

WORLD **DRUGSAFETY**

CONGRESS EUROPE 2019

10–11 September 2019

Hilton, Amsterdam

ADDRESSING KEY CHALLENGES FOR SAFETY PROFESSIONALS

Europe's Most Exciting Drug Safety & Pharmacovigilance Event



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ADDRESSING KEY CHALLENGES FOR SAFETY PROFESSIONALS

EMPOWERING PATIENTS, PHYSICIANS, DRUG MANUFACTURERS AND CONSUMERS TO MAKE THE BEST DRUG SAFETY DECISIONS

The World Drug Safety Congress Europe will bring together key thought leaders and experts to explore these worldwide challenges. Explore the use of big data and AI in pharmacovigilance, examine benefit-risk management strategies and patient-centric approaches; discuss how you can tackle the challenges of social media and drug safety legislation globally. Make sure you are at the heart of the new drug safety era and participate in these critical discussions.

The meeting is set to bridge the gap between international regulatory bodies, industry professionals and academic representatives and will address how to drive pharmacovigilance operations forward into the 21st Century.

WORLD DRUG SAFETY FOCUSES ON

1. How to plan for the wider international drug safety landscape
2. How to work compliantly with a global regulatory overview and recent developments
3. How to establish a robust approach to safety in oncology and advanced therapies
4. How to harness Big Data and emerging technologies such as AI to support your safety measures
5. How to manage drug safety operations in light of increasing complexities
6. How to manage data and electronic submissions better
7. How to effectively process the volume of cases
8. How to operate within financial and logistical constraints

COMPRISED OF:

1. 60+ sessions
2. Dedicated networking sessions
3. Interactive roundtables
4. 5 streams covering a range of key areas over two days

All companies in the pharma industry have an enormous opportunity to better their drug safety capabilities, technological functions and risk management measures. It is core to ensuring regulatory compliance and establishing a robust PV strategy. It is core to your professional future.

CHECK ALL THE BOXES

- Signal Detection & Management
- Risk Management
- Big Data & AI in Safety
- Safety in Oncology
- Safety in Advanced therapies
- Vaccine Safety
- Biosimilars in Drug Safety
- Regulation
- Case Processing
- Real World Evidence in PV
- PV in Emerging Markets
- And so much more...

FOR WORLD-CLASS SOLUTION PROVIDERS

World Drug Safety Europe 2019 offers outstanding opportunities for solutions providers, from senior sponsorship to a range of exhibition booths on a fantastic floor plan. If you are looking to the future of the Pharmacovigilance sector in biopharma industry, then this is your best ROI in 2018.



Contact Edmond now on
edmond.rama@terrapinn.com to secure your position.

2019 SPEAKERS

KEYNOTE SPEAKERS



Felix Arellano

Global Head of Pharmacovigilance and Drug Safety, **Roche**



Howard Snow

Chief Medical Officer & Patient Safety, **Novartis**



Andrea Best

Executive Medical Director, Pharmacovigilance and Patient Safety, **AbbVie**



Songlin Xue

Executive Vice President and Global Head of Pharmacovigilance, **Astellas**



Phil Tregunno

Signal Management Unit Manager, and IMI WEB-RADR project lead at **MHRA**



Shinobu Uzu

Chief Safety Officer, **Pharmaceuticals and Medical Devices Agency Japan**



Steinar Madsen

Medical Director, **Norwegian Medicines Agency**



Nneka Onwudiwe

Regulatory Reviewer, **FDA**



Stewart Geary

Senior Vice President, Chief Medical Officer, Director, Corporate Medical Affairs Headquarters, **EISAI**



Jens-Ulrich Stegmann

Vice President Head Clinical Safety and Pharmacovigilance, **GSK**



Diane Beck

Vice President, Head of Pharmacovigilance Services, **Takeda**



Arvind Bellur

Global Head of Safety Systems and Data Management, Global Pharmacovigilance, **Sanofi**



Attila Oláh

Head Global Pharmacovigilance, EU-QPPV, **Gedeon Richter**



Lykke Bjerglund Graff

Head of Global Safety, **Leo Pharma**



Felix Arellano

Global Head of Pharmacovigilance and Drug Safety, **Roche**



Patrick Caubel

SVP, Global Head Pharmacovigilance, **Pfizer**



Scott Chandler

Vice President and Global Head, Licensing and Early Development (LEAD) Safety, **Roche**



Jefferson Guillon

Head of PV operation, **Seqirus**



Andrea Best

Executive Medical Director, Pharmacovigilance and Patient Safety, **AbbVie**



Anupam Agarwal

VP Global Head of Drug Safety and PV, **Zogenix**



David Chonzi

VP, Head of Pharmacovigilance and Epidemiology (PVE), **Allogene Therapeutics**



Mariette Boerstoeel Streefland

SVP, Global Drug Safety, **Alexion**



Ale (Maria) Vazquez-Gragg

VP, Global Patient Safety, **Argenx**



Keya Pitts

Global Head of PV Q/A, **Astellas**



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Global Head of PV Q/A, **Astellas**



Phil Tregunno

Signal Management Unit Manager, and IMI WEB-RADR project lead at **MHRA**



Songlin Xue

Executive Vice President and Global Head of Pharmacovigilance, **Astellas**



Lykke Bjerglund Graff

Head of Global Safety, **Leo Pharma**



Andrew Olaharski

Senior Toxicology Director, **K.S.Q. Therapeutics**



Salvatore Giorgio Cicirello

Senior Director Pharmacovigilance Innovation, Global Drug Safety & Risk Management, **Celgene**



Stewart Geary

Senior Vice President, Chief Medical Officer, Director, Corporate Medical Affairs Headquarters, **EISAI**



Michael Richardson

VP Global Pharmacovigilance & Epidemiology, **Bristol-Myers Squibb**



Archi Wani

Principal MAP Vendor Lead US Drug Safety, Market Research and Patient Support Programs, **Genentech**



