22nd Pharmacovigilance 2020

#VIphv

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

09th – 10th December 2020, Virtual Conference (Time Zone – EST)

AGENDA AT A GLANCE

Key Speakers Include

SONGLIN XUE
Executive Vice President and Global Head of Pharmacovigilance, Astellas Pharmaceuticals

DIANE E. BECK
Vice President & Head of PV Affiliate Relations Global Patient Safety Evaluation
Takeda Pharmaceuticals

SHARON REID
Director, Risk Management Product Lead
Pfizer

BRUNO MENDEZ
VP Global Quality Head Pharmacovigilance
Sanofi

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

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

SHAUN COMFORT
Principal Scientific Enablement Director
Roche – Genentech

DEEPA VENKATARAMAN
Senior Director, Patient Safety Operations
Abbvie

SHEETAL KHEDKAR
Medical Safety Officer- Oncology, Global Medical Safety, Janssen, Pharmaceutical Companies of Johnson and Johnson

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

AMGAD SHEBL
Director, Global Clinical Safety & PV / Clinical R&D, CSL Behring

RICKY RUDRARAJU
Sr. Principal Scientist - Global Patient Safety Evaluation, Takeda Oncology

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

MARIA ESTRADA
Medical Director, Pharmacovigilance
Deciphera Pharmaceuticals

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation, Takeda

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

SANDRINE VALIERE
Global PV Audit/Inspection Readiness Head
Sanofi

JAYLAXMI NALAWADE
Associate Director - Pharmacovigilance & REMS, Lupin

TOYIN ADEWOLE
Assistant Director, Drug Safety
Supernus Pharmaceuticals

HUMAIRA QURESHI
President
Bioclinica

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

DAVID HUTCHINSON
Founder and Owner
Brookwood Gobal

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

KATARINA ILLIC
Senior Clinical Pharmacology Medical Leader
Takeda Pharmaceuticals

ANKA G. EHRHARDT
Director, Clinical Research
CHDI Foundation

ADEDEJI ADEFUYE
Head, Medical Safety, Rare Diseases & PDT and Head, CoE for Medical Device Safety
Takeda

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

BEN LOCWIN
Senior VP, Quality
Lumicell

Plus more COMING SOON.....

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AGENDA AT A GLANCE

OUR HISTORY

After the successful journey of a series of 21 Pharmacovigilance conferences, Virtue Insight is proud to announce its **22nd Pharmacovigilance 2020**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade.** For the 2020 edition, the agenda includes a host of new and exciting features. Take a chance and make it count by attending our 22nd Pharmacovigilance 2020 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 **22nd Pharmacovigilance 2020**. 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
- Regulations, Legal & Brexit 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
- RWE & RWD
- 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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AGENDA AT A GLANCE

DAY ONE - 09th December 2020

09:30 - Chairperson opening remarks

BEN LOCWIN
Senior VP, Quality
Lumicell

MARKET TRENDS & WAY FORWARD

09:40 – Pharmacovigilance - Emerging Markets

- Pharmacovigilance: What comes next for the Pv industry?
- Making medicines safe in an increasingly complex world
- Challenges of Global PV function in a changing business environment
- Does the shift towards emerging markets pose a risk to drug safety and biased data reports?
- Postmarketing safety monitoring

DIANE E. BECK
Vice President & Head of PV Affiliate Relations Global Patient Safety Evaluation, Takeda Pharmaceuticals

10:20 – Combination product safety – Successful PMSR Implementation

- Paradigm shifts needed in Pharmacovigilance for imple mentation of PMSR requirements
- Leveraging risk management for a holistic approach to reportability decision-making for combination products
- New Data governance model to consider

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

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?
- Documentation (RMPs, PSURs, PADERs, PBRERs)
- 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:

BEN LOCWIN
Senior VP, Quality
Lumicell

Panellists:

SONGLIN XUE
Executive Vice President and Global Head of Pharmacovigilance, Astellas Pharmaceuticals

RICKY RUDRARAJU
Sr. Principal Scientist - Global Patient Safety Evaluation
Takeda Oncology

