

34th Pharmacovigilance 2024

#Vlphv

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

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



ALINA TUDOR
Senior Director, Pharmacovigilance
Kyowa Kirin International



FABIO DE GREGORIO
Vice President, Head of Drug Safety Europe
Shionogi Europe



PETAR GJORGIEV
Medical Director & Safety Risk Lead
Pfizer



SUMIT MUNJAL
Global Head of Medical Safety
Otsuka Pharmaceuticals



SABINE POLTERMANN
Head of Country Patient Safety Switzerland
Bristol-Myers Squibb



TANUJA HALADY
Senior Medical Director, Head of GPS
Oncology Group III, Merck KGaA



ERIKA BARBAROSIE
Associate Director PV Compliance
Gilead Sciences



GEORGIA GAVRIILIDOU
Associate General Counsel (Executive Director)
Amgen



JUDY BARRETTO
Global Process Owner, Signal Management
Director, Roche



JOHN SOLOMON
Head of Pharmacovigilance - UK & Ireland
Sanofi



EVI MATHIOU
Legal, Compliance & Quality Director
Novo Nordisk



YVONNE NANCIU
Country Head Pharmacovigilance
Bayer



ZINA SADEQ
Director, Regional PV & Alliance Management
Amicus Therapeutics



PAV RISHIRAJ
Director, Head of Pharmacovigilance & ABPI
PV Expert Chair, Ipsen



MARIANA CALZADA MIJANGOS
CHC Country Safety Head
Sanofi



MIJAL CHAVDA
Senior Director, Global Head of GxP
Inspections & GVP Quality, Kyowa Kirin



YUUNG YUUNG YAP
Head Legal Pharma Operations
Vifor Pharma



RAJ BHOGAL
Sr. Director, R&D Business Strategy &
Operations, Jazz Pharmaceuticals



DNYANESHWAR SANAP
EU/UK QPPV, Head Regional Pharmacovigilance
Glenmark



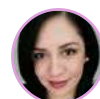
VALENTINA MANCINI
Senior Director Pharmacovigilance, QPPV
Shionogi Europe



SIMON ASHWORTH
Head of Pharmacovigilance and Medical Safety
ONO PHARMACEUTICAL



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



CINTHYA GALICIA QUINTANAR
Senior Manager, Country Safety Lead
Pfizer

Conceptualised By



+44-20 3509 3779

info.uk@virtueinsight.com

34th Pharmacovigilance 2024

#Vlphv

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Conference Info

Floor Plan

Key Speakers Include



MARIANNE MOUNIR
Senior Global System Auditor
Bayer



GAURI UTTURKAR
Patient Safety Physician
UCB



JOHN POUSTIE
EMA Director Pharmacovigilance and UK
QPPV, **Haleon**



LIZANNE PISTORIUS
Senior Manager Global Patient Safety
Operations, QMS & RMP
Nestlé / Aimmune Therapeutics



MARIJA BRIEDE
Head of Pharmacovigilance, QPPV
Grindeks



ENIKO BARTA-KONDAS
Head Global PV Operations
Gedeon Richter



DARIUS-JEAN NAMDJOU
Head of Regulatory Affairs & Pharmacovigilance
Immunic Therapeutics



GURPREET SINGH
VP, Global Head of Pharmacovigilance
Freyr



FATIMA YOUSEF GHETHAN
Quality Culture & Implementation Manager,
Executive Administration of Quality & Patient
Safety, **Makkah Healthcare Cluster (UAE)**



KAPIL BHUTADA
Senior Director
Inozyme Pharma



DANIELA DI COSMO
Senior Safety Advisor, Global Safety
Ferring Pharmaceuticals



MARIA BEATRICE PANICO
Principal Consultant
Scendea



VERONICA SANCHEZ-BARRIGA BORRERO
Global PV QA Compliance Manager
ITALFARMACO



ALEXANDER ROUSSANOV
International Partner, Life Sciences and Privacy
Arnold & Porter



DIMITRIS ZAMPATIS
Global Program Safety Lead
Sandoz

Plus More Coming Soon...

