Tentative Program

11th Annual Congress on
Pharmacovigilance and Clinical Trials

March 28-29, 2018   Orlando, USA

Theme: “Safer Drug Innovations & Critical Considerations in Clinical Trials”

For Available Speaker Slots
clinicaltrial@conferencesamerica.org
# 11th Annual Congress on Pharmacovigilance and Clinical Trials

**March 28-29, 2018  Orlando, USA**

## Scientific Program - Day 1

### Keynote Session

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>08:45-09:15</td>
<td>Keynote Talk 1</td>
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<tr>
<td>09:15-09:45</td>
<td>Keynote Talk 2</td>
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<tr>
<td>09:45-10:15</td>
<td>Keynote Talk 3</td>
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<td>10:15-10:45</td>
<td>Keynote Talk 4</td>
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### Coffee/Tea Break 10:45-11:00

### Pre-Lunch Session 11.00-12.40

- Plenary Session 1 | Tracks 1 & 2
  - Pharmacovigilance and Drug Safety | Pre-Clinical and Clinical Trials

### Networking Lunch 12.40-13.30

### Post Lunch Sessions 13.30-15.30

- Plenary Session 2 | Tracks 3 & 4 | Track 5
  - Pharmacodynamics and Pharmacokinetics | Clinical Data Management
  - Adverse Event Reporting

### Coffee/Tea Break 15.30-15.45

### Evening Sessions 15.45-18.00

- Plenary Session 3 | Track 6 & 7
  - Clinical and Medical Case Reports | Pharmacovigilance
  - Data Base Management
  - Panel Discussions | Extended Networking
## Keynote Session

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Keynote Talk 5</td>
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<tr>
<td>09:45</td>
<td>Keynote Talk 6</td>
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<td>10:15</td>
<td>Keynote Talk 7</td>
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**Coffee/Tea Break 10.45-11.00**

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<td>11:00</td>
<td>Pre-Lunch Session</td>
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<td>Plenary Session 4</td>
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**Networking Lunch 12.40-13.30**

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<tr>
<td>13:30</td>
<td>Post Lunch Sessions</td>
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<td>15.30</td>
<td>Plenary Session 5</td>
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**Coffee/Tea Break 15.30-15.45**

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<td>15.45</td>
<td>Evening Sessions</td>
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<tr>
<td>18.00</td>
<td>Plenary Session 3</td>
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<td>Panel Discussions</td>
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**Closing and Award Ceremony**
Glimpses of Pharmacovigilance and Clinical Trials
TOURIST DESTINATIONS IN ORLANDO

Blizzard Beach Pool

Discovery Cove

Disney Hollywood Studios

Disneys Animal Kingdom

Harry P Leu Gardens

Hollywood Drive In Glof

Island of Adventure

Lake Eola Park

Magic Kingdom

Morocco Pavilion
Conference Venue
Orlando, Florida, USA
Proceedings of
6th Pharmacovigilance Congress

September 28-30, 2016
Toronto, Canada

Hosting Organizations

Conference Series Ltd
Heathrow Stockley Park Lakeside House
1 Furzeground Way, Heathrow,
UB11 1BD, UK, Tel: +1-800-216-6499

Conference Series Ltd
2360 Corporate Circle., Suite 400 Henderson
NV 89074-7722, USA

Email: pharmacovigilancecongress@conferenceseries.net
# Conference Sessions

## Day 1  
**September 28, 2016**
### Meighen Room

- **08:30-09:15** Registrations

- **09:15-09:35** Opening Ceremony

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:35-09:40</td>
<td>Introduction</td>
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</table>
| 09:40-10:40   | **Title:** Pharmacovigilance and compliance of drugs labeling information with the 2015 FDA lactation guidelines  
**Gamal Hussein**, South College School of Pharmacy, USA |
| **Group Photo:** 10:40-10:45 | Networking & Refreshments Break 10:45-11:00 @ Foyer |
| 11:00-12:00   | **Title:** Efficacy, safety and pharmacokinetic profiles of a plasma-derived VWF/FVIII concentrate (Voncento) in subjects with haemophilia A (SWIFT-HA study)  
**Aleksander Skotnicki**, Szpital Uniwersytecki w Krakowie, Poland |
| 12:00-13:00   | **Title:** The use of laser therapy in dermatology (Benign pigmented lesions)  
**Ossama Roshdy**, Alexandria University, Egypt |
| **Lunch Break:** 13:00-14:00 | @ Cabinet Room |

