen

••

16:30 – "How Good Is Good Enough?" regarding human performance at causality assessment for ICSRs

SHAUN COMFORT
Principal Scientific Enablement Director
Roche - Genentech

••

17:00 – End of day 01 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 - info.uk@virtueinsight.com

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DAY TWO - 23rd September 2021

09:30 – Quantitative Drug Safety and Benefit Risk Evaluation - Practical and Cross-Disciplinary Approaches

- Regulatory Landscape and Interdisciplinary Collaboration in Safety Evaluation
- Design and Analysis Considerations in RCT and RWE for Safety Decision Making
- Safety/Benefit-Risk Evaluation and Visualization
- A reflection on an interdisciplinary book project on Safety

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

JUDY LI
Senior Director, Biostatistics Lead, San Diego Site
Bristol-Myers Squibb

MELVIN MUNSAKA
Senior Director, Head Safety Statistics
Abbvie

JIM BUCHANAN
President
Covilance

DATA COLLECTION – MANAGEMENT

10:30 – Panel Discussion - PV Audit & Inspections – Knowing what is to be done

- Data Quality Management and Analysis
- Real world data: are you sure you have the relevant data?
- PV Inspection readiness: What to expect? How ready can we be?
- Risk based selection criteria for auditing
- Methodologies, scope and oversight
- Preparing and managing safety data exchange agreements
- Relationship to other GxPs

Moderator:

KATARINA ILIC
Senior Medical Director, Clinical Sciences
Takeda Pharmaceuticals

Panellists:

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

RENA PANDIT
Global Director & Global Patient Safety Head of PV Compliance and Training, Amgen

KISHAN NANDHA
PVQA Manager & Lead Auditor
Astellas Pharmaceuticals

TEA BABIC
Director, PV Audits and Inspections
Teva Pharmaceuticals

NICOLE BAKER
CEO
Biologit

ARUN TIRUMALAI
Sr. Technical Consultant
GSK

11:20 – Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:40 – Keynote Panel Discussion: Pharmacovigilance and Patient Safety

- Driving patient centricity into your PV plans
- Patient Support Program in Pharmacovigilance
- 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
- A practical approach to reshaping patient safety
- Next generation pharmacovigilance for enhanced patient safety

Moderator:

DEEPA VENKATARAMAN
Head of Global Patient Safety and Pharmacovigilance
Summit Therapeutics

Panellists:

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation
Takeda Pharmaceuticals

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Head Global Patient Safety Neurology & Immunology
Merck KGaA

KAVYA KADAM
Consultant Global Clinical Trials

12:30 – Solution Provider Presentation

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12:50 – Networking luncheon

RISK MANAGEMENT & PLANNING

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

- Risk management in the lifecycle of a drug
- How effective is your risk management?
- Challenges and overcoming problems in Pharmaceutical product life cycle management
- Implementation and maintenance of RMP's – Overcoming its challenges
- Development and Operations of REMS – Challenges and Mitigations
- Risk management in different jurisdictions
- Benefit/Risk ratio: the common denominator
- New approaches to managing benefit-risk
- Research and development improvement

Moderator:

BEN LOCWIN
Executive SME
Black Diamond Networks

Panellists:

CARMIT STRAUSS
Global Safety Director (Benefit Risk Management Officer)
Amgen

KAL ELHOREGY
Director, Risk Evaluation and Mitigation Strategy (REMS) Programs, Amneal Pharmaceuticals

MOHAMED ABDILLAHI
Director, Risk management Product Lead
Pfizer

NANCY DUBOIS
Associate Director, Local Safety Officer, US Region
Alexion Pharmaceuticals

OYINKANSOLA ODEBO
Assistant Director, Drug Safety Clinical Research
Supernus Pharmaceuticals

KATARINA ILIC
Senior Medical Director, Clinical Sciences
Takeda Pharmaceuticals

REGULATION OVERVIEW & UPDATE

14:40 – Panel Discussion: PV - Regulatory Updates

- Key current changes and their impact on current PV
- Pharmacovigilance and the role of regulatory affairs: How to achieve compliance across the business
- Future Legislation: Pharmacovigilance – Industry Vision
- PV System Legislation Updates
- Enhancing communication between regulators, regional authorities and patients
- What's next? Ways to proceed forward.

Moderator:

BEN LOCWIN
Executive SME
Black Diamond Networks

Panellists:

AYSE BAKER
Vice President of Regulatory Affairs
Almatica (Alvogen)

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Senior Director, BioResearch Regulatory Compliance
Johnson & Johnson

YUUNG YUUNG YAP
Assistant General Counsel, Global Legal Regulatory
Viatris

KENNETH LIPETZ
Global Patient Safety Medical Business Advisor and Process Owner, Eli Lilly

MARJAN DZEPAROSKI
RA and PV Manager
Bionika Pharmaceuticals

ALEXANDER ROUSSANOV
International Partner
Arnold & Porter

15:30 - Afternoon Tea/Coffee

15:50 - What are the benefits of applying AI for medical literature monitoring?

- Are sources important?
- Are search strings redundant?
- How can you validate AI?

NICOLE BAKER
CEO
Biologit

PRE-CLINICAL & CLINICAL TRIALS

16:20 – Merging adverse events throughout clinical trials and post marketing surveillance

- Building the continuum of pharmacovigilance across pre-marketing and post-marketing
- Emerging challenges to monitoring adverse drug events in clinical trials
- Establishing key performance indicators for making timely safety reports and continuous quality improvements
- Targeted event collection
- Strengthening the link between a drug and its related ad verse events from pre-clinical to post-marketing

GIHAN ATALLA
Vice President, Head of Global Drug Safety & Pharmacovigilance, Genmab

ABHISHEK PITTI
Associate Director, Global Drug Safety & Pharmacovigilance Physician, Genmab

MINA EBEID
Associate Director, Drug Safety & Pharmacovigilance Scientist, Genmab

17:00 – End of the conference

FOR SPONSORSHIP OPPORTUNITIES:-

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 - info.uk@virtueinsight.com

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REGISTER ONLINE :

Link : https://www.virtueinsight.com/pharma/25th-Pharmacovigilance-2021-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

Fax

Email

How to Pay
(Choose one of the following payment options)

RESERVATION PRICING:

STANDARD PRICE (NOT VALID FOR UK BASED ATTENDEES)

1 Delegate @ £599
3 Delegates @ £1299

STANDARD PRICE (FOR UK BASED ATTENDEES)

1 Delegate @ £599 + VAT
3 Delegates @ £1299 + VAT

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Signature

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CERTIFICATION

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

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Account Number - 53278603

Bank Name - Barclays Bank PLC **Sort Code -** 20-84-20

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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.

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