DEEPA VENKATARAMAN
Senior Director, Patient Safety Operations
Abbvie

MARIA ESTRADA
Medical Director, Pharmacovigilance
Deciphera Pharmaceuticals

IMPACT OF TECHNOLOGY

12:00 – PharmaTech – Modern Technologies in Pharmacovigilance - The Way Forward

- Technology is the key to innovation in Pharmacovigilance
- How Pharma companies capitalize on technology?
- AI, IoT and Blockchain - Benefits, challenges & future directions
- Implementation Challenges - Preparing for a smooth transition
- Pitfalls and Learnings
- Vigilance in the era of digital media
- Building trust and openness with technology

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

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DAY ONE - 09th December 2020

12:40 - Networking luncheon

QUALITY - SAFETY – SIGNAL DETECTION

13:40 – Panel Discussion – Quality, Safety & Signal Detection - Future of 2020

- 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
Senior VP, Quality
Lumicell

Panellists:

SHEETAL KHEDKAR
Medical Safety Officer- Oncology, Global Medical Safety
Janssen, Pharmaceutical Companies of Johnson and Johnson

SHAUN COMFORT
Principal Scientific Enablement Director
Roche – Genentech

OYINKANSOLA ODEBO
Assistant Director, Drug Safety Clinical Research
Supernus Pharmaceuticals

AMGAD SHEBL
Director, Global Clinical Safety & PV / Clinical R&D
CSL Behring

14:20 – How Service Providers are adapting to deliver in a COVID-19

HUMAIRA QURESHI
President
Bioclinica

14:50 – Afternoon Tea/Coffee

OUTSOURCING

15:10 - PV and Outsourcing - How to evaluate and implement sourcing alternatives

- Outsourcing vs Innovation
- Preliminary set up steps – what are all to be looked into?
- Moving forward – what are the deals that are to be communicated
- Steps to be taken in order to maintain efficacy and quality
- Monitoring constantly and effects of proper communication
- Benefits and risks of managing a pharmacovigilance-out sourced organization

PRE-CLINICAL & CLINICAL TRIALS

15:50 – 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 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

16:30 - Chairperson's closing remarks and end of conference

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DAY TWO - 10th December 2020

09:30 – Chairperson opening remarks

BEN LOCWIN
Senior VP, Quality
Lumicell

PV FOR 2021

09:40 – Harmonisation in PV requirements in resource limited settings

TANJA PETERS
Head Global Patient Safety Neurology & Immunology
Merck KGaA

10:20 – Impact of COVID 19 On PV Quality

- Oversight of BCP
- Conduct of Remote audits and inspections

BRUNO MENDEZ
VP Global Quality Head Pharmacovigilance
Sanofi

11:00 – Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:20 – Keynote Panel Discussion: Pharmacovigilance and Patient Safety

- 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
- A practical approach to reshaping patient safety
- Next generation pharmacovigilance for enhanced patient safety

Moderator:

BEN LOCWIN
Senior VP, Quality
Lumicell

Panellists:

ADEDEJI ADEFUYE
Head, Medical Safety, Rare Diseases & PDT and Head, CoE for Medical Device Safety, Takeda

HEIDE CUNNING
US Pharmacovigilance Officer-Safety Services Operations
Janssen Pharmaceuticals

TOYIN ADEWOLE
Assistant Director, Drug Safety
Supernus Pharmaceuticals

RISK MANAGEMENT & PLANNING

12:00 – Panel Discussion – PV – Risk Management and Planning

- Assessing effectiveness of risk management - Challenges and overcoming problems in Pharmaceutical product life cycle management
- How effective is your risk management?
- Implementation and maintenance of RMP's – Overcoming its challenges
- Risk management/minimization rules in different regions
- Challenges and how to weigh evidence of efficacy and safety in assessment of Benefit-Risk?
- New approaches in assessment and managing benefit-risk
- Impact of early and evolving Benefit-Risk in Research and development improvement

Moderator:

BEN LOCWIN
Senior VP, Quality
Lumicell

Panellists:

SHARON REID
Director, Risk Management Product Lead
Pfizer

SUMIT MUNJAL
Vice President, Global Patient Safety Evaluation
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JAYLAXMI NALAWADE
Associate Director - Pharmacovigilance & REMS
Lupin

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

12:50 – Networking luncheon

14:00 – Solution Provider Presentation

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

14:30 – Topic TBC

WILLIAM WANG
Executive Director, Clinical Safety Statistics
Merck

15:10 - Afternoon Tea/Coffee

DATA COLLECTION – MANAGEMENT

15:30 – Panel Discussion - PV Audit & Inspections – What really is inspection readiness?