Katrien Soleme

Head, Global Quality Regulatory Compliance & Clinical Trials & Safety, **BMS**



Haris Shaikh

Senior Director Pharmacovigilance, **Orchard Therapeutics**



Dennis Vargo

Global Safety Leader, **Takeda**



Hal Ward

Vice President of Drug Safety, **Kyowa Kirin**



Shinobu Uzu

Chief Safety Officer, **Pharmaceuticals and Medical Devices Agency Japan**



Jackie Roberts

Executive Director – Regulatory, Pharmacovigilance and Medical, **Accord-UK Ltd**



Matthias Bödding

Head Global Drug Safety Medicine, **Merck**



Andrea Oliva

Head of Pharmacovigilance, Italy, **Mylan**



Tanja Peters

Deputy EU-QPPV, Head PV Intelligence, **Boehringer Ingelheim Pharma GmbH & Co. KG**



Bruce Donzanti

Senior Group Director, Regulatory Pharmacovigilance Policy, **Genentech**



David Power

Senior Drug Safety Specialist/ Deputy EU QPPV, **Helsinn Birex Pharmaceuticals**

2019 SPEAKERS



Vipin Sethi

Head – Global Pharmacovigilance and Medical Affairs, **Cadila Pharmaceuticals Ltd**



Anastasia Philippova

MD, QPPV, Senior Pharmacovigilance Specialist, Clinical Development, **Geropharm**



Doris Stenver

Former Chief Medical Officer, **Danish Medicines Agency**



Rudi Scheerlinck

Global Head Pharmacovigilance Risk Management, **Nestlé Skin Health**



Nicole Baker

Former EEA QPPV, Head of Global Pharmacovigilance, **Besins Healthcare**



Attila Oláh

Head Global Pharmacovigilance, EU-QPPV, **Gedeon Richter**



Catherine Cohet

Director, Senior Epidemiology Expert, Clinical R&D Belgium, **GSK Vaccines**



Steinar Madsen

Medical Director, **Norwegian Medicines Agency**



Jabeen Ahmad

Regional PV Director, EMEA, **AbbVie**



Fernando Solimando

Senior Risk Management Physician, **Boehringer Ingelheim**



Christelle Boeynaems

Multi Country Safety Head Benelux, **Sanofi**



Elena Davison

Director, Pharmacovigilance Informatics, **Sunovion**



Maria Maddalena

Therapeutic Area Safety Head, **Seqirus**



Raj Bhogal

Regulatory Inspection Lead, Safety & International, R&D Quality Assurance & Compliance, **Shire**



John Solomon

Head of Pharmacovigilance-UK & Ireland, **Sanofi**



Amgad Shebl

Director, Clinical Safety Physician, **CSL Behring**



Ricarda Tiemeyer

Head of the Drug Safety Department Germany, **Biogen**



Heinz Weidenthaler

Director Pharmacovigilance, QPPV, **Bavarian Nordic GmbH**



Sergiy Kryvych

Drug Safety Officer & Medical Advisor, **Pfizer**



Maritess Esguerra

Principal Pharmacovigilance Process Leader, **Genentech**



Syed Zafeeruddin

Pharmacovigilance & Clinical Trial Manager, **Julphar**



Essam Ghanem

Head of Pharmacovigilance, **Vigi-Care BVBA**



Pedro Lima

Regions Medical Safety Head (Brazil), **Sanofi**



Francesco Tescione

EU Qualified Person for Pharmacovigilance QPPV, **Molteni Farmaceutici**



Liana Gross-Martirosyan

Alternate PRAC Member, **Medicines Evaluation Board Netherlands**



Nneka Onwudiwe

Regulatory Reviewer, **FDA**



Sutirtha Mukhopadhyay

Global Safety Officer, **Sanofi**



Anupam Agarwal

VP Global Head of Drug Safety and PV, **Zogenix**



Marco Sardella

Chief Pharmacovigilance Officer, European QPPV, **ADIENNE Pharma**



Rawya Al Kredly

Deputy QPPV, **Julphar Pharma**



Monika Manske

Lead Quality Management, PSRM, Pharmacovigilance Safety & Risk Management, **Mylan Healthcare GmbH**



Marcus Schartau

Safety Surveillance Risk Management Specialist, Safety Surveillance, **Novo Nordisk**



Jorgen Matz

Head of Global Pharmacovigilance and Drug Safety, **InsudPharma**



Rie Matsui

Director, Regional Labeling Head of Asia, **Pfizer**



Moin Don

CEO & President PVCON, Govt. of India's National Pharmacovigilance Program 'Advisor' and 'Trainer', **DCGI & CDSCO**



Margherita D'Antuono

EU QPPV, **Italfarmaco**



Deepa Arora

Former Global Head, Drug Safety and Risk Management, **Lupin Pharma**



Vivek Ahuja

Vice President of Medical Affairs and Global Pharmacovigilance, **Sun Pharmaceuticals**



Omar Aimer

Pharmacovigilance Specialist & device officer, **Independent** (Ne Sanofi Canada)



Tarik Messaoud

Drug Safety Specialist Pharmacovigilance Specialist, **Independent** (Ne Merck)



Marqus Hamwright

Senior Director, **Argenx**



Andrea Maulwurf

Head of Pharmacovigilance, EU-QPPV, **Allergy Therapeutics**



Jens-Ulrich Stegmann

Vice President Head Clinical Safety and Pharmacovigilance, **GSK**



Elizabeth Baker

Pharmaceutical Policy Program Director, **Physicians Committee for Responsible Medicine**



Ashlyn E. Bassiri

Head of Translational Pharmacovigilance, **CSL-Behring**



Marjan Dzevaroski

RA&PhV Manager, **Bionika Pharmaceuticals**



Qi Tang

Associate Director of Clinical Data Analytics, **Sanofi**



Adolf Meister

PhV Manager, Innovative and Developmental Products Safety Strategy, Global Patient Safety & Pharmacovigilance, **Teva**

2019 SPEAKERS



Timo Faltus

Research Associate / Project Manager at Martin-Luther-Universität Halle-Wittenberg, Germany



Philip Eichorn

Senior Director of Worldwide Safety and Regulatory, **Pfizer**



Raj Long

Deputy Director, Integrated Development, Global Health, **Bill and Melinda Gates Foundation**