BRONZE SPONSOR



SUPPORTED BY

Eventbrite

CONFERENCE
locate.com

Townscript
A BookMyShow Enterprise

34th Pharmacovigilance 2024

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Key Speakers

Conference Info

Day One

Day Two

Floor Plan

Booking Details

KEY THEMES DISCUSSED

- Market trends and the way forward - Future of pharmacovigilance
- Pharmacovigilance: What comes next for the industry?
- Current Challenges & Opportunities in Pharmacovigilance - Pragmatic Approaches
- Collaboration among all the parties (industry, regulators, patients, healthcare professionals, WHO, etc)
- Rethinking relationship between Sponsor, Site, CRO & Patients - Working together
- Impact of Technology (AI / ML)
- Quality, Safety, Signal Detection - Traditional and innovative approaches
- Outsourcing Pharmacovigilance: Benefits of a Specialized Safety Partner
- Pharmacovigilance & Risk Management - Current Status & Future Needs
- Plan, develop and implement the PV Audit strategy plan
- Medical devices - Increasing safety perspective
- Prioritising patients in quest to achieve Patient Safety
- Regulatory - EU and UK Regulations & Guidelines in Pharmacovigilance
- Best practices & the way forward
- Be part of a major networking opportunity

OUR HISTORY

After the successful journey of a series of 33 Pharmacovigilance conferences, Virtue Insight is proud to announce its **34th Pharmacovigilance 2024**. We have been delivering the conference through close collaboration with the industry leaders for **more than a decade**. For the 2024th 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.

The global pharmacovigilance (PV) market size is expected to reach USD 14.85 billion in 2028 from USD 6.28 billion in 2021, and estimated to grow at a CAGR of 13.1% during forecast period (2021-2028). Rising prevalence of chronic disorders has increased the usage of drugs for disease management. This has increased the number of ADRs and created a lot of awareness about its potential health risks. Across the world governments are investing heavily in Pharmacovigilance to detect, understand and to prevent the increasing ADRs which is definitely fuelling the market progress. 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 34th Pharmacovigilance 2024. 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.

34th Pharmacovigilance 2024

“Latest developments in pharmacovigilance, drug safety & risk management”

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Conference Info

Floor Plan

DAY ONE - 30th January 2024

08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

.....

09:30 – Chairperson opening remarks

PAV RISHIRAJ
Director, Head of Pharmacovigilance & ABPI PV Expert Chair, Ipsen

.....

RWD & RWE

09:40 – Role of RWD and RWE in future of drug safety and PV- preferred option

TANUJA HALADY
Senior Medical Director, Head of GPS Oncology Group III Merck KGaA

.....

SAFETY

10:20 – Drug Quality Reports and ADE

- Drug Quality reports investigation and Reporting
- Adverse Drug reaction work flow Reporting
- ADE triggers tool
- National and international standard Requirements
- Patient involvement
- ADR & Drug quality reporting to SFDA

FATIMA YOUSEF GHETHAN
Quality Culture & Implementation Manager, Executive Administration of Quality & Patient Safety Makkah Healthcare Cluster (UAE)

.....

10:50 – Morning Coffee / Tea & Networking

.....

CHALLENGES & OPPORTUNITIES

11:20 – Keynote Panel Discussion: Current Challenges & Opportunities in Pharmacovigilance - Pragmatic Approaches

- A new era of Pharmacovigilance
- Challenges with implementation of a global PV System while remaining compliant with global regulations
- Key challenges and areas of focus

- Innovative technologies and systems
- Staying ahead in the race - Current trends for PV, and new and future guidelines
- Collaboration among all the parties (industry, regulators, patients, healthcare professionals, WHO, etc
- Best practices & the way forward

Moderator:

PAV RISHIRAJ
Director, Head of Pharmacovigilance & ABPI PV Expert Chair, Ipsen

Panellists:

GEORGIA GAVRIILIDOU
Associate General Counsel (Executive Director) Amgen

JOHN POUSTIE
EMA Director Pharmacovigilance and UK QPPV Haleon

SABINE POLTERMANN
Head of Country Patient Safety Switzerland Bristol-Myers Squibb

MARIJA BRIEDE
Head of Pharmacovigilance, QPPV Grindeks

SIMON ASHWORTH
Head of Pharmacovigilance and Medical Safety ONO PHARMACEUTICAL

.....

