#VIphv

28th Pharmacovigilance 2022

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

15th & 16th June 2022, Embassy Suites by Hilton Boston Logan Airport Boston, USA

ABSOLUTELY THRILLED TO ANNOUNCE OUR FIRST LIVE (IN PERSON) EVENT AFTER NEARLY 2 YEARS. WE CANT WAIT TO MEET ALL OUR ATTENDEES AND SPEAKERS IN PERSONS

AGENDA AT A GLANCE

Key Speakers Include

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

MICHAEL FRIES
Head, Biostatistics
CSL Behring

JIM BUCHANAN
President
Covilance

BRIAN DREYFUS
Senior Director -Solid Tumor Oncology Epidemiology, Bristol-Myers Squibb

ELENA YURENEVA
Executive Director, Head of Medical Safety and Risk Management, Alnylam Pharmaceuticals

AJINKYA INAMDAR
Director, Global Medical Safety, Global Safety Strategy and Risk Management, Janssen Pharmaceuticals

NANCY DUBOIS
Head of Global Drug, Safety, United States Region, Merck-EMD Serono

SHARON REID
Director, Risk Management Product Lead
Pfizer

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

FATIMA GHETHAN
Head of Quality and Medication Safety Department, King Abdullah Medical City (KAMC) – MAKKAH (Saudi Arabia)

HUMAIRA QURESHI
CEO
Synowledge

MOHAMMED BASEER AHMED
Executive Director, Drug Safety
Ionis Pharmaceuticals

TARAK THAKKER
Director, Safety Systems
BeiGene

NIRJHAR CHATTERJEE
Medical Director PharmacovigilanceMedical Safety Rare Genetics and Hematology & PDT
Takeda

KATARINA ILIC
Sr Medical Director, Clinical Science, Rare, Genetics & Hematology TAU
Takeda Pharmaceuticals

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

AYSE BAKER
Vice President of Regulatory Affairs
Almatica (Alvogen)

SUTAPA MUKHOPADHYAY
Director, Pharmacovigilance Operations
Deciphera Pharmaceuticals

MARCIN VON GROTTHUSS
Principal Scientist, Investigative Toxicology
Takeda Pharmaceuticals

HEMANG MAISURIA
Director, Global Safety Lead
Servier Pharmaceuticals

Conceptualised By

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KAPIL BHUTADA
Director, Pharmacovigilance Compliance and Training, Medicago

BILL HADDOCK
Head of Safety
Ovid Therapeutics

NIBHA MISHRA
Senior Scientist, Investigative Toxicology
Takeda Pharmaceuticals

JERRY K. KOUNGA
Investigational Drug Lead Clinical Research Pharmacist, Ascension Wisconsin Research Institute

BEN LOCWIN
Executive SME
Black Diamond Networks

JESSICA VAUGHN
Attorney at Law
Wiley Rein

ELIZABETH WHITE BAKER
Associate Professor
Virginia Commonwealth University

LYNN MEHLER
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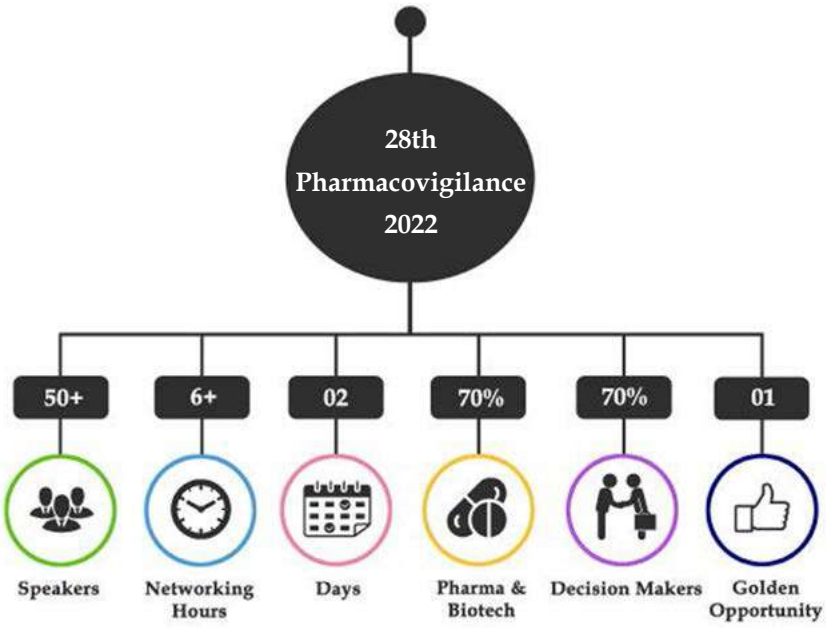
AGENDA AT A GLANCE

WHO ATTENDS?



