32nd Pharmacovigilance 2023

#VIphv

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

26th & 27th April 2023,
The Conference Center at Waltham Woods, Waltham (Boston-MA)

AGENDA AT A GLANCE

Key Speakers
Conference Info
Day One
Day Two
Floor Plan
Booking Details

Key Speakers Include

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

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

BRUNO MENDEZ
VP Global Quality Head Pharmacovigilance
Sanofi

ELIZABETH SMALLEY
Director, Product Management
Aris Global

JEREMY JOKINEN
VP Global Risk Management & International Patient Safety, Bristol-Myers Squibb

NANCY DUBOIS
Head of Global Patient Safety US
Merck-EMD Serono

CARMIT STRAUSS
Executive Director, Head of Risk Management and Organ Toxicity, Takeda Pharmaceuticals

NICOLE BAKER
CEO
Biologit

SHARON REID
Director, Risk Management Product Lead
Pfizer

YILONG JIA
Senior Manager, Pharmacovigilance Informatics
Sunovion

AYSE BAKER
Vice President, Regulatory Affairs
Innocoll

NISHITH JOBANPUTRA
Disease Area Cluster Lead, Worldwide Safety
Pfizer

ALEX QIU
Executive Director
Bristol-Myers Squibb

GURPREET SINGH
Vice President, Global Head of Pharmacovigilance, Freyr Solutions

HUMAIRA QURESHI
President
Qinecsa Solutions

CAMILLE DISS
CPO
EDGYN

MARITESS ESGUERRA
Senior PV Process Director
Genentech

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

FARIDA ABANE
Senior Medical Director, Pharmacovigilance
Deciphera Pharmaceuticals

BILL HADDOCK
VP Pharmacovigilance & GXP Quality
Ovid Therapeutics

GRAEME LADDS
CEO
PharSafer

NIBHA MISHRA
Investigator II, Principal Toxicologist
CSL Seqirus

MARCIN VON GROTTHUSS
Principal Scientist, Investigative Toxicology
Takeda Pharmaceuticals

AJINKYA INAMDAR
Senior Director (Global Medical Safety Strategy), BioNTech SE

Conceptualised By

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

BENJAMIN BROWN
Executive Director
American Society of Pharmacovigilance

LINA OGBU
Medical Director Drug Safety & PV
Arcus biosciences

JESSICA VAUGHN
Attorney at Law
Wiley Rein

KAPIL BHUTADA
Consultant

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FOCUSES ON

- Pharmacovigilance: What comes next for the PV industry?
- Challenges and opportunities for better future of Pharmacovigilance
- Outsourcing - Best Practices, Challenges & key consideration in choosing right vendor
- Proper communication between - Sponsor – Site – CRO – Patients
- Quality, Safety & Signal Detection – Best practice
- Modern Technologies in Pharmacovigilance - The Way Forward
- Automation in Pharmacovigilance: A Closer look at use cases
- Prioritising patients – Ensuring patient safety first
- Next generation pharmacovigilance for enhanced patient safety
- PV operations within financial and logistical constraints
- Risk Management – Proper plans for a perfect tomorrow
- Why does pharmacovigilance sometimes fail and where could the fault lie?
- Managing Pharmacovigilance Audits & Inspections
- The developing regulatory framework in advanced and developing markets
- Boldly shaping the future
- Best practices and lessons learnt from the pandemic
- Be part of a major networking opportunity

OUR HISTORY

After the successful journey of a series of 31 Pharmacovigilance conferences, Virtue Insight is proud to announce its **32nd Pharmacovigilance 2023**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade**. For the 2023 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 market for Pharmacovigilance estimated at USD 4874.3 million in the year 2022, is projected to reach a revised size of USD 7778 million by 2028, growing at a CAGR of 8.1% during the forecast period 2022-2028. The USA market for Pharmacovigilance is estimated to increase from USD million in 2022 to reach USD million by 2028, at a CAGR of % during the forecast period of 2023 through 2028. 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 **32nd Pharmacovigilance 2023**. I wish and pray that all our efforts will be beneficial to our industries and to our all at large.