Bert van Leeuwen

Deputy QPPV, **Astellas**



Kevin Leary

Director, Global Medical Safety, **Janssen Inc.**



Ruth Osahon

Director, Pharmacovigilance, **Summit Therapeutics**



Diane Beck

Vice President, Head of Pharmacovigilance Services, **Takeda**



Mate Balazs

Country Head – Patient Safety – Hungary, National QPPV – Hungary, **Novartis**



Santiago Garnica Velandia

Drug Safety Coordinator, **VITALIS SACI**



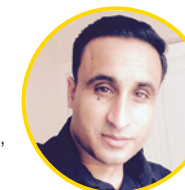
Tauqeer Karim

Vice President of Drug and Device Safety Officer, **Fresenius Medical Care North America**



Uwe Gudat

Head of Clinical Safety & Pharmacovigilance Clinical Safety & Pharmacovigilance, **Fresenius Kabi**



Pav Rishiraj

Director, Head of Patient Safety -UK & Ireland, Drug Safety & ABPI Chairman of the Pharmacovigilance Expert Network (PEN), **Merck KGaA**



Nadia Español

Senior Drug Safety Specialist, **mAbxience**



Elizabeth Ciyou – Allee

Senior Director Case Processing Center of Expertise/ US Contact Center. Leading in pharmacovigilance, Change Agent, Leadership Development, **AbbVie**



Tracey Boone

Director, Business Technology - Case Processing Center of Expertise, RSI Officer, **AbbVie**



Hildia Schreuder

Country Lead, **Sanofi**



Manni Kuthiala

PV Affiliate Strategic Alliance Manager, **Roche**



Maria Tello

Executive Director, Safety & PV, **Rakuten Medical**



Vishakha Oza

Drug Safety Lead Scientist, **Grünenthal**



Israel Gutierrez

Vice President Pharmacovigilance and Drug Safety, **Geron Corporation**



Akhilesh Sharma

Fellow-Royal College (Liverpool; U.K.), President and Chief Medical Officer, **Alkem Laboratories**



Howard Snow

Chief Medical Office & Patient Safety, **Novartis**



Susanne Reymann

Head PV Quality Systems & Compliance, Global Pharmacovigilance, **Abbott Laboratories**



Peter De Veene

QPPV (France), **Alexion Pharmaceuticals, Inc.**



Mohamed Abdel Hady

Pharmacovigilance and Epidemiology Manager, **Gilead Sciences**



Yemi Osibamowo

Global Head of Safety and Global QPPV, **Alimera Sciences**



Leona Houghton

Director, Global Head of Pharmacovigilance Quality & Compliance, **Jazz Pharmaceuticals**



Cristina Damatarca

VP Drug Safety, **Samumed**



David Gerrett

Senior Pharmacist Patient Safety Improvement, **NHS**



Arvind Bellur

Global Head of Safety Systems and Data Management, Global Pharmacovigilance, **Sanofi**



Karen Naim

Head of CoE Aggregate Reporting, **Pfizer**



John Poustie

Senior Director, Global Pharmacovigilance, **Norgine**



James Whitehead

Principal, **AstraZeneca**



Rishi Chopra

Director. Head of Global PVNO. Deputy EU QPPV, **Biogen**



Luz Adriana Aristizábal Ruiz

Medical Director, **Vitalis**



Priya Singhal

Head of Research and Development, **Zafgen**



Phillipa Evans

Safety Medical Writer, **Novo Nordisk**



Yvonne Nanciu

Local QPPV Switzerland, **Abbvie**



Esther Onolememen

CEO, **Sickle Cell Foundation Ireland**



Mary Lynne Van Poelgeest-Pomfret



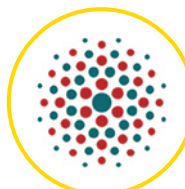
Klaudia Traudtner

Head of Pharmacovigilance and Safety, **Kiadis Pharma**



Rachna Bedi

Renal Pharmacist, **Imperial College Healthcare NHS trust**



Paul Wang

Senior Director, PV & Epi, **Kite Pharma**



Steven McMahon

Director, **Irish Patient Association**



Rotimi Jaiyesimi

Associate Medical Director for Patient Safety, **Basildon and Thurrock University Hospitals NHS Foundation Trust**



Ivan Arias

PV Manager & EU-QPPV, **Chemo**

DAY 1
AGENDA

Tuesday 10th September 2019

Registration & refreshments

Chair's opening remarks

Howard Snow, Chief Medical Office & Patient Safety, **Novartis**

Patient-Perspectives in Benefit-Risk Assessments

Songlin Xue, Executive Vice President and Global Head of Pharmacovigilance, **Astellas**

Title sponsor

Digital ICSR intake – The AbbVie experience with WEB-RADR

Howard Snow, Chief Medical Office & Patient Safety, **Novartis**

Phil Tregunno, Signal Management Unit Manager, and IMI WEB-RADR project lead, **MHRA**

Questions and Answers

Speed Networking

Morning refreshments

Bruce Palsulich, Vice President Product Strategy, **Oracle**

Topic tbc

Glenn Carroll, Principal | LSHC, **Deloitte Consulting LLP**

Topic tbc

ROUNDTABLES

ROUNDTABLE 1:
Exploring patient support and marketing research programs from a safety perspective

Sergiy Kryvych, Drug Safety Officer & Medical Advisor, **Pfizer**

Archi Wani, Principal MAP Vendor Lead US Drug Safety, Market Research and Patient Support Programs, **Genentech**

ROUNDTABLE 2:
Brexit and QPPV

Maritess Esguerra, Principal Pharmacovigilance Process Leader, **Genentech**

Andrea Maulwurf, Head of Pharmacovigilance, EU-QPPV, **Allergy Therapeutics**

Bert van Leeuwen, Deputy QPPV, **Astellas**

ROUNDTABLE 3:
Regulatory updates in LatAm and Mexico

Pedro Lima, Regions Medical Safety Head (Brazil), **Sanofi**

ROUNDTABLE 4:
SME Round Safety Signal Detection

Sutirtha Mukhopadhyay, Associate Director – Pharmacovigilance physician, **Ablynx**

ROUNDTABLE 5:
With pressure on Pharmacovigilance departments- How do we not over engineer our systems for quality rather than patient safety needs?