We are committed to running a safe event, which will follow Covid-19 guidelines set by state of Massachusetts in relation to wearing mask or vaccine requirements as well as social distancing. Our venue holds the highest standard of daily enhanced cleaning and following strict Covid-19 guidelines.

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AGENDA AT A GLANCE

OUR HISTORY

After the successful journey of a series of **27 Pharmacovigilance conferences**, Virtue Insight is proud to announce its **28th 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.

It gives me great pleasure in welcoming all of you to the Virtue Insight's **28th 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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AGENDA AT A GLANCE

DAY ONE - 15th June 2022

09:30 – Welcome address and Chairperson opening remarks

BEN LOCWIN
Executive SME
Black Diamond Networks

MARKET TRENDS & WAY FORWARD

09:40 – Development of successful safety teams for optimized signal detection and management

ELENA YURENEVA
Executive Director, Head of Medical Safety and Risk Management, Alnylam Pharmaceuticals

10:20 – Algorithm based approach to Phase 1 risk management/stopping rules and adverse reactions

- Key aspects to consider
- Anticipated effects based on mechanism of action
- Trial design: Single Ascending Dose and Multiple Ascending Dose
- Regulatory requirements

BILL HADDOCK
Head of Safety
Ovid Therapeutics

11:00 – Morning Coffee/Tea & Discussion

11:20 – Keynote Panel Discussion: Optimising the PV ecosystem for betterment

- Pharmacovigilance in the US: What comes next for the industry?
- Impacts of pandemic over PV – Areas for improvisations
- Outsourcing in PV especially during this pandemic - Best Practices, Challenges and key consideration in choosing right vendor
- How global PV impacts day to day operations?
- New ways to generate evidence including real world evidence
- Importance of proper communication - Sponsor – Site – CRO & Patients
- Best practices and lessons learnt from the pandemic

Moderator:

BEN LOCWIN
Executive SME
Black Diamond Networks

Panellists:

HUMAIRA QURESHI
CEO
Synowledge

HEMANG MAISURIA
Director, Global Safety Lead
Servier Pharmaceuticals

TARAK THAKKER
Director, Safety Systems
BeiGene

12:10 – Outsourcing pharmacovigilance Post Covid

HUMAIRA QURESHI
CEO
Synowledge

12:30 – Networking luncheon

QUALITY - SAFETY – SIGNAL DETECTION

13:30 – Panel Discussion – Quality, Safety & Signal Detection – What is the way forward?

- Prioritizing drug safety
- A hybrid approach to signal detection and management
- Implementing signal detection in RWD: the necessary steps.
- Strategies for best practice in Signal Detection
- How should we approach?
- Safety Signalling and Evaluation: Practical Considerations and tools
- Latest updates and hot topics

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DAY ONE - 15th June 2022

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Executive SME
Black Diamond Networks

Panellists:

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

FATIMA GHETHAN
Head of Quality and Medication Safety Department, King Abdullah Medical City (KAMC) – MAKKAH (Saudi Arabia)

JIM BUCHANAN
President
Covilance

14:20 – Quantitative Drug Safety and Benefit Risk Evaluation: Practical and Cross-Disciplinary Approaches

MICHAEL FRIES
Head, Biostatistics
CSL Behring

JIM BUCHANAN
President
Covilance

15:20 - Afternoon Tea/Coffee

15:40 – Operationalizing PV: Small & Big Pharma

- Rigor & Structure
- US Vs global requirements
- Launch readiness
- Embracing changes
- Establishing the required balance

SUTAPA MUKHOPADHYAY
Director, Pharmacovigilance Operations
Deciphera Pharmaceuticals

16:20 - Safety-Radar: toxicity awareness and warning systems. Towards autonomous reasoning in investigative toxicology

- Here, we present an architecture of Safety-Radar – a system for evaluating drug safety.
- The platform will support automated reasoning and serendipitous discovery of new 'facts' or interesting and testable hypotheses.
- We discuss the strategies of how to integrate and provide high-value AI-ready data sources an how to develop (semi) autonomous reasoning agents

MARCIN VON GROTTHUSS
Principal Scientist, Investigative Toxicology
Takeda Pharmaceuticals

16:50 – Closing remarks by chairperson

17:00 – 18:00 – Networking Drinks

NETWORKING DRINKS

Meet with your industry peers for a relaxed drink at the end of day one

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 - 16th June 2022

09:30 – Welcome address and Chairperson opening remarks

BEN LOCWIN
Executive SME
Black Diamond Networks

09:40 – Pharmacovigilance Operations during Pandemic

- How did the PV ops adapt to Pandemic
- What were the challenges faced by sponsor and service providers
- How does the future of PV ops look like.