- Will your data stand up to regulatory inspection?
- Will your real world PV data be respected by authorities?
- What in particular is PV inspection readiness?
- Ensuring data quality in PV.

Moderator:

DAVID HUTCHINSON
Founder & Owner
Brookwood Gobal

Panellists:

SANDRINE VALIERE
Global PV Audit/Inspection Readiness Head
Sanofi

ANKA G. EHRHARDT
Director, Clinical Research
CHDI Foundation

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

KATARINA ILLIC
Senior Clinical Pharmacology Medical Leader
Takeda Pharmaceuticals

16:10 - 16:20 - Chairperson's closing remarks and end of 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

FOR DELEGATE REGISTRATIONS:-

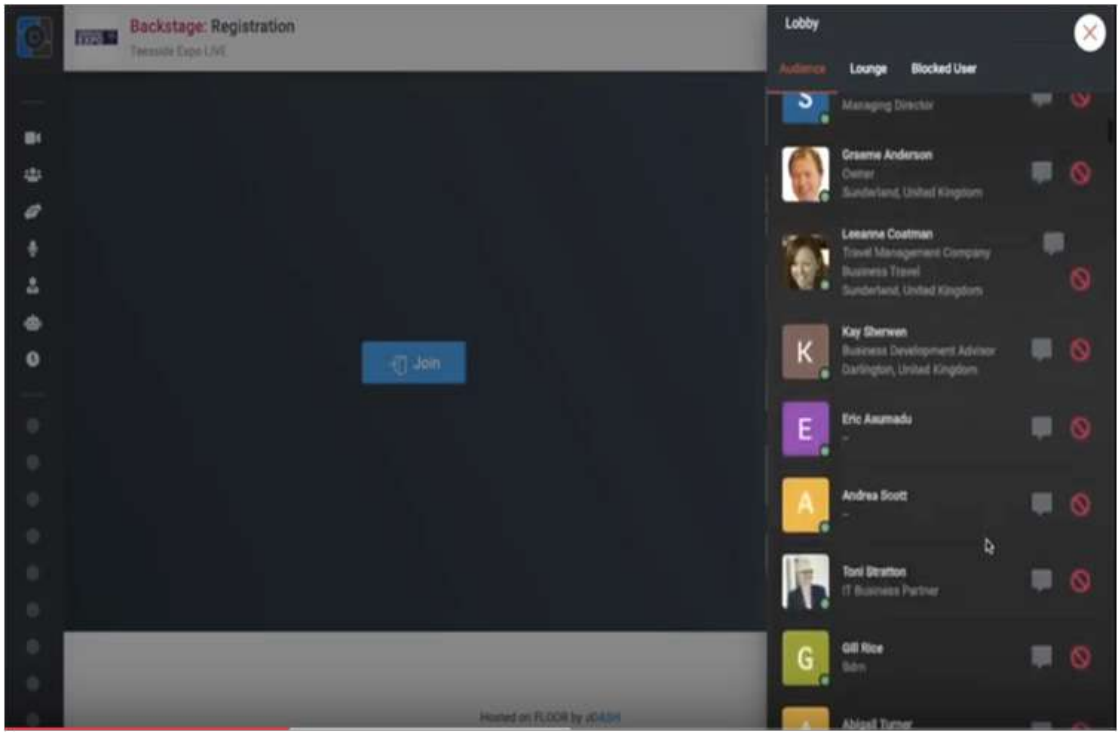
Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - info.uk@virtueinsight.com

