# THE EUROPEAN DRUG SAFETY SUMMIT 2018

7/8 March 2018 LONDON, UK

SAFETY FIRST

## 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

## SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Hubert Sosnowski Tel:+48 616469780 email:hubert@acieu.net

# European Drug Safety 2018

*London, UK*

7 – 8 March 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,

## 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:

Dana Mukanova
+44(0)20 3141 0611
dmukanova@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
**Hubert Sosnowski**

**+48 61646 9780/ hubert@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) 2031410623
cwilliams@acieu.net
http://www.acius.net
Postal Address:
10 Gough Square, London, EC4A 3DE

# European Drug Safety Summit

*London, UK*

7th & 8th March 2018

## DAY 1

Wednesday 7th March

**08:00** **REGISTRATION & COFFEE**

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

**09:00** **CHAIRMAN'S OPENING REMARKS**

**09:15** **SESSION ONE**

### Meeting Safety Requirements: Regulator's Perspective

- 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

Albert van der Zeijden
PRAC Member appointed by
**European Commission**

Uwe Gudat
Safety Head
**Fresenius - Kabi**

**10:30** **MORNING REFRESHMENTS**

**11:00** **SESSION TWO**

### Evolving PV Strategies for the Future

- Identifying emerging tools to effectively assess safety data from clinical trials to support safety detection & strategy
- Cortellis Competitive Artificial Intelligence: What it could mean for drug safety ?
- Evolving PV Audit Strategies
- Developing pharmacovigilance strategies to incorporate social media platform

Katrien Soleme`
Pharmacovigilance Strategy Lead, Global Quality
**Bristol-Myers Squibb**

**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 may 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**

**12:50** **LUNCH**

**SESSION THREE**

### Technological Advancement in Drug safety

- Innovative technologies in drug safety for risk minimisation and capturing the data
- Longitudinal databases analyses i.e Sentinel, IMEDS, OHDSI
- Future development of new tools

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

**15:05** **AFTERNOON REFRESHMENTS**

**15:35** **CONFERENCE PRESENTATION**

### 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**

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16:20 **SESSION FOUR**

**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

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

Vicki Edwards
QPPV Head Affiliate Vigilance Excellence
**AbbVie**

17:35 **CLOSE OF DAY ONE**

## 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**

Elizabeth Ursell
Director, Pharmocovigilance
**Mapi Group**

11:00 **MORNING REFRESHMENTS**

11:30 **SESSION SIX**

**Latest Development and Approach in 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**

**Using Big Data to detect safety signals earlier and more effectively**

Mircea Ciuca
Head of Medical & Clinical Drug Safety
**Vifor Pharma**

12:45 **LUNCH**

13:45 **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
- Pharmaceutical industry reflection on the new EudroVigilance: Ensuring smooth implementaions
- Sensible use of Big Data

Alison Monckton
Principal Clinical Data Manager
**Allergy Therapeutics**

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

14:45 **SESSION SEVEN**

**Pharmacovigilance for advanced therapies**

- Cell and gene therapies Pharmacovigilance
- Regenerative medicine Pharmacovigilance

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

**Preclinical safety assessment of cell-based therapies**

Dominic Bowers
Head of Clinical Operations
**Cell and Gene Therapy Catapult**

16:00 **CHAIRMAN'S CLOSING REMARKS**

16:15 **END OF CONFERENCE & AFTERNOON REFRESHMENTS**

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+44 (0) 203 141 0623

cwilliams@acieu.net

Postal Address: http://www.acius.net

10 Gough Square, EC4A 3DE, London, UK


## Registration Is Simple

| | |
|---|---|
| Conference (Includes Access to All Documentation) 7th & 8th March 2018 | £1,595.00 |
| Documentation Packet Only | £420.00 |

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 £395 (+£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) 2031410623 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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