MOHAMMED BASEER AHMED
Executive Director, Drug Safety
Ionis Pharmaceuticals

PV FOR FUTURE

10:10 – Leveraging AI technologies to advance patient safety

- AI/NLP approaches to capturing data from free text safety forms (e.g. CIOMS) and other real world data sources such as social media and the literature.
- Using ML techniques with real world data (e.g. electronic health records and/or administrative claims) to elucidate potential predictors for AEs.

BRIAN DREYFUS
Senior Director -Solid Tumor Oncology Epidemiology
Bristol-Myers Squibb

10:40 – The landscape of Adverse events for various modalities

- Providing insights on the safety profile of newer modalities by capturing the most frequently observed serious adverse events for cell therapies, gene therapies, and oligonucleotide therapies by comparing them with small molecules therapy.
- Past 20 years trends in the safety profile of small molecule therapies and the impact of regulatory guidelines. Focusing on the area of drug-induced cardiovascular events, seizures, tumorigenicity, and hepatic disorders.

NIBHA MISHRA
Senior Scientist, Investigative Toxicology
Takeda Pharmaceuticals

11:10 – Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:30 – Keynote Panel Discussion: Pharmacovigilance and Patient Safety

- Pharmacovigilance – ensuring patient safety first
- Driving patient centricity into your PV plans
- Patient Support Program in Pharmacovigilance
- 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
- What has this pandemic thought us towards patient safety

Moderator:

BEN LOCWIN
Executive SME
Black Diamond Networks

Panellists:

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

BRIAN DREYFUS
Senior Director -Solid Tumor Oncology Epidemiology
Bristol-Myers Squibb

ELIZABETH WHITE BAKER
Associate Professor
Virginia Commonwealth University

12:10 – Updates on Combination product related observations

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DAY TWO - 16th June 2022

KHAUDEJA BANO
Vice President, Combination Product Quality
Amgen

12:50 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:40 – Panel Discussion – PV – Risk Management and Planning

- How does the new RMP compare with its US counterpart, the REMS?
- How effective is your risk management?
- Implementation and maintenance of RMP's – Overcoming its challenges
- Risk management in different jurisdictions
- New approaches to managing benefit-risk
- Research and development improvement

Moderator:

BEN LOCWIN
Executive SME
Black Diamond Networks

Panellists:

SHARON REID
Director, Risk Management Product Lead
Pfizer

AJINKYA INAMDAR
Director, Global Medical Safety, Global Safety Strategy and Risk Management, Janssen Pharmaceuticals

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

14:30 – Why pharmacovigilance sometimes fails and how to bridge the gaps?

- How does risk blindness show up in industry, by the health authorities
- It's not my fault – case examples
- Best practices for minimizing the risks and learning from previous experiences

NANCY DUBOIS
Head of Global Drug, Safety, United States Region
Merck-EMD Serono

15:00 – Worldwide mandated adverse events reporting as new approach for effective global pharmacovigilance

JERRY K. KOUNGA
Investigational Drug Lead Clinical Research Pharmacist
Ascension Wisconsin Research Institute

15:30 - Afternoon Tea/Coffee

REGULATION OVERVIEW & UPDATE

15:50 – Key current changes and their impact on current PV

- 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
- Impact of Brexit – Regulatory aspect
- What's next? Ways to proceed forward.

AYSE BAKER
Vice President of Regulatory Affairs
Almatica (Alvogen)

AUDITS & INSPECTIONS

16:20 – Panel Discussion - Plan, develop and implement the PV Audit Strategy Plan

- Review of FDA and EMEA requirements for risk based PV audits
- PV Audit & Inspections – Knowing what is to be done
- Develop a high-level PV audit strategy
- Real world data: are you sure you have the relevant data?