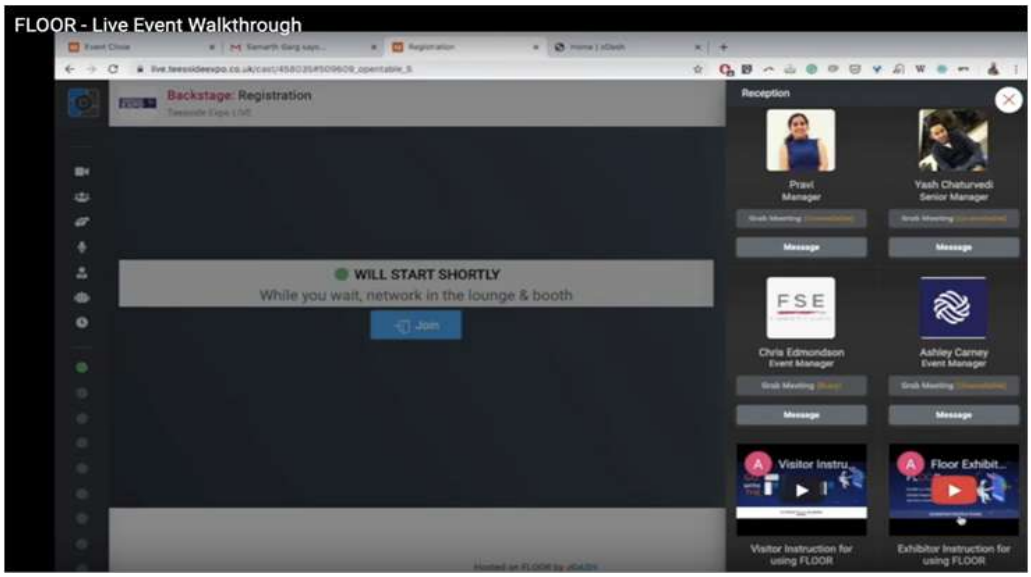
Features of our Virtual Conference

NETWORKING

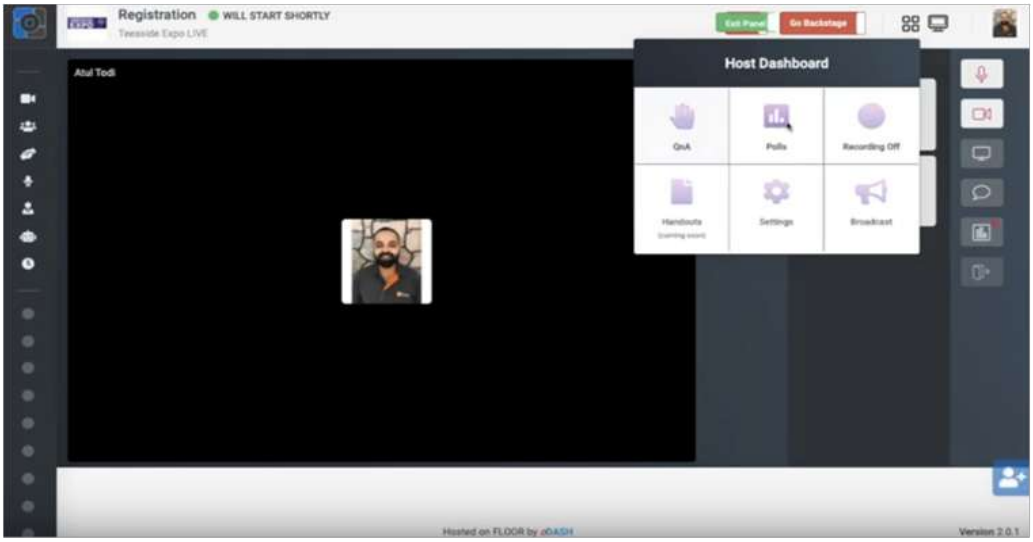
Lobby – Here at the lobby, all attendees can see the other participants. You can choose to start a conversation privately at any time with any of the other co-participants– For more details – check out the links (YouTube videos in the last page)



Reception – Should you have any questions to the organisers, you can find them at the reception - For more details – check out the links (YouTube videos in the last page)



Q&A, Polls & Handouts– We can have Q&A from the audience at the end of every session as usual and also have polls and handouts done - For more details – check out the links (YouTube videos in the last page)