12:20 – Solution Provider Presentation

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

.....

12:40 – Networking luncheon

.....

QUALITY - SAFETY - SIGNAL DETECTION

13:50 – Panel Discussion – Quality, Safety, Signal Detection – Traditional and innovative approaches

- Statistical methodologies for signal detection
- Best practices for safety management in pharmacovigilance

34th Pharmacovigilance 2024

“Latest developments in pharmacovigilance, drug safety & risk management”

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Conference Info

Floor Plan

DAY ONE - 30th January 2024

- Signal evaluation and management: future improvements
- Practical aspects of early detection of signals in pharmacovigilance
- Signal detection in drug development: post marketing vs development stages
- Developing a global safety intelligence process
- Quality assurance and compliance
- Latest updates and hot topics

Moderator:

PAV RISHIRAJ

Director, Head of Pharmacovigilance & ABPI PV Expert Chair, Ipsen

Panellists:

FABIO DE GREGORIO

Vice President, Head of Drug Safety Europe
Shionogi Europe

JUDY BARRETTO

Global Process Owner, Signal Management Director
Roche

MARIANA CALZADA MIJANGOS

CHC Country Safety Head
Sanofi

CINTHYA GALICIA QUINTANAR

Senior Manager, Country Safety Lead
Pfizer

14:40 – PV operations within financial and logistical constraints

MARIA BEATRICE PANICO

Principal Consultant
Scendea

15:00 – Afternoon Tea / Coffee

IMPACT OF TECHNOLOGY

15:20 – New technologies in Pharmacovigilance

- 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
- Conclusions / Discussion

15:40 – How to tailor safety surveillance for new and well established products: our experience

- Safety surveillance when the company portfolio contains both well-established and new products
- How the signal management process follows
- Some results from our experience

DANIELA DI COSMO

Senior Safety Advisor, Global Safety
Ferring Pharmaceuticals

REGULATION OVERVIEW & UPDATE

16:10 – Panel Discussion: Regulatory - EU and UK Regulations & Guidelines in Pharmacovigilance

- Navigating the latest regulations for Pharmacovigilance
- Challenges in communications between pharmacovigilance and regulatory departments
- Evaluating Regulatory Assessment of Risk Management Strategies
- Key current changes and their impact on current PV
- Future Legislation: Pharmacovigilance – Industry Vision
- Enhancing communication between regulators, regional authorities and patients

Moderator:

PAV RISHIRAJ

Director, Head of Pharmacovigilance & ABPI PV Expert Chair, Ipsen

Panellists:

MICHAEL BEAN

Senior Director, BioResearch Regulatory Compliance
Johnson & Johnson

EVI MATHIOU

Legal, Compliance & Quality Director
Novo Nordisk

YUONG YUONG YAP

Head Legal Pharma Operations
Vifor Pharma

34th Pharmacovigilance 2024

#Vlphv

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Key Speakers

Conference Info

Day One

Day Two

Floor Plan

Booking Details

DAY ONE - 30th January 2024

DARIUS-JEAN NAMDJOU

Head of Regulatory Affairs & Pharmacovigilance
Immunic Therapeutics

ALEXANDER ROUSSANOV

International Partner, Life Sciences and Privacy
Arnold & Porter

.....
17:00 - Chairperson's closing remarks and end of conference

.....
17:10 - 18:10 - Networking Drinks Session

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

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

34th Pharmacovigilance 2024

#Vlphv

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Key Speakers

Conference Info

Day One

Day Two

Floor Plan

Booking Details

DAY TWO - 31st January 2024

08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

09:30 – Chairperson opening remarks

PAV RISHIRAJ

Director, Head of Pharmacovigilance & ABPI PV Expert Chair, **Ipsen**

PV FOR FUTURE

09:40 – PV challenges with implementing IVDR and Diagnostics

- Does your portfolio include products that leverage diagnostics?
- What are companion Diagnostics?
- How has your PV organization prepared for IVD and IVDR reporting ? People / Process / Technology