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 - 26th April 2023

09:30 – Chairperson opening remarks

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

SAFETY

09:40 – IVDR and its impact to PV / Safety going forward

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

10:20 – Sanofi experience to close affiliate to evolve to distributor/ service provider: how to ensure Patient safety first and being compliant?

BRUNO MENDEZ
VP Global Quality Head Pharmacovigilance
Sanofi

11:00 – Morning Coffee / Tea & Discussion

MARKET TRENDS & WAY FORWARD

11:20 – Keynote Panel Discussion: Challenges and Opportunities for better future of Pharmacovigilance

- What comes next for the industry?
- Automating pharmacovigilance: Are we ready for the upcoming future?
- Outsourcing - Best Practices, Challenges and key consideration in choosing right vendor
- How global PV impacts day to day operations?
- Proper communication between - Sponsor – Site – CRO - Patients
- Best practices and lessons learnt from the pandemic

Moderator:

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

Panellists:

JEREMY JOKINEN
VP Global Risk Management & International Patient Safety, Bristol-Myers Squibb

MARITESS ESGUERRA
Senior PV Process Director
Genentech

GURPREET SINGH
Vice President, Global Head of Pharmacovigilance
Freyr Solutions

AJINKYA INAMDAR
Senior Director (Global Medical Safety Strategy)
BioNTech SE

12:10 – Case Processing – The Perils, Pitfalls and Solutions

- Reviewing the current industry landscape for clinical and post marketing drug safety
- Identifying and highlighting of key issues Companies face and how this influences safety data capture and processing
- Exploring how AI & Automation can provide a complete solution

GRAEME LADDS
CEO
PharSafer

12:30 – Networking luncheon

QUALITY - SAFETY – SIGNAL DETECTION

13:30 – Panel Discussion – Quality, Safety & Signal Detection – Best practice

- Developing a global safety intelligence process
- Exploring patient support and marketing research programs from a safety perspective
- Statistical signal detection as a routine pharmacovigilance practice
- Implementing signal detection in RWD: the necessary steps.
- Moving towards a better future: bigger and better
- Lessons learned from covid-19 vaccine related to signal detection and evaluation, and its vast impact on both global HAs' and MAHs' safety concerns and responses

Moderator:

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

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Head of Global Patient Safety US
Merck-EMD Serono

MARCIN VON GROTTHUSS
Principal Scientist, Investigative Toxicology
Takeda Pharmaceuticals

NISHITH JOBANPUTRA
Disease Area Cluster Lead, Worldwide Safety
Pfizer

BILL HADDOCK
VP Pharmacovigilance & GXP Quality
Ovid Therapeutics

14:20 – Fit for future sourcing for Pharmacovigilance.

HUMAIRA QURESHI
President
Qinecsa Solutions

14:50 – "Challenges in developing safety strategy for newer therapies-brief overview"

- Understanding newer therapies adverse events
- Developing preclinical models and guidelines for safety evaluation
- Special requirements in manufacturing and storage conditions to control impurities
- Post marketing strategies to predict drug mediated adverse events

NIBHA MISHRA
Investigator II, Principal Toxicologist
CSL Seqirus

15:30 – Afternoon Tea / Coffee

PRE-CLINICAL & CLINICAL TRAILS

15:50 – Merging adverse events throughout clinical trails 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 Challenges in monitoring adverse drug events in clinical trials
- Establishing key performance indicators for making timely safety reports and continuous quality improvements
- Future of outsourced phase I, II and III trials and post-marketing studies
- Targeted event collection
- Strengthening the link between a drug and its related adverse events from pre-clinical to post-marketing

LINA OGBU
Medical Director Drug Safety & Pharmacovigilance
Arcus biosciences

16:20 – We can all do better with AI

NICOLE BAKER
CEO
Biologit

16:50 – Closing remarks by chairperson

17:00 – End of day 01 conference

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09:20 – Chairperson opening remarks

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

SIGNAL MANAGEMENT

09:30 – Signal Management from small company perspective

- Importance and relevance of Signal Management in the current environment
- Developing and implementation of signal management process
- Signal communications – measures and challenges
- Signaling regulations and guidelines and practical applications of regulatory requirements