John Poustie, Senior Director, Global Pharmacovigilance, **Norgine**

ROUNDTABLE 6:
Patient Centric Drug Safety

Matthias Bödding, Head Global Drug Safety Medicine, **Merck**

ROUNDTABLE 7:
Signal Detection and Management

Rudi Scheerlinck, Global Head Pharmacovigilance Risk Management, **Nestlé Skin Health**

ROUNDTABLE 8:
PSMF, license partner audit – requirement & burden

Monika Manske, Lead Quality Management, PSRM, Pharmacovigilance Safety & Risk Management, **Mylan Healthcare GmbH**

ROUNDTABLE 9:
AI and Social Media Signal Detection

Omar Aimer, Pharmacovigilance Specialist & device officer, **Independent (Ne Sanofi Canada)**

Tarik Messaoud, Drug Safety Specialist Pharmacovigilance Specialist, **Independent (Ne Merck)**

ROUNDTABLE 10:
Pitfalls in the implementation of combinational product safety

Lykke Bjerglund Graff, Head of Global Safety, **Leo Pharma**

ROUNDTABLE 11:
Enabling PV departments through education on simple IT tools

Philip Eichorn, Senior Director of Worldwide Safety and Regulatory, **Pfizer**

ROUNDTABLE 12:
PV Outsourcing

Katrien Soleme, Head, Global Quality Regulatory Compliance & Clinical Trials & Safety, **BMS**

Ruth Osahon, Director, Pharmacovigilance, **Summit Therapeutics**

DAY 1
AGENDA

Tuesday 10th September 2019

ROUNDTABLES

ROUNDTABLE 13:

Evolving World of PV: Priorities and changes in the Indian PV system

Vipin Sethi, Head – Global Pharmacovigilance and Medical Affairs, **Cadila Pharmaceuticals Ltd**

Pankaj Bhardwaj, EU QPPV, **Cadila Pharmaceuticals Limited**

ROUNDTABLE 14:

Implementation of Risk Management Plans and solutions at Grunental

Fabian Heisig, Head of Safety, Benefit Risk and Global Drug Safety, **Grunenthal**

ROUNDTABLE 15:

Monitoring of local and global PV systems - what are the challenges faced by international companies?

Susanne Reymann, Head PV Quality Systems & Compliance, Global Pharmacovigilance, **Abbott Laboratories**

ROUNDTABLE 16:

Preparing for Inspections

Raj Bhogal, Safety & International Director, Regulatory Inspections, Global Quality, **Takeda**

ROUNDTABLE 17:

Accenture - topic to be confirmed

ROUNDTABLE 18:

Reserved for Deloitte - topic to be confirmed

Networking Lunch

SIGNAL DETECTION & MANAGEMENT

RISK MANAGEMENT

BIG DATA, AUTOMATION & AI IN SAFETY

SAFETY IN ONCOLOGY

CASE PROCESSING

Chair's remarks

Rudi Scheerlinck, Global Head Pharmacovigilance Risk Management, **Nestlé Skin Health**

Chair's remarks

Priya Singhal, Head of R+D, **Zafgen**

Chair's remarks

Arvind Bellur, Global Head of Safety Systems and Data Management, Global Pharmacovigilance, **Sanofi**

Chair's remarks

Michael Richardson, VP Global Pharmacovigilance & Epidemiology, **Bristol-Myers Squibb**

Chair's remarks

Safety Signal detection in rare diseases

Sutirtha Mukhopadhyay, Global Safety Officer, Rare Diseases, **Sanofi**

The regulatory point of view from PRAC

Liana Gross-Martirosyan, Alternate PRAC Member, **Medicines Evaluation Board Netherlands**

The importance of a safety systems and technology group in a pharmaceutical company

Arvind Bellur, Global Head of Safety Systems and Data Management, Global Pharmacovigilance, **Sanofi**

Risk management for oncology drugs

Niraj Chhaya, Lead Risk Management, Global Pharmacovigilance, **Boehringer Ingelheim**

(No) Regulatory Drug Safety in Cell- and Tissue-based Therapies within Point-of-Care Settings

Timo Faltus, Research Associate, Principal Investigator Pharmaceutical Law, Germany, **Martin Luther University Halle-Wittenberg**, Faculty of Law, Economics and Business

Sponsor presentation

Andrew Rut, CEO, **MyMeds&Me**
Topic tbc

Aman Wasan, VP, Global PV & Global Client Partners, **Aris Global**

Sponsor presentation

Sponsor presentation

How to perform safety surveillance in one compound with multiple indications, different patient populations

Marqus Hamwright, Senior Director, **Argenx**

Patient centricity in PRAC

Doris Stenver, Independent Pharmacovigilance Adviser and Former Chief Medical Officer, **Danish Medicines Agency**

What AI is Telling Us: Stochastic Behavior in Reporter Causality Assessments

Bruce Donzanti, Senior Group Director, Pharmacovigilance Innovation Policy, **Genentech**

Presentation

Kevin Leary, Director, Global Medical Safety, **Janssen Inc.**

PSMF, license partner audit – requirement & burden

Monika Manske, Lead Quality Management, PSRM, Pharmacovigilance Safety & Risk Management, **Mylan Healthcare GmbH**

DAY 1
AGENDA

Tuesday 10th September 2019

A second use of Eudravigilance data Bert van Leeuwen , Deputy QPPV, Astellas	Using Inspection Metrics for Analytical Insight in to Deficiencies in PV System Moin Don , CEO & President PVCON, Govt. of India's National Pharmacovigilance Program as 'Advisor' and 'Trainer', DCGI & CDSCO	RESERVED FOR ACCENTURE	Presentation Keya Pitts , Global Head of PV Q/A, Astellas	Patient centric case processing Mate Balazs , Country Head – Patient Safety – Hungary, National QPPV – Hungary, Novartis
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Afternoon Refreshments

