THE EUROPEAN DRUG SAFETY SUMMIT 2018

17th & 18th October, London, UK

Key Topics

- Meeting Safety Requirement: Regulators Perspective
- Building a Pharmacovigilance Strategies
- Evolving PV Strategies for Tomorrow
- Technological Advancement in Pharmacovigilance
- Clinical Data Management
- The Role of Big Data and Social Media in Pharmacovigilance
- Ensure Drug Safety & Risk Minimisation Measures
- Development of Qualified Personal Responsible for Pharmacovigilance (QPPV)
- Pharmacovigilance for Advanced Therapies

Speakers Include

Mircea Ciuca
Global Head Medical & Clinical Drug Safety
Vifor Pharma

Marco Sardella
Chief Pharmacovigilance Officer & EU QPPV
ADIENNE Pharma & Biotech

David Lewis
Senior Adviser Pharmacovigilance
Novartis

Lisa Stagi
Drug Safety & Quality Head
Roche S.p.A

Ricarda Tiemeyer
Head of Drug Safety & PoC Medical Information
Roche Pharma (Schweiz) AG

Lucy Hampshire
Director, Medicines Quality Organisation - Europe
Eli Lilly and Company

Sponsorship & Exhibition Opportunities

For sponsorship & Exhibition opportunities please contact Joshua Hill on:
+44 (0) 203 141 0610 or email jhill@acieu.net

European Drug Safety Summit 2018

London, UK

17 – 18 October 2018

ACI's European Drug Safety Summit 2018 is the European strategy—led drug safety event for pharma and biotech organisations. The two day event will bring together key industry personnel from pharmacovigilance and will address the challenges in monitoring and maintaining drug safety strategies, will discuss how to apply new technologies and strategic approaches to effectively manage drug safety and will discover key developments in the handling, analysis and reporting of adverse events during trials and understand the regulators requirements with the aim of speeding drugs to market whilst mitigating the risk of recall.

Conference Location: London, UK

Confirmed Topics for Discussion:

- Meeting Safety Requirement: Regulator's Perspective
- Building a Pharmacovigilance Strategy
- Evolving PV Strategies for Tomorrow
- Technological Advancement in Pharmacovigilance
- Clinical Data Management
- The Role of Big Data and Social Media in PV
- Ensure Drug Safety & Risk Minimisation Measures
- Latest Development & Innovation Approach for effective signal management
- Development of Qualified Personal Responsible for Pharmacovigilance (QPPV)
- Pharmacovigilance for Advanced Therapies

Industry professionals networking at an ACI event

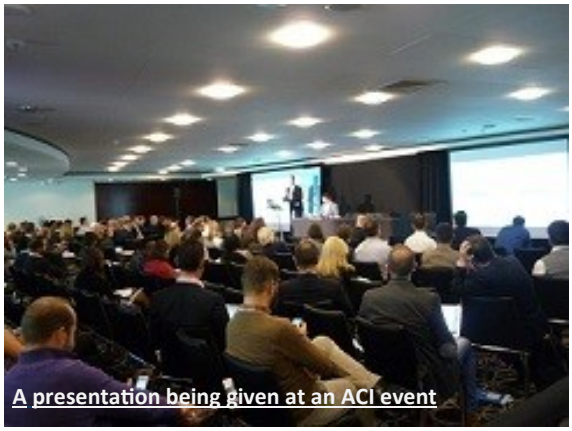
Who Should Attend:

Attendees will be drawn primarily from pharmaceutical, biotechnology and contract research organisations and include VPs, Directors and Managers/Scientists working in Drug Safety, Toxicology, Pharmacology, Pharmacovigilance. Epidemiology, Clinical Research and Development, Clinical Trial Management, Regulatory Affairs and Compliance, Strategy and Business Development

Speaking Opportunities:

If you would like to be considered as a speaker for the event for a 30—45 minute presentation please submit an abstract for consideration to:

Mikhail Kryukov
+44(0)20 3141 0649
mkryukov@acieu.net



A presentation being given at an ACI event

Opportunities to Meet your Target

For information on available sponsorship and exhibition opportunities, Please contact
Joshua Hill
+44 20 3141 0610 / jhill@acieu.net