### Sessions: Drug Safety | Case Study | Pharmacy Practice and its Challenges

**Session Chair:** Sutapa Bandyopadhyay Neogi

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<tr>
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| 14:00-14:30   | **Title:** Tablet splitting of psychotropic drugs for patients with dementia: A pharmacoepidemiologic study in a Brazilian sample  
**Patricia Medeiros-Souz**, Universidade de Brasilia, Brazil |
| 14:30-15:00   | **Title:** Nucleoside drug safety improvement via pronucleotide approaches  
**Zhihong Xu**, South College, USA |
| 15:00-15:30   | **Title:** Blockade of the NMDA receptor in developing cortex induces autophagy-mediated death of migrating cortical GABAergic interneurons: an ex vivo and in vivo study in GAD67-GFP mice  
**Bruno J Gonzalez**, Normandy University/Inserm NeoVasc, Rouen, France |
| 15:30-16:00   | **Title:** Pattern of hospital-acquired pneumonia in intensive care unit of Suez Canal University hospital  
**Nermine El maraghy**, Suez Canal University, Egypt |
| **Networking & Refreshments Break:** 16:00-16:20 | @ Foyer |
| 16:20-16:50   | **Title:** Pharmacovigilance as a tool for conducting clinical trials with plant-based medicines  
**Liaquat Ali**, Bangladesh University of Health Sciences, Bangladesh |

### Panel Discussion

### Day 2  
**September 29, 2016**
### Algonquin Room A

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<tr>
<th>Time</th>
<th>Session</th>
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| 09:45-10:45   | **Title:** Can Pharmacist ensure drug safety in the healthcare system or are there barriers  
**Panjasaram Naidoo**, University of KwaZulu Natal, South Africa |
| **Networking & Refreshments Break:** 10:45-11:00 | @ Foyer |

### Sessions: Pharmacy Practice & its Challenges

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| 11:00-11:30   | **Title:** Indigenous medicine use for sex selection during pregnancy and risk of congenital malformations and stillbirths  
**Sutapa Bandyopadhyay Neogi**, Indian Institute of Public Health-Delhi (IIPH-D), India |
Title: The synthesis of potentially bioactive new compounds in the field of 3,4-Disubstituted-5-Mercapto-1,2,4-Tiazoles Y
Melanya A. Samvelyan, Yerevan State University, Armenia

Young Research Forum

Sessions: Drug safety | Pharmacy Practice & Challenges | Preclinical and Clinical Trials on various disorders

12:00-12:15
Title: Survey on counterfeiting of Amoxicillin and Amoxicillin + Clavulanic acid marketed in Lubumbashi
Pierrot Mwamba T, University of Lubumbashi, Congo

12:15-12:45
Title: Over-the-counter (OTC) products withdrawn from the United States due to the inclusion of undeclared prescription ingredients in the past 15 years
Lavesh Patel, South College School of Pharmacy, USA & Maame Twum, South College School of Pharmacy, USA

12:45-13:00
Title: Targeting population for AST: previous allergy history and Cephalosporin skin test positivity
Dong-Yoon Kang, Seoul National University Hospital, Korea

Lunch Break: 13:00-14:00 @ Cabinet Room

Poster Presentation Session @ 14:00-15:45

PVC01
Title: Derivatives of 1,2,4-Triazoles: Synthesis and study of biological activity
Armen S Galstyan, Yerevan State University, Armenia

PVC02
Title: New syntheses in the field of γ-Lactones and biological studies of the obtained compounds
Tariel V Ghochikyan, Yerevan State University, Armenia

PVC03
Title: Radical scavenging activity and phytochemical constituent of Tulipa Systola Stapf
Mohammed Farhad Ibrahim, University of Salahaddin, Iraq

PVC04
Title: Prenatal exposure to alcohol impairs the long term integration of GABA interneurons and the proteolytic endothelial activity in mouse neonates
Cecile Leger, Normady University, France

PVC05
Title: Prospective observational study for Oxaliplatin induced hypersensitivity: experience in a single institute during 2 years
Kyoung-hee Sohn, Seoul National University College of Medicine, South Korea

PVC06
Title: Pharmacovigilance and compliance of drugs labeling information with the 2015 FDA lactation guidelines
Faten Sabbagh, South College School of Pharmacy, USA

PVC07
Title: Audit of the introduction of MYMATHLAB for first year and second year mpharm students
Majdi Garsan Algarsan, University of Hertfordshire, UK

