CORVUS
GLOBAL EVENTS

EUROPEAN **PHARMACOVIGILANCE & CLINICAL TRIALS** 2016

"A COMPREHENSIVE PERCEPTION OF
ATTAINING MUCH WIDER AND DISCRETE LANDSCAPE"

25TH AND 26TH OCTOBER 2016,
STRAND PALACE HOTEL, LONDON, UNITED KINGDOM.

OUR PROMINENT SPEAKERS

MORE GREAT SPEAKERS JOINING OUR LINE UP SOON.

KAREN CHENG HEIL
Safety Medical Director
AstraZeneca

SHELAGH ANDERSON
Vice President of Global Regulatory Affairs,
Janssen Pharmaceutical Companies of Johnson & Johnson

ANA CLAUDIA IANOS
Director - Safety Risk Lead,
Pfizer

EMANUEL LOHRMANN
Lead Safety Physician,
Boehringer Ingelheim

HEIKE SCHOEPPER
Head Global Drug Safety,
Merck Serono

KASHIF SHEIKH
Senior Safety Surveillance Advisor
Novo Nordisk

ALEXANDRU IONEL
Chief Scientific Officer & DRA Head,
Novartis Pharma

JULIA APPELSKOG
QPPV, Head of Pharmacovigilance,
Bluefish Pharmaceuticals

SANDY EISEN
Chief Medical Officer,
Frontline Pharma Consulting

JONATHAN SELTZER
President,
ACI Clinical

ANNE GRAMKOW
Head of Safety and QPPV,
Pharmacosmos

LEO AYERAKWA
Consultant,
European Regulatory Solutions.

NAWAB QIZILBASH
Head & Honorary Senior Lecturer in Pharmacoepidemiology,
OXON Epidemiology

SIMON INGATE
Principal Consultant
SafetyGauge Product Manager,
Pope Woodhead & Associates

RACHEL SPOKES
Vice President of Pharmacovigilance,
EmasPharma

PURCHASE YOUR CONFERENCE PASS NOW AND SAVE!

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CONFERENCE FOCUS

With the rise in the occurrence of diseases, there has been the rise in consumptions of drugs, which in turn has led to increased reporting of adversities and drug toxicities. This has led to the rise in regulatory concerns and public health safety issues and hence provided the indispensable stimulus for the Pharmacovigilance market. According to the report provided by transparency market research, the global Pharmacovigilance market is estimated to reach USD 5,008.2 million in 2019 globally, at a CAGR of 12.9% from 2013 to 2019. Among the clinical trial phases, Phase IV clinical trial safety reporting market has the biggest market share of 74.7% (USD 1,604.8 million in 2012) and is estimated to hold this position till 2019.

Pharmacovigilance and clinical trials have evolved considerably in the past few decades to meet the expectations of the public and modernization of human health. With the ever-increasing globalization, communication, Internet access, free trade across countries and easy access to drugs there is continuing demand for further development and stringencies in PV and clinical trials. The new EU Clinical Trials Regulation (No 536/2014), which will be applicable in the near future, would revise the current framework of clinical trials and guarantee uniformity and harmonization within the EU.

The recent developments in the UK (BREXIT referendum) have raised many questions and panic within all major sectors, and pharma industry is no exception. Though the full impact of these developments on pharma industry is difficult to visualize, but the complexities and the consequences involved need to be understood to ensure drug safety and quality. Hence it is demanding for all to keep them abreast with the latest in the field.

European Pharmacovigilance and clinical trials conference 2016 will provide an opportunity to all its attendees to discuss, share and stay updated with present state of affairs in Pharmacovigilance and clinical trials. It will also allow all its participants to discuss the various developments, challenges faced and innovations in the field. The conference will attempt to explore the reforms required to enhance drug safety and public health. The conference will also provide all its participants an opportunity to network with various pharmaceutical industries; clinical research organizations and PV service providers. It gives us a great pleasure welcoming you to the **European Pharmacovigilance and Clinical Trials 2016 conference.**

KEY HIGHLIGHTS

- Harmonization and Pharmacovigilance
- PV regulations and challenges
- The new EU legislation on clinical trials, its impact and future
- Risk management and minimization
- Adverse drug reactions reporting
- Signal detection and post authorization safety
- Business development and models in clinical trials
- Clinical data management
- Good Clinical Practices and Good Pharmacovigilance practices
- IT and new technologies for improvement of PV and clinical research
- Strategies to improve clinical trials and PV
- Implications of BREXIT