Registration is Simple:

If you would like to register for this event or wish to find out more information, you can contact Cheryl Williams by using any of the following methods:

+44 (0) 203 141 0623
cwilliams@acieu.net
http://www.acius.net
Postal Address:
10 Gough Square, London, EC4A 3DE

European Drug Safety Summit

London, UK

17th & 18th October 2018

DAY 1

Wednesday 7th March

08:00 REGISTRATION & COFFEE

09:00 CHAIRMAN'S OPENING REMARKS

Monica F. Buchberger (Rusu)
Director PV Governance & QPPV
Global Pharmacovigilance Innovation & Development
Abbott Laboratories GmbH

09:15 SESSION ONE

Meeting Safety Requirements

- The effect of Brexit on pharmacovigilance
- MHRA business plan for post-Brexit drug and medical device regulation in the UK
- Staying ahead for regulatory guidelines: Practical use of EU documents in pharmacovigilance
- Achieving greater collaboration with medicines regulators across Europe and ensure smoother launch of new products
- Determining the best strategy to secure drug safety approval

Uwe Gudat
Safety Head
Fresenius - Kabi

Panel Q&A

10:30 MORNING REFRESHMENTS

11:00 SESSION TWO

Evolving PV Strategies for the Future

Evolving PV Audit Strategies

- Life cycle of the audit
- Lessons learned from audits / inspections

Elizabeth Ursell
Director, Pharmocovigilance
Mapi Group

12:00 **Case Study on Effective Partnership with Service Provider to Enhance Drug Safety Activities and the Oversight Model Needed to Make this Model a Benefit for a Company**

- The case study wil be presented both from Global and from involved Affiliate perspective, showing advantages for both sides

Lisa Stagi
Drug Safety & Quality Head
Roche S.p.A

Manni Kuthiala
PV Affiliate - Strategic Alliance
Roche S.p.A

12:30 **Panel Q&A**

12:50 LUNCH

13:50 CONFERENCE PRESENTATION

Pharmacovigilance System Master File (PSMF) – Audits and Inspections

Monika Manske
Associate Director, Global Pharmacovigilance Governance, Head Pharmacovigilance
Mylan Healthcare GmbH

14:35 SESSION THREE

Good Pharmacovigilance Outsourcing Practice

- Establishing effective collaboration between pharmaceutical companies and service providers

Ricarda Tiemeyer
Head of Drug Safety& PoC Medical Information
Roche Pharma (Schweiz) AG

15:05 **Proposals for Good Outsourcing Practices**

- The pharmaceutical industry has increasingly outsourced its activities, including the
- In order to avoid failures, both clients and service providers should understand and openly
- Clients should ensure the outsourced project is adequately resourced in terms of time allocated
- Clients should always have in house someone who has a good knowledge of

15:35 **Panel Q&A**

15:50 AFTENOON REFRESHMENTS

SESSION FOUR

16:20 **Development of Qualified Person Responsible for Pharmacovigilance (QPPV) and the Importance of Effective Delegations**

- Importance of effective delegation in pharmacovigilance practice
- Role of QPPV in establishing and maintaining a pharmacovigilance system
- Role pf QPPV as contact point for audits / inspections

16:40

Monica F. Buchberger (Rusu)
Director PV Governance & QPPV
Global Pharmacovigilance Innovation & Development
Abbott Laboratories GmbH

17:10 **Presentation TBC**

Vicki Edwards
QPPV Head Affiliate Vigilance Excellence
AbbVie

17:40 CLOSE OF DAY ONE

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DAY 2

Thursday 8th March 2018

08:30 REGISTRATION & COFFEE

09:00 CHAIRMAN'S OPENING REMARKS

09:10 SESSION FIVE

Ensure Drug Safety & Risk Minimisation Measures

- Effective risk minimisation measurements of adverse reactions by using evidence form clinical trials and epidemiology
- Strategies for best practices in benefit–risk management

Saad Shakir
Director
Drug Safety Research Unit

09:40 How to manage a pharmacovigilance crisis in the XXI century?