SIGNAL DETECTION & MANAGEMENT	RISK MANAGEMENT & BENEFIT-RISK MANAGEMENT	BIG DATA, AUTOMATION & AI IN SAFETY	BIG DATA, AUTOMATION & AI IN SAFETY	CASE PROCESSING
Chair's remarks	Chair's remarks	Chair's remarks	Chair's remarks Katrien Soleme , Head, Global Quality Regulatory Compliance & Clinical Trials & Safety, BMS	Chair's remarks
AI and Social Media Signal Detection Omar Aimer , Pharmacovigilance Specialist, Independent (Ne Sanofi Canada) Tarik Messaoud , Drug Safety Specialist Pharmacovigilance Specialist, Independent (Ne Merck)	Risk management in a Generics Company Ivan Arias , PV Manager & EU-QPPV, Chemo	Bridging the gap between clinical and non-clinical safety Ashlyn E. Bassiri , Head of Translational Pharmacovigilance, CSL-Behring	Sponsor presentation	PANEL: Harmonization across the safety ecosystem – Do we have the right priorities- Chair: Andrea Best , Executive Medical Director, Pharmacovigilance and Patient Safety, AbbVie Tanja Peters , Deputy EU-QPPV, Head PV Intelligence, Boehringer Ingelheim Pharma GmbH & Co. KG Vipin Sethi , Head – Global Pharmacovigilance and Medical Affairs, Cadila Pharmaceuticals Ltd Antonella Fretta , Team Lead Aggregate Reports, Safety Evaluation & Reporting, Pfizer
Sponsor presentation	Effectiveness of complex additional risk minimization measures – A success story Amgad Shebl , Director, Clinical Safety Physician, CSL Behring	Sponsor presentation	Service Provider Management Ricarda Tiemeyer , Head of the Drug Safety Department Germany, Biogen	Pharmacovigilance for business purpose? Andrea Oliva , Head of Pharmacovigilance, Italy, Mylan
Signal management – implementing the postmarketing process into clinical trials arena Mircea Ciuca , Global Head of Medical and Clinical Drug Safety, Vifor Pharma Group	Patient centric risk minimization John Solomon , Head of Pharmacovigilance-UK & Ireland, Sanofi	Predicting patient safety by analysing clinical trial data or real-world data using AI methods Qi Tang , Associate Director of Digital and Data Science Platform, Sanofi	Ensuring Effective Sponsor-Vendor Relationships Hal Ward , Vice President of Drug Safety, Kyowa Kirin	Risks in RMPs and PBRERs, why we do not aim to align Marcus Schartau , Safety Surveillance Risk Management Specialist, Safety Surveillance, Novo Nordisk
			How to expand a safety department from National to Global Andrea Maulwurf , EU-QPPV, Head of Pharmacovigilance, Allergy Therapeutics	Rapid ID of safety signals with the help of AI Anupam Agarwal , VP Global Head of Drug Safety and PV, Zogenix

DAY 1
AGENDA

Tuesday 10th September 2019

Practical Approach: End to End Management of Safety Updates – Signal to Label Vishakha Oza , Drug Safety Lead Scientist, Grünenthal	Risk information and drug promotion- from clinical trials to practice Nneka Onwudiwe , Founder, CEO, PECA	Dave Nestor , Director, Deloitte MCS Limited Topic tbc	Managing a strategic service provider on behalf of local safety affiliates, how the local and global can work together and benefits of a model like this Manni Kuthiala , PV Affiliate Strategic Alliance Manager, Roche	Using a vendor for end to end case processing Jefferson Guillon , Head of PV operation, Seqirus
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Afternoon Refreshments

SIGNAL DETECTION & MANAGEMENT	RISK MANAGEMENT	BIG DATA, AUTOMATION & AI IN SAFETY	SAFETY FOR ADVANCED THERAPIES	CASE PROCESSING
Chair's remarks	Chair's remarks	Chair's remarks	Chair's remarks	Chair's remarks
Proactive Approach to Patient-Centric Safety Scott Chandler , Vice President and Global Head, Licensing and Early Development (LEAD) Safety, Roche	EU HaRP Project for RMPs Adolf Meister , PhV Manager, Innovative and Developmental Products Safety Strategy, Global Patient Safety & Pharmacovigilance, Teva	Advancing best practices to optimize compliance with emerging regulations with deployment of automation & AI: A new paradigm of medical device safety risk management Tauqeer Karim , Vice President of Drug and Device Safety Officer, Fresenius Medical Care North America	Safety in personalized medicine Steinar Madsen , Medical Director, Norwegian Medicines Agency	A right size PV system – How harmonized or disharmonized are we Tanja Peters , Deputy EU-QPPV, Head PV Intelligence, Boehringer Ingelheim Pharma GmbH & Co. KG
Sponsor presentation	Oversight and tracking of risk minimisation activities (from planning to execution) Peter De Veene , QPPV (France), Alexion Pharmaceuticals, Inc	RESERVED FOR KINAPSE	Outsourcing in Pharmacovigilance- Best Practices, Challenges and key consideration Deepa Arora , Global Head, Drug Safety and Risk Management, Lupin Pharma	Sponsor presentation
Pharmacovigilance for business purpose? Andrea Oliva , Head of Pharmacovigilance, Italy, Mylan	Risks in RMPs and PBRERs, why we do not aim to align Marcus Schartau , Safety Surveillance Risk Management Specialist, Safety Surveillance, Novo Nordisk	Rapid ID of safety signals with the help of AI Anupam Agarwal , VP Global Head of Drug Safety and PV, Zogenix	Presentation Haris Shaikh , Senior Director Pharmacovigilance, Orchard Therapeutics	Monitoring and engaging with vendors to ensure safety monitoring is followed Philip Eichorn , Senior Director of Worldwide Safety and Regulatory, Pfizer

Networking drinks reception



DAY 2
AGENDA

Wednesday 11th September 2019

Chair's opening remarks

Felix Arellano, Global Head of Pharmacovigilance and Drug Safety, **Roche**

Evolving safety as a value provider rather than a pure necessity

Felix Arellano, Global Head of Pharmacovigilance and Drug Safety, **Roche**

Platinum presentation

Perspective for utilising artificial intelligence in Pharmacovigilance

Patrick Caubel, SVP, Global Head Pharmacovigilance, **Pfizer**

KEYNOTE PANEL: Importance of proactively addressing safety early in development

- Using safety as a differentiator for development decisions
- Developing new predictive tools to make assessing safety more strategic
- How do you address safety proactively at your company?