WHO SHOULD ATTEND THE CONFERENCE

CEO's, CTO's, CIO's, Presidents, Vice Presidents, Directors, Heads & Managers, Scientific Advisors, Consultants and professionals from pharmaceutical and biotechnology industries, CROs and service providers involved in Pharmacovigilance or Clinical Trials. Attendees' job responsibilities include:

- Pharmacovigilance
- Safety & Risk management
- Drug safety
- QPPV
- PV Compliance
- PSMF
- Safety Surveillance
- Medical Affairs
- Signal detection
- Regulatory Affairs
- Inspection and Audit
- Pharmacoepidemiology
- Clinical Operations
- Clinical Research and Development
- Clinical Quality Assurance/Control
- Clinical Compliance
- GCP
- Clinical Monitoring
- Clinical Data Management
- Contract outsourcing service providers

GET IN TOUCH WITH THE TEAM

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CONFERENCE SCHEDULE

DAY 1 - 25TH OCTOBER 2016

08:30 Registration & Morning Coffee

09:30 Chairperson's opening remarks

REGULATIONS, HARMONIZATION & MARKET

09:40 Opening Keynote Address : Topic TBC

KAREN CHENG HEIL
Safety Medical Director, AstraZeneca

10:10 Morning Keynote Address 2 - Emerging Economies and PV Harmonization

- Major differences in PV legislation between US and EU
- How they differ from rest of the world (Canada, Australia, Japan)
- ICH and harmonization through common standard for periodic benefit-risk evaluation on marketed products among ICH regions (EU, Japan, US)
- Harmonization with developing countries- Bypassing economic and cultural hurdles
- Maintaining and managing of global databases housing various reporting necessities and safety data

10:40 The Monitoring Medicines project (MM) its outcomes and benefits in globalization of PV

- Did the project help in globalization and its impacts on ADR reporting, methods developed
- How did the project bring together WHO, other organizations, regulators, medical practitioners and patients to work together?
- Outputs from the MM project and progress made to date and with support from WHO and other global health initiatives.
- Impact of the project

11:10 Networking and Refreshment Break

11:30 Meeting the pharmacovigilance requirements in small pharma

- Implementation of a PV system
- Areas of challenge
- Risk management

ANNE GRAMKOW
Head of Drug Safety, QPPV, **Pharmacosmos**

ADVERSE EVENT REPORTING & MANAGEMENT

12:10 Adverse event reporting and PV

- Global national Pharmacovigilance systems
- Reliability of spontaneous reporting
- Implementation of cohort event monitoring (CEM) and targeted spontaneous reporting (TRS) by the WHO
- Requirement for introduction of new guidelines for AER
- Challenges in reporting and data collection of ADRs in structured manner

12:40 Use of Safety Assessment Committees for Oversight and Reporting

- Implications of the FDA IND Safety Reporting Draft Guidance
- Recommend SAC membership and Event Reporting Flow
- How to perform aggregate safety data analysis and establish reporting thresholds
- Relationship between Safety Assessment Committees and EAC/DMCs

JONATHAN SELTZER
President, **ACI Clinical**

13:10 Networking Luncheon

NEW CLINICAL TRIALS REGULATIONS & IMPLEMENTATION

14:20 The New EU Clinical Trial Regulation

- Problems or Lacunae in the old regulation
- Concerns addressed in the new legislation
- Advantages of the new legislation-an regulatory perspective
- Greater harmonization and transparency
- How will Brexit affect the single application for clinical trials using single portal

14:50 GCP inspections and breach reporting tracking compliance

- Co-ordination of GCP inspections and centralized procedure
- Common findings during inspections
- How to prepare for inspections? Updating and maintaining files in accordance to guidelines
- Challenges from new regulations

15:20 Networking and Refreshment Break

15:40 Panel Discussion: Preparing towards implementation of new regulation- an industry perspective.