FARIDA ABANE
Senior Medical Director, Pharmacovigilance
Deciphera Pharmaceuticals

10:00 – New and modern approach from technology perspective: Mobile Applications Use in Pharmacovigilance Adverse Event Reporting

In the contemporary era of the proliferation of new technologies, mobile applications have been utilized by regulatory agencies and drug manufacturers to facilitate adverse event reporting. This presentation reviews some recent uses of mobile apps and elaborates on the benefits of having apps as a new reporting channel in addition to traditional adverse event reporting routes. It will also cover the technical details, best practices, unique opportunities, and associated challenges of mobile apps use in pharmacovigilance.

YILONG JIA
Senior Manager, Pharmacovigilance Informatics
Sunovion

10:30 – Why the fingerprint technology has taken over physical solutions in brand protection?

CAMILLE DISS
CPO
EDGYN

11:00 – Morning Coffee / Tea & Discussion

PATIENT SAFETY

11:20 – Keynote Panel Discussion: Securing patient safety and monitoring in PV

- Prioritising patients – Ensuring patient safety first
- Protecting patients and pharmacovigilance compliance in extraordinary circumstances
- Inducing patient centricity into your PV plans
- Encouraging patient support programs in Pharmacovigilance
- A practical approach to reshaping patient safety
- Next generation pharmacovigilance for enhanced patient safety
- What has this pandemic thought us towards patient safety

Moderator:

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

Panellists:

SHARON REID
Director, Risk Management Product Lead
Pfizer

NIBHA MISHRA
Investigator II, Principal Toxicologist
CSL Seqirus

BENJAMIN BROWN
Executive Director
American Society of Pharmacovigilance

12:10 – Proactive Signal Detection with RWD

Join this powerful session to learn why sponsors and regulators are moving from acceptance towards reliance of RWD/RWE and how this new paradigm makes embracing proactive signal detection and advanced cognitive computing for signal analysis a critical component to the future of drug development.

ELIZABETH SMALLEY
Director, Product Management
Aris Global

12:40 – Networking luncheon

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RISK MANAGEMENT & PLANNING

13:40 – Panel Discussion- Risk Management – Proper plans for a perfect tomorrow

- What is the appropriate time to start the Risk Management Planning?/ When should you start working on RMP?
- Risk Evaluation and Mitigation Strategies(REMS) – New challenges and chances
- Risks of a half hearted approach in Risk Management and pitfalls of not having the culture of patient safety.
- Benefit-Risk profile; Is it deductive of or interactive with CDP/TPP?
- One RMP to fit all or all to fit within one RMP?
- Benefit/Risk ratio: the common denominator

Moderator:

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

Panellists:

CARMIT STRAUSS
Executive Director, Head of Risk Management and Organ Toxicity, Takeda Pharmaceuticals

SHARON REID
Director, Risk Management Product Lead
Pfizer

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

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

14:40 – Methodologies used in prediction of severe infection in relapsed and refractory multiple myeloma patients

Grade ¾ or higher of infection is a common safety concern in new drug discovery to treat relapsed and refractory multiple myeloma patients. To mitigate this risk, we used machine leaning and logistic regression modeling to analyze the baseline risk factors which will put patient at higher risk to develop severe infection. We used the internal clinical study data set, performed the risk factor analysis, the results enabled us to develop a risk predication algorithm to help investigator to apply adequate anti-microbial strategy to mitigate the severe infections.

ALEX QIU
Executive Director
Bristol-Myers Squibb

15:10 - Afternoon Tea / Coffee

AUDITS & INSPECTIONS

15:40 – Panel Discussion – Managing Pharmacovigilance Audits & Inspections

- Staying ahead in the race - Current trends for and future guidelines
- How to prepare and what to expect?
- Remote audits and inspections - Logistical issues
- PV Inspection readiness: Keeping on the right side of inspectors
- Methodologies, scope and oversight
- Boldly shaping the future
- What has this pandemic thought us towards audits and inspections?