Chair: Felix Arellano, Global Head of Pharmacovigilance and Drug Safety, **Roche**

Scott Chandler, Vice President and Global Head, Licensing and Early Development (LEAD) Safety, **Roche**

Andrea Best, Executive Medical Director, Pharmacovigilance and Patient Safety, **AbbVie**

Ale (Maria) Vazquez-Gragg, VP, Global Patient Safety, **Argenx**

David Chonzi, VP, Head of Pharmacovigilance and Epidemiology (PVE), **Allogene Therapeutics**

Sponsor

Morning refreshments

ROUNDTABLES

ROUNDTABLE 1:

Benefit risk assessment- subjective vs quantitative – Mitigating the human factors

Francesco Tescione, EU Qualified Person for Pharmacovigilance QPPV, **Molteni Farmaceutici**

ROUNDTABLE 2:

How to expand a safety department from National to Global

Andrea Maulwurf, Head of Pharmacovigilance, EU-QPPV, **Allergy Therapeutics**

ROUNDTABLE 3:

Deriving commercial value from safety signal detection

Andrea Oliva, Head of Pharmacovigilance, Italy, **Mylan**

ROUNDTABLE 4:

Pitfalls in rolling out an Automation and AI project

Diane Beck, Vice President, Head of Pharmacovigilance Services, **Takeda**

ROUNDTABLE 5:

Outsourcing and compliance

Jackie Roberts, Executive Director – Regulatory, Pharmacovigilance and Medical, **Accord Healthcare**

ROUNDTABLE 6:

Reporting in Medical Devices and Drug Combinational Products

Tauqeer Karim, Vice President of Drug and Device Safety Officer, **Fresenius Medical Care North America**
James Whitehead, Principal, **Astrazenica**

ROUNDTABLE 7:

PV in Emerging Markets

Nadia Español, Senior Drug Safety Specialist, **mAbxience**

ROUNDTABLE 8:

Patient centric pharmacovigilance

Mate Balazs, Country Head – Patient Safety – Hungary, National QPPV – Hungary, **Novartis**

ROUNDTABLE 9:

A second use of Eudravigilance data

Bert van Leeuwen, Deputy QPPV, **Astellas**

ROUNDTABLE 10:

Biosimilars vs Branded Biologics

Uwe Gudat, Head of Clinical Safety & Pharmacovigilance Clinical Safety & Pharmacovigilance, **Fresenius Kabi**

ROUNDTABLE 11:

Evolving AI and Automation across your PV Department

Elizabeth Ciyou – Allee, Senior Director Case Processing Center of Expertise/ US Contact Center. Leading in pharmacovigilance, Change Agent, Leadership Development, **AbbVie**
Tracey Boone, Director, Business Technology - Case Processing Center of Expertise, RSI Officer, **AbbVie**

ROUNDTABLE 12:

Literature Search

Christelle Boeynaems, Multi Country Safety Head Benelux, **Sanofi**
Hildia Schreuder, Country Lead, **Sanofi**



DAY 2
AGENDA

Wednesday 11th September 2019

ROUNDTABLES

ROUNDTABLE 13:

Fast evolving PV regulations, “Industry efforts to keep with the pace”, examples from GCC

Mohamed Abdel Hady, Pharmacovigilance and Epidemiology Manager, **Gilead Sciences**

ROUNDTABLE 14:

Topic to be confirmed

ROUNDTABLE 15:

Topic to be confirmed

ROUNDTABLE 16:

Driving patient centricity into your PV plans

Mary Lynne Van Poelgeest-Pomfret, President, **Netherlands Interstitial Cystitis Patients Organization**

ROUNDTABLE 17:

Pharmacovigilance – Clinical Management of the Ulipristal Acetate Global Safety Alert

Rotimi Jaiyesimi, Associate Medical Director for Patient Safety, Basildon and Thurrock **University Hospitals NHS Foundation Trust**, **UK**

Networking Lunch

SAFETY & LABELING

VACCINE SAFETY & ADVANCED THERAPIES

REGULATION

REAL WORLD EVIDENCE & SAFETY

BIG DATA, AI AND AUTOMATION IN DRUG SAFETY

Chair's remarks

Chair's remarks

Chair's remarks

Chair's remarks

Jorgen Matz, Head of Global Pharmacovigilance and Drug Safety, **InsudPharma**

Chair's remarks

Israel Gutierrez, Vice President Pharmacovigilance and Drug Safety, **Geron Corporation**

Making safer medicines: Improving labelling and packaging to prevent medication errors

Santiago Garnica Velandia, Drug Safety Coordinator, **Vitalis**

How to assess safety signaling in vaccines

Maria Maddalena, Therapeutic Area Safety Head, **Seqirus**

Pharmacovigilance in the middle east

Syed Zafeeruddin, Pharmacovigilance & Clinical Trial Manager, **Julphar**

Improving multi drug safety

David Gerrett, Senior Pharmacist Patient Safety, **NHS Improvement**

AI and PV workshop

Elizabeth Ciyou – Allee, Senior Director Case Processing Center of Expertise/ US Contact Center. Leading in pharmacovigilance, Change Agent, Leadership Development, **AbbVie**
Tracey Boone, Director, Business Technology - Case Processing Center of Expertise, RSI Officer, **AbbVie**

Update of PV planning and labeling in Japan

Shinobu Uzu, Chief Safety Officer, **Pharmaceuticals and Medical Devices Agency Japan**

Sponsor presentation

Exploring patient support and marketing research programs from a safety perspective

Archi Wani, Principal MAP Vendor Lead US Drug Safety, Market Research and Patient Support Programs, **Genentech**

e-Labeling: APAC Outlook

Rie Matsui, Director, Regional Labeling Head of Asia, **Pfizer**

RWE and Vaccines

Catherine Cohet, Director, Senior Epidemiology Expert, Clinical R&D Belgium, **GSK Vaccines**

Hot topics in Asia for Pharmacovigilance

Stewart Geary, Senior Vice President, Chief Medical Officer, Director, Corporate Medical Affairs Headquarters, **EISAI**

Challenges in Implementing the CTFG Q&A on Reference Safety Information

Maritess Esguerra, Principal PV Process Lead, **Genentech**, a member of the Roche group