- Ensuring smooth transition
- Advantages of new legislation with an industry perspective
- Requirement for communication within the organization and globally
- Potential problems one might face and how to overcome them

MODERATOR :

LEO AYERAKWA
Consultant, **European Regulatory Solutions.**

PANELISTS :

ANA CLAUDIA IANOS
Director - Safety Risk Lead, **Pfizer**

SHELAGH ANDERSON
Vice President of Global Regulatory Affairs,
Janssen Pharmaceutical Companies of Johnson & Johnson

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16:20 **Campfire Session- Brexit: Implication on PV and clinical trials. Is it the end of accessibility and uniformity?**

- Has the core motive of EMA for greater harmonization and transparency been hampered?
- Separate licensing, marketing authorization application- extra burden on companies
- Will UK regulatory framework remain the same as EU?
- Current EMA in London? Relocation and transition difficulties
- Impact on access to wide database of PV, clinical trials and patient data and sharing of data

16:50 **Chairperson's closing remarks**

17:00 **Networking Drinks Session**

DAY 2 - 26TH OCTOBER 2016

08:30 **Registration & Morning Coffee**

09:20 **Chairperson's opening remarks**

RISK MANAGEMENT AND MINIMIZATION

09:30 **Review of RMP's for Renewal**

- Revision of Risk management Plans for Renewal
- '10 years experience' in Risk Management Plans
- New risk Management Plan Guideline and Template

EMANUEL LOHRMANN
Lead Safety Physician, **Boehringer Ingelheim.**

10:00 **New digital approaches to risk minimization And effectiveness evaluation**

- Issues with traditional risk minimisation measures (RMMs)
- Implementing digital RMMs
- Options for data collection
- Using effectiveness data to optimise benefit-risk.

SIMON INGATE
Principal Consultant -SafetyGauge Product Manager,
Pope Woodhead & Associates

SIGNAL DETECTION AND MANAGEMENT

10:30 **Clinical Trials Signal Detection**

- Withdrawals of approved drugs from global markets
- Need for increased regulatory assessment of a drug's safety report earlier to approval
- Well-designed clinical trial databases
- Lacunae in the present methods used
- Need for development of new graphical and statistical tools to detect signals during trials

KASHIF SHEIKH
Senior Safety Surveillance Advisor, **Novo Nordisk**

11:00 **Networking and Refreshment Break**

11:30 **Post-marketing Signal Detection and management**

- Will stringent clinical trials eliminate the need for post marketing surveillance?
- Limitation in clinical trial signal and risk assessment
- Sources for identifying safety signals -Data mining, spontaneous report, literature and other sources
- Present Drug safety signal detection systems and tools and what do they lack
- Precise detection and analysis of drug signals, aggregating reports to detect signals that were not acquired by ICSRs
- Emerging techniques and tools in detection and management of signals

HEIKE SCHOEPPER
Head Global Drug Safety, **Merck Serono**

DATA MANAGEMENT, INFORMATION TECHNOLOGY AND OUTSOURCING

12:00 **PSMF - PV SYSTEM MASTER FILE**

- PSMF summary design, role of QPPV and managing audits
- Responsibilities of stakeholders
- Accessibility of PSMF and Transparency and ensuring compliance
- Challenges in the managing data collection, audit information and documenting changes in logbooks, transferring information to license partners or third parties
- Databases and computerized systems required

RACHEL SPOKES
Vice President of Pharmacovigilance, **EmasPharma.**

12:30 **Clinical data management (CDM) and statistics**

- Importance of Clinical data management
- Improving CDM to meet new regulatory requirements
- Various statistical methods and interpretation of clinical report data
- Challenges in CDM and the future

13:00 **Networking Lucheon**

14:20 **Impact of EU data protection laws on clinical research**

- How different is the proposed directive from the current regulation
- Processing health data for public interest and restrictions on profiling to evaluate health
- Flexibilities for research and public health organizations
- Ambiguities in the draft

15:00 **Advanced health IT and Big Data in clinical trials and PV**

- Enormous flow of data and information, compliance with regulatory bodies- how to manage them
- Big data in managing the safety reports
- Challenge in bringing together different regulatory requirements under the same roof
- IT innovations and future

15:30 Networking and Refreshment Break

15:50 Outsourcing and clinical trials

- What are the different business models?
- Is outsourcing required? Building partnerships
- Identifying the key areas for outsourcing
- Strategies and benefits of outsourcing
- The main challenges faced and impact of new legislation

16:20 Panel Discussion : Innovation and the future of Pharmacovigilance

- Importance of bringing patients on board
- The need for patient database and effective communication
- Emerging technologies, digitization and social platform
- Benefits of digital technology and regulatory hurdles

JULIA APPELSKOG
QPPV, Head of Pharmacovigilance,
Bluefish Pharmaceuticals

16:50 Chairperson's closing remarks and end of conference

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