Ramon Lopez
Clinical Research Manager
Thrombotargers Europe S.L

10:10 Panel Q&A

10:25 MORNING REFRESHMENTS

10:55 SESSION SIX

Latest Development and Approach in Signal Management

WEB-RADR and led the EFPIA response to the EMA's GVP IX Module covering Signal Management

- Analysis of the procedure: Signal detection activity on EudraVigilance data
- New aspect of signal management across the EEA.

David Lewis
Senior Adviser Pharmacovigilance
Novartis

11:25 Using Big Data to detect safety signals earlier and more effectively

Mircea Ciuca
Head of Medical & Clinical Drug Safety
Vifor Pharma

11:55 Panel Q&A

12:10 LUNCH

13:10 PANEL DISCUSSION

Effective Data Management and Quality Assurance

- Management of safety data from Patient Support Programmes (PSPs) and Market Research Programmes(MRPs)
- Challenges in effective safety data handling
- Sensible use of Big Data

Lucy Hampshire
Director, Medicines Quality Organisation - Europe
Eli Lilly and Company Limited

14:10 SESSION SEVEN

Pharmacovigilance for advanced therapies

- Pharmacovigilance System in the Rare Disease Setting against New PV Requirements

Marco Sardella
Chief Pharmacovigilance Officer EU-QPPV
ADIENNE Pharma & Biotech

Paolo Boscani
Deputy EU QPPV & PV Physician
ADIENNE Pharma & Biotech

14:40 Preclinical safety assessment of cell-based therapies

Dominic Bowers
Head of Clinical Operations
Cell and Gene Therapy Catapult

15:10 Panel Q&A

15:25 CHAIRMAN'S CLOSING REMARKS

15:40 END OF CONFERENCE & AFTERNOON REFRESHMENTS

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Registration Is Simple

Conference (Includes Access to All Documentation) 17th & 18th October 2018	£1,595.00
Documentation Packet Only	£470.00

Please Note.
Members and customers of all supporting organizations are entitled to a discount off their conference package.

For more information please call +44 (0) 2031410623.

Documentation Packet Available

We are selling the European Drug Safety Summit papers at just £445 + £25 P&P). Simply tick the box on the booking form, send it with payment and your copy will be on its way to you after the meeting.
This important manual will be a source of invaluable reference for the future.

Terms & Conditions

Payment
Payment must be received within five business days of returning the signed contract. After receiving payment a VAT receipt will be issued. If you do not receive a letter outlining details two weeks prior to the event, please contact the Conference Coordinator at ACI Europe Ltd.

Discounts are available for multiple/group bookings. Please call Cheryl Williams +44 (0) 203 141 0623 for more information.

Cancellations
Substitutions are welcome up to 24 hours prior to the event. Cancellations must be received in writing no less than 3 weeks prior to the start of the conference; a full credit voucher towards a future ACI conference will be issued. Any cancellation received less than 3 weeks prior to the start of the event shall be deemed to be a breach of this contract by client, and accordingly, no credits will be given. Cancellations must be received in writing by mail or fax three weeks before the conference. Thereafter the full conference fee is payable. If for any reason ACI Europe Ltd decides to amend, cancel or postpone this conference, the conference fee will not be refunded. Furthermore, ACI Europe Ltd will not be responsible for covering airfare, hotel or other costs incurred by registrants. In the event that ACI Europe Ltd cancel or postpone the event, ACI Europe Ltd reserves the right to transfer this booking to another conference to be held in the following twelve months, or to provide a credit of an equivalent amount to another conference within the following twelve months. The construction, validity and performance of this agreement shall be governed in all respects by the laws of England to the exclusive jurisdiction of whose courts the Parties hereby agree to submit.

Accommodation
The cost of accommodation is not included in the event fee. Preferential rates will be arranged with or near the event venue, and all confirmed delegates will be given details of how to book accommodation at this rate in due course.

About ACI

ACI, a UK owned company, has been running successful conferences in the USA since 1999. Headquartered in Chicago with offices all around the States, ACI opened its European head office at the end of 2005 and has expanded rapidly, launching a series of events in key industries including maritime, energy, oil & gas, cosmetics, chemicals & media.

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