DAY 2
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Wednesday 11th September 2019

Safety & Labeling in non-EU Countries Marjan Dzeperoski , RA&PhV Manager, Bionika Pharmaceuticals	Leveraging pharmacology to better predict toxicity Andrew Olaharski , Senior Director and Head of Toxicology, K.S.Q. Therapeutics	Non-European (Commonwealth of Independent States, CIS) PhV legislation development and implementation into Global requirements Anastasia Philippova , MD, QPPV, Senior Pharmacovigilance Specialist, Clinical Development, Geropharm	Presentation Mariette Boerstoeel Streefland , SVP, Global Drug Safety, Alexion	Business strategy and the implementation of AI Israel Gutierrez , Vice President Pharmacovigilance and Drug Safety, Geron Corporation
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Afternoon Refreshments

INSPECTIONS	DRUG SAFETY IN BIOSIMILARS & BIOLOGICS	REGULATION	PV IN EMERGING MARKETS	BIG DATA, AI AND AUTOMATION IN DRUG SAFETY
Chair's remarks	Chair's remarks	Chair's remarks Rodrigo Ruiz Ramirez , Head of Country Pharmacovigilance Mexico, Bristol-Myers Squibb	Chair's remarks	Chair's remarks
Presentation	Safety challenges with allogeneic CAR T therapies David Chonzi , VP, Head of Pharmacovigilance and Epidemiology (PVE), Allogene Therapeutics	Developing Pharmacovigilance and Risk Management strategies with impact. What is the Role of Innovation? Cristina Damatarca , VP Drug Safety, Samumed	Launching products in emerging markets Margherita D'Antuono , EU QPPV, Italfarmaco	Big Data, AI and Automation in Drug Safety Akhilesh Sharma , Fellow-Royal College, President and Chief Medical Officer, Alkem Laboratories Ltd
Sponsor presentation	Assessing biosimilar safety: when not exactly the same is no different Uwe Gudat , Head of Clinical Safety & Pharmacovigilance Clinical Safety & Pharmacovigilance, Fresenius Kabi	Pharmacovigilance quality management system. MAHs' challenges for compliance Essam Ghanem , Head of Pharmacovigilance, Vigi-Care BVBA	Challenges in entering emerging markets – Perspectives from global PV Nicole Baker , Independent	The Nonclinical Innovation and Patient Safety Initiative (NIPSI): Supporting Human-Based Nonclinical Approaches Through Global Advances in Regulation, Policy, Science, Education and Training Elizabeth Baker , Pharmaceutical Policy Program Director, Physicians Committee for Responsible Medicine
Presentation	Biosimilars and Biologics-Drug Safety Considerations Yvonne Nanciu , Local QPPV Switzerland, Abbvie	Regulatory updates in LatAm and Mexico Pedro Lima , Regions Medical Safety Head (Brazil), Sanofi	Diversifying local pharmacovigilance development and periodic reporting requirements across the globe Philippa Evans , Safety Medical Writer, Novo Nordisk	Presentation Vivek Ahuja , Vice President of Medical Affairs and Global Pharmacovigilance, Sun Pharmaceuticals

Close of conference

OUTSTANDING SPONSORSHIP OPPORTUNITIES

Can you help biotech and pharma companies evaluate future industry innovations and disruptions in Pharmacovigilance ?

Will your products and services help deliver the next generation of drug safety industry solutions?

Are you excited about what your product can deliver to the biopharma industry in PV space?

ARE YOU LOOKING FOR THE BEST BUSINESS DEVELOPMENT AND MARKETING OPPORTUNITY IN 2019?

FOR WORLD CLASS PHARMACOVIGILANCE SOLUTIONS PROVIDERS

World Drug Safety Europe 2019 offers outstanding opportunities for solutions providers, from senior sponsorship to a range of exhibition booths on a large floor plan. If you are looking to access and influence the Pharmacovigilance sector in the biopharma industry, then this is your best ROI opportunity in 2019. Contact Edmond Rama now on edmond.rama@terrapinn.com to secure your position.

MAKE A SPLASH, MAKE A STATEMENT

Do you want to make a big statement and create pre-eminence with a community hungry for change and needing to embrace the new technology?

If so, we have some big sponsorship opportunities for you, including:

Title Sponsorship

Platinum Sponsorship

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Large exhibition stands with dominant floor positions

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Sponsoring World Drug Safety Europe 2018! is guaranteed to produce great ROI before, during and after the event.

THE EXHIBITION

The exhibition floor offers over thirty booths from large customer positions to value packages: something for every budget. But you need to act fast – the floor will sell out.

World Drug Safety Europe 2019 is all about the opportunity. Contact Edmond now on edmond.rama@terrapinn.com to secure your position.

WHO SHOULD SPONSOR AND EXHIBIT?

Our sponsors and exhibitors are drawn from across the industry, including:

CROs
Data Solution providers
Drug Safety Solution Providers
Niche CROs
IT Solutions providers
Consulting services

WHO WILL YOU MEET ?

Professionals in:

Drug Safety
Risk Management & Surveillance
Clinical Safety
Pharmacoepidemiology
Post Authorisation Safety
Data Management
Patient Safety
QPPV
Pharmacovigilance

WORLD LEADING BRANDS WHO HAVE SUPPORTED THE EVENT INCLUDE:



Book your space today. Contact Edmond Rama today on +44 20 7092 1052 or email edmond.rama@terrapinn.com to secure your space.

SPONSORSHIP PACKAGES

Package/Benefits	Title Sponsor	Platinum	Gold	Silver	Bronze	Exhibitor	Breakfast Briefing
Plenary Keynote Morning day 1	x						
Plenary Keynote day 2:		x					
Chair a session:	x		x				
Presenting in the relevant session:			x	x			
Chair Roundtable:	x	x			x		
Breakfast Presentation:							x
Access to networking manager (face to face meetings)	x	x	x	x			x
Full passes for your Staff (including Speaker):	6	5	4	3	3	2	3
Space for stand(meters):	6x2	3x2	3x2	3x2	3x2	3x2	3x2
Attendee List:	x	x	x	x	x		x
Logo on the event brochure:	x	x	x	x	x	x	x
Logo on onsite signage	x	x	x	x	x	x	x

THE EXHIBITION

There are around 30 exhibition stands available on the show floor and the earlier you reserve the better position you'll secure.