DAY TWO - 16th June 2022

- Risk based selection criteria for auditing
- Relationship to other GxPs
- What has this pandemic thought us towards audits and inspections

Moderator:

NIRJHAR CHATTERJEE
Medical Director PharmacovigilanceMedical Safety Rare Genetics and Hematology & PDT, Takeda

KATARINA ILIC
Sr Medical Director, Clinical Science, Rare, Genetics & Hematology TAU, Takeda Pharmaceuticals

Panellists:

KAPIL BHUTADA
Director, Pharmacovigilance Compliance and Training
Medicago

JESSICA VAUGHN
Attorney at Law
Wiley Rein

LYNN MEHLER
Partner
Hogan Lovells

17.00 – Chairperson closing remarks

17:15 - 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 - sponsor.uk@virtueinsight.com

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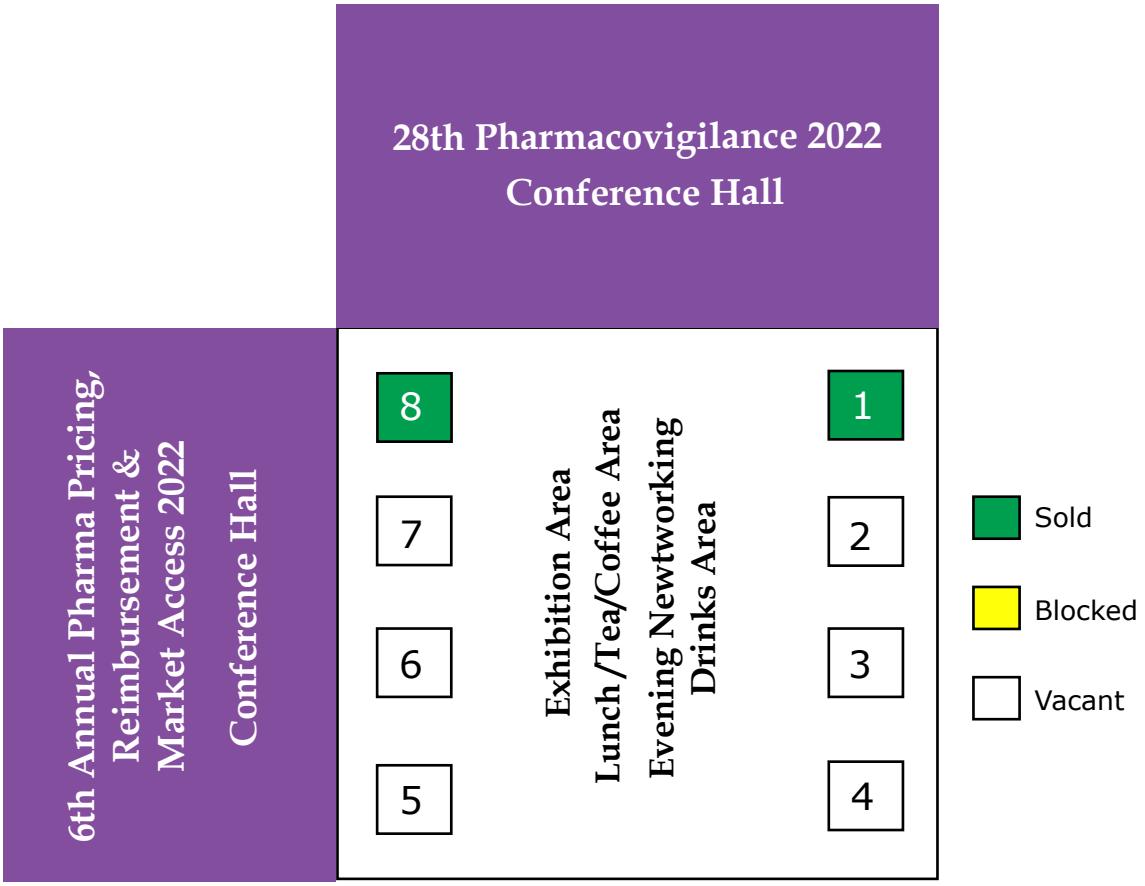
FLOOR PLAN - Book your stalls now before they run out !!!



1 Augustresearch

2

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4

5

6

7

8 **SYNOWLEDGE**
(Drug Safety and Solutions)

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

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REGISTER ONLINE :

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

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:

1 Delegates US $ 1599

Group Booking (Amazing Savings)

3+ Delegates US $ 999 (per delegate)
(minimum 3 attendees required)

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

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

ROUTING Code: 026002574

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.

VENUE

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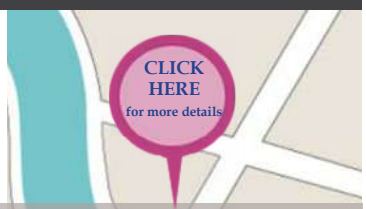

MAP & DIRECTIONS

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