Moderator:

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

Panellists:

BRUNO MENDEZ
VP Global Quality Head Pharmacovigilance
Sanofi

KAPIL BHUTADA
Consultant

REGULATION OVERVIEW & UPDATE

16:20 – 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

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- Enhancing communication between regulators, regional authorities and patients
- What's next? Ways to proceed forward.

Moderator:

BEN LOCWIN
Vice President, Project Solutions
Black Diamond Networks

Panellists:

AYSE BAKER
Vice President, Regulatory Affairs
Innocoll

JESSICA VAUGHN
Attorney at Law
Wiley Rein

17:00 – Chairperson's closing remarks and end of 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

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 - sponsor.uk@virtueinsight.com

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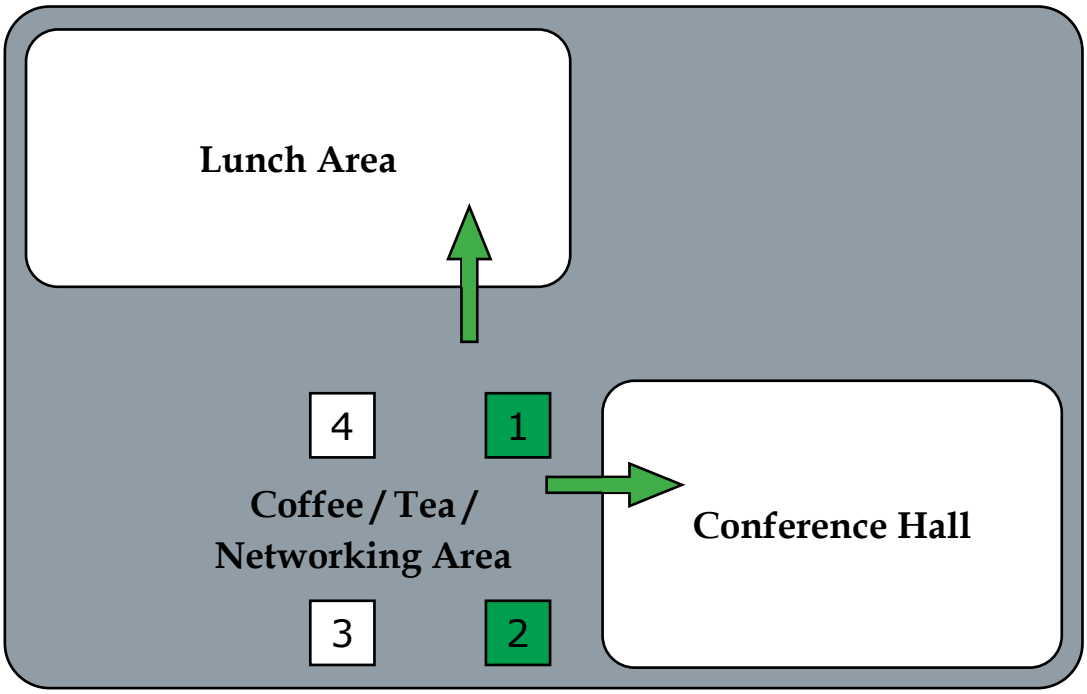
FLOOR PLAN - Book your stalls now before they run out !!!



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4

Sold Blocked Vacant

Note :- The floorplan is subject to change at the discretion of the organisers.

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REGISTER ONLINE :

Link : https://usa-canada.virtueinsight.com/event/pharmacovigilance/

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

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How to Pay
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STANDARD PRICE

1 Delegate @ **$1699**

Group Discount @ **$3398** (3 Delegates for the price of 2)

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CERTIFICATION

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

FOR BANK TRANSFER:

Account Name - Virtue Insight Events Ltd

Account Number - 53278603

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

SWIFT Code: BARCGB22 **IBAN Code:** GB36BARC20842053278603

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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.

Presentation: If you cannot attend the conference, you can still purchase the presentations (Subject to availability) - Please email to bookings@virtueinsight.com

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.

Fee: The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel or hotel accommodation.

Payment Charges: We are a UK registered company and use Barclaycard payment gateway. Some card providers do charge a small foreign transaction fees for international payment (this is not charged from our end). If not sure please contact your card provider before making payment.

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