Book your space today. Contact Contact Edmond Rama today on +44 20 7092 1052 or email edmond.rama@terrapinn.com to secure your space

“The excellent program covering a wide range of topics and perspectives within drug safety and great network opportunities.”
**Chief Medical Officer,
Danish Medicines Agency**

“It was a great platform for information sharing and gathering new ideas. Speakers were excellent.”
**TA Med Evaluation Lead,
CSL**

“The event is quite ahead in terms seminar topics with vision from world class leaders”
**Global Safety Lead Scientist,
Grünenthal GmbH**

YEAR ROUND MARKETING PLAN



DIGITAL MARKETING

Working with a leading digital advertising agency adverts will be placed on Google, the display networks and LinkedIn. Google remarketing will be used extensively.



SOCIAL MEDIA

Posts and event alerts are regularly posted to our dedicated Twitter feed, Facebook page and LinkedIn group, as well as posted to relevant 3rd party groups and pages.



ADVERTISEMENTS AND EDITORIAL COVERAGE IN KEY PUBLICATIONS

Including business, trade and national press.



PARTNERSHIPS

We will be partnering with leading press, associations and media. Digital advertising, email blasts and page adverts will be used in the run up to the event to extend our audience reach.



DIRECT SALES

Our dedicated direct sales team ensures that no lead is left unconverted.



E-MAIL CAMPAIGNS

We run a sophisticated lead generation and lead nurture campaign to our comprehensive database. Once registered they receive regular show updates and prompts to log on to our online community and networking service.



DIRECT MAIL

Show collateral such as the visitor tickets will be mailed to a targeted database. Inserts will be placed in leading business publications in the weeks running up to the show.



WEBSITE

Our dedicated event website is fully responsive and consistently updated with event news. The conference, seminar sessions, sponsors and exhibitors will be heavily promoted on the site to attract attendees to the show.



PRESS RELATIONS

Working with a leading global PR agencies to ensure the best coverage and onsite press relations.



YOU

We'll work closely together with every sponsor and exhibitor. You'll be updated with the latest marketing plans for the show. We'll discuss with you how we can help you drive traffic to the show, to your stand and to your seminar.

To sponsor or exhibit call Karina Kusova on +44 (0) 207 092 1071 or email karina.kusova@terrapinn.com to secure your space

EXHIBITOR PACKAGES

PACKAGE BENEFITS:

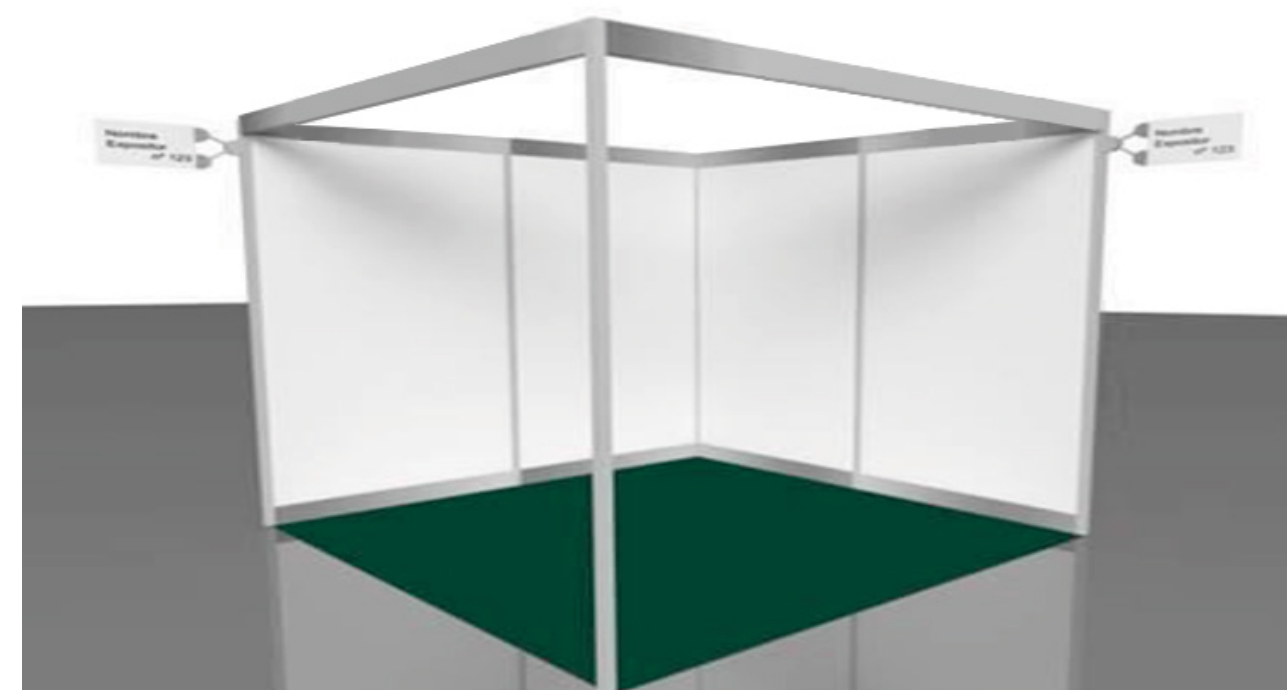
- A stand or space in a prominent position on the exhibition floor
- Unlimited use of the networking app for setting up sales meetings
- Your logo and profile will appear on the show website with link to your site

Stands up to 12 sqm will be provided with shell scheme.

YOUR SHELL SCHEME STAND INCLUDES:

- Unit including blank backdrop
- 1 x power socket
- 1 table + 2 chairs

Example of how your stand will look:



Contact Edmond Rama today on +44 20 7092 1052 or email edmond.rama@terrapinn.com to secure your space

Building upon the success of this year's event, 2018 will be adding further content such as the role of Big Data & AI in Drug Safety.

Sign up now if you want to take advantage of greater speakers, more streams and innovative content.



CONTACT US NOW



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