KHAUDEJA BANO

Vice President, Combination Product Quality
Amgen

10:20 – Risk management & effectiveness of aRMMs

- Risk categorization
- Handling of Risk Minimization measures
- How to measure effectiveness of aRMMs
- RMP for Biosimilars, Biologics

DIMITRIS ZAMPATIS

Global Program Safety Lead
Sandoz

10:50 – Morning Coffee / Tea & Discussion

PATIENT SAFETY

11:20 – Keynote Panel Discussion: Prioritising patients in quest to achieve Patient Safety

- Patient centricity as important pillar for the development, regulation and safety use of medicines
- Looking at importance of patient experience as a vital factor for quality and safety
- Reshaping patient safety
- Driving patient centricity into your PV plans
- Patients involvement for a better PV knowledge - Patient support programs

- Patient-Perspectives in benefit-risk assessments
- A review of general issues and the specific challenges with patients
- Next generation pharmacovigilance for enhanced patient safety

Moderator:

YVONNE NANCIU

Country Head Pharmacovigilance
Bayer

Panellists:

JOHN SOLOMON

Head of Pharmacovigilance - UK & Ireland
Sanofi

SUMIT MUNJAL

Global Head of Medical Safety
Otsuka Pharmaceuticals

ALINA TUDOR

Senior Director, Pharmacovigilance
Kyowa Kirin International

FATIMA YOUSEF GHETHAN

Quality Culture & Implementation Manager, Executive Administration of Quality & Patient Safety
Makkah Healthcare Cluster (UAE)

12:20 – Solution Provider Presentation

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

12:40 – Networking luncheon

RISK MANAGEMENT & PLANNING

13:50 – Panel Discussion – Pharmacovigilance & Risk Management - Current Status & Future Needs

- Safety risk management strategies: process and oversight
- Measuring the effectiveness of risk minimization measures (RMMS)
- Advancements of patient centricity in benefit risk evaluation
- Tools & Approaches
- Guidance on risk management plans
- Tailored approaches towards benefit-risk evaluations
- Risk management in different jurisdictions
- New approaches to managing benefit-risk

34th Pharmacovigilance 2024

#Vlphv

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Conference Info

Floor Plan

DAY TWO - 31st January 2024

Moderator:

PAV RISHIRAJ

Director, Head of Pharmacovigilance & ABPI PV Expert
Chair, **Ipsen**

Panellists:

PETAR GJORGIEV

Medical Director & Safety Risk Lead
Pfizer

DNYANESHWAR SANAP

EU/UK QPPV, Head Regional Pharmacovigilance
Glenmark

GAURI UTTURKAR

Patient Safety Physician
UCB

LIZANNE PISTORIUS

Senior Manager Global Patient Safety Operations, QMS &
RMP, **Nestlé / Aimmune Therapeutics**

AUDITS & INSPECTIONS

14:40 – Panel Discussion – Plan, develop and implement the
PV Audit strategy plan

- PV Inspection readiness: What to expect? How ready can we be?
- PV Inspection Readiness from inspector perspective
- PV Audit Readiness from auditor perspective
- Data quality management and analysis
- Update of PSURs, Risk Management Plans and PASS
- Methodologies, scope and oversight
- Preparing and managing safety data exchange agreements

Moderator:

RAJ BHOGAL

Sr. Director, R&D Business Strategy & Operations
Jazz Pharmaceuticals

Panellists:

VALENTINA MANCINI

Senior Director Pharmacovigilance, QPPV
Shionogi Europe

MIJAL CHAVDA

Senior Director, Global Head of GxP Inspections & GVP
Quality, **Kyowa Kirin**

MARIANNE MOUNIR

Senior Global System Auditor
Bayer

KAPIL BHUTADA

Senior Director
Inozyme Pharma

VERONICA SANCHEZ-BARRIGA BORRERO

Global PV QA Compliance Manager
ITALFARMACO

OUTSOURCING

15:30 – Panel Discussion – Outsourcing
Pharmacovigilance: Benefits of a Specialized Safety
Partner

- The era of outsourcing: recent developments and insights
- Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration
- Proper communication between - Sponsor - Site - CRO & Patients
- How should you safely outsource pharmacovigilance?
- Best Practices in Pre-Screening before selecting your partner
- How can you maximize the effectiveness of your partnership?
- Working together to improve drug safety
- Mistakes that will doom a CRO-Sponsor partnership