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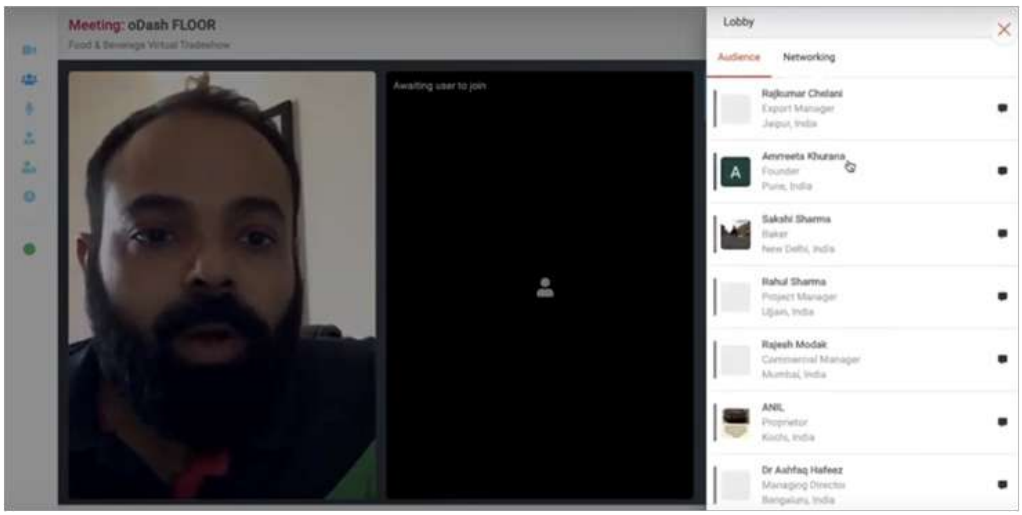
LIVE STREAMING

Solo Presentations & Panel Sessions– Interactive panel sessions and solo presentations sessions - For more details – check out the links (YouTube videos in the last page)

SPONSORS & EXHIBTORS

Exhibitors– Exhibitors have booths where they can start a conversation with any of the attendees and also attend to the attendees who visit their stall - For more details – check out the links (YouTube videos in the last page)



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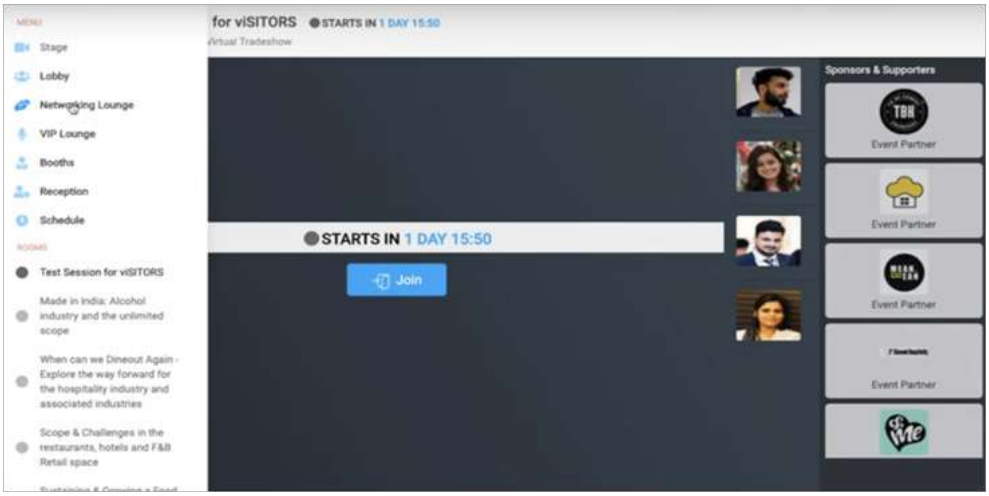
Sponsors– Sponsors can have speaking slot sessions and their logos would be visible in all sessions for their branding purposes - For more details – check out the links (YouTube videos in the last page)



Links to YouTube videos of the conference webinar platform

Live Event Walkthrough - https://www.youtube.com/watch?v=KRX5j3gQeF0

Exhibitor Instructions - https://www.youtube.com/watch?v=uOvH46TeYrw

Visitor Instructions - https://www.youtube.com/watch?v=c4WSfp9RFP0

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REGISTER ONLINE :

Link : https://www.bookmytrainings.com/catalogue/event/78920-22nd-pharmacovigilance-2020

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:

EARLY BIRD PRICING

1 Delegate @ US$399 (Valid Till 16th November 2020)

3 Delegates@ US$1099 (Valid Till 16th November 2020)

STANDARD RATE

1 Delegate @ US$599 (From 17th November 2020)

3 Delegates@ US$1,499 (From 17th November 2020)

PAYMENT:

Please send me a invoice ☐

Please charge my card US$

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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
Account Type	- Current
Account Number	- 915020031763553
Bank Name	- Axis Bank
Swift Code	- AXISINBB211
NEFT / IFSC Code	- UTIB0000211
Micro Code	- 600211010

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 US$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 US$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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