Moderator:

PAV RISHIRAJ

Director, Head of Pharmacovigilance & ABPI PV Expert
Chair, **Ipsen**

Panellists:

ERIKA BARBAROSIE

Associate Director PV Compliance
Gilead Sciences

ENIKO BARTA-KONDAS

Head Global PV Operations
Gedeon Richter

GURPREET SINGH

VP, Global Head of Pharmacovigilance
Freyr

ZINA SADEQ

Director, Regional PV & Alliance Management
Amicus Therapeutics

16:20 – Chairperson's closing remarks

16:30 – Evening Tea / Coffee and end of the conference

34th Pharmacovigilance 2024

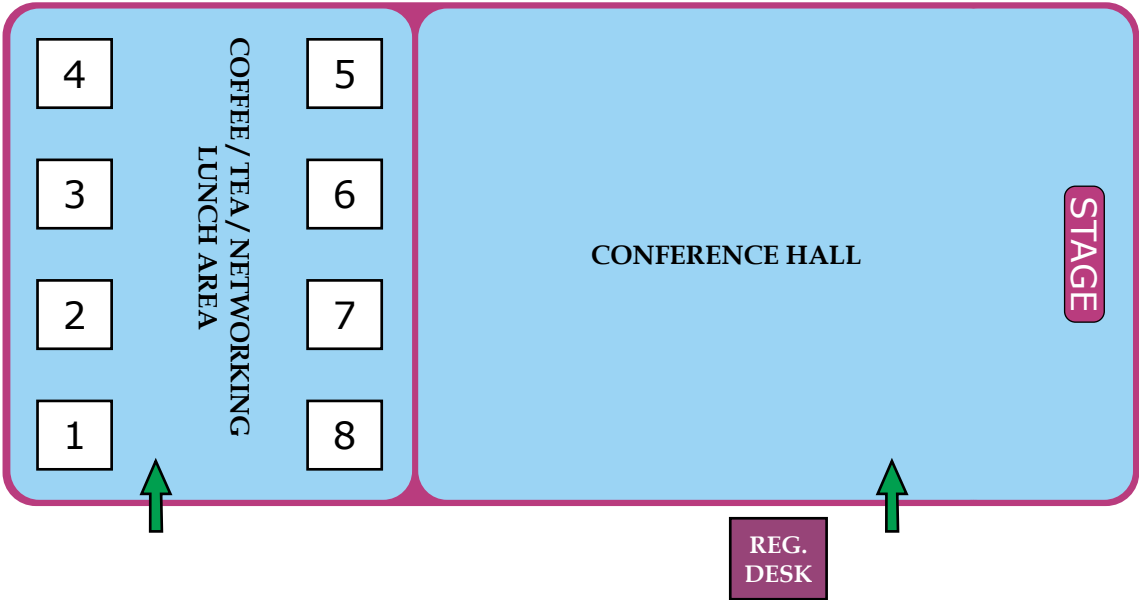
“Latest developments in pharmacovigilance, drug safety & risk management”

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

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

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



1

5

2

6

3

7

4

8

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

34th Pharmacovigilance 2024

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

30th & 31st January 2024, Sheraton Skyline, Heathrow, London

AGENDA AT A GLANCE

Conference Info

Floor Plan

REGISTER ONLINE :

Link : <https://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	
Email	

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

RESERVATION PRICING:

SUPER EARLY BIRD PRICE (Valid Till 23rd October)

1 Delegate @ **£799 + VAT**

Group Discount @ **£1598 + VAT** (3 Delegates for the price of 2)

STANDARD PRICE

1 Delegate @ **£1299 + VAT**

Group Discount @ **£2598 + VAT** (3 Delegates for the price of 2)

PAYMENT:

Please send me a VAT invoice ☐

I enclose a cheque for £

Please charge my card £

Card Number

Security No

Expiry Date

Cardholder's Name

Cardholder's Registered Address

Signature

Our purchase order no.is

Payable to Virtue Insight Events Ltd

Card type: Visa ☐ Mastercard ☐ Maestro ☐ Amex ☐

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

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.

Conceptualised By