PVC08
Title: The distribution of CYP2B6 variants in Roma from Croatia
Branka Janicijevic, Institute for Anthropological Research, Croatia

PVC09
Title: Epidemiologic study based on adverse drug events in patients visiting emergency department: a retrospective observational study in three university hospitals
Min-Gyu Kang, Chungbuk National University, Korea

PVC10
Title: Bronchoprovocation study of Albuterol inhalation on asthma patients: A Pharmacodynamic Bioequivalence Study
Nailesh Patel, Ganpat University, India

Networking & Refreshments Break: 15:45-16:00 @ Foyer

Panel Discussion
Award Ceremony

Day 3  September 30, 2016

Algonquin Room A

B2B Meetings @ 10:00-10:45

Academic Research Meetings @ 11:00-13:00

Lunch Break: 13:00-14:00 @ Cabinet Room

Panel Discussion
Award Ceremony
Thanks Giving Ceremony
Scientific Program

Day 1  August 10, 2015

08:30-09:30  Registrations

Gates Suite

09:30-09:55  Opening Ceremony

Keynote Forum

09:55-10:00  Introduction
10:00-10:30  Greg Koski
Alliance for Clinical Research Excellence and Safety, USA
10:30-11:00  Angela van der Salm
DADA Consultancy B.V., Netherlands

Networking and Refreshment Break: 11:00-11:15

11:15-11:45  Peter Lannon
Lanpharm Consulting T/A Lanpharm Services, UK
11:45-12:15  Kieran O’Donnell
TMC Pharma Services, UK
12:15-12:45  Alistair Coates
Oviya MedSafe, UK

Track 1: Concept of Pharmacovigilance and its Significance and Scope
Track 7: Pharmacovigilance and Risk Management
Track 8: Clinical Research and Statistics
Session Chair: Kieran O’Donnell, TMC Pharma Services, UK
Session Co-Chair: Peter Lannon, Lanpharm Consulting T/A Lanpharm Services, UK

Scientific Program

Session Introduction

12:45-13:10  Title: MedDRA SMQs: Physician ratings of important terms for diagnosis of cardiac failure and acute pancreatitis- A Delphi study
Michelle Perry, Aspen Pharmacare Trading Limited, Ireland

Lunch Break 13:10-14:10

14:10-15:10  Workshop
Inefficiencies in pharmacovigilance: What we can do now and what could be done in the future
Giovanni Furlan, Helsinn Birex, Ireland

15:10-15:35  Title: Over a century of Alzheimer and still no cause in sight: Is pharmacovigilance asleep on the job?
G Robert Jones, Cancer Research Unit, UK

Networking & Refreshment Break 15:35-15:50

15:50-16:25  Workshop
The EU-RMP - Planning risk management in a feasible fashion
Angela van der Salm, DADA Consultancy B.V., Netherlands

16:25-16:45  Title: Extended EudraVigilance medicinal products dictionary (xevmpd)
Alistair Coates, Oviya MedSafe, UK

Workshop

16:45-17:15  Tomorrow, today: Systems approaches to enhance pharmacovigilance and risk management
Greg Koski, Alliance for Clinical Research Excellence and Safety, USA
Day 2
August 11, 2015

Gates Suite

Track 2: Pre-Clinical and Clinical Trials & Case Report
Track 3: Clinical Trials on Drugs used in Various Disorders, Pharmacotherapy and Pharmacotherapeutics
Track 4: Adverse Drug Reactions
Track 10: Good Pharmacovigilance Practice and Pharmacoepidemiology

Session Chair: Subodh Bhardwaj, Arable Corporation, USA
Session Co-Chair: Pramod Wable, Daiichi Sankyo Development Ltd., UK

10:00-10:25
Title: Combining quantitative and qualitative methods in signal detection and evaluation in pharmacovigilance
Michelle Perry, Aspen Pharmacare Trading Limited, Ireland

10:25-11:25
Title: Vaccine vigilance- Towards strengthening pharmacovigilance
Subodh Bhardwaj, Arable Corporation, USA

Workshop

 Networking & Refreshment Break 11:25-11:40

11:40-12:05
Title: Evaluation of the clinical indications, adverse drug reactions, and Finasteride use in patients with benign prostatic hyperplasia in Poland
Tomasz Zabkowski, Military Medical Institute, Poland

12:05-12:30
Title: ADR is a threat more to children and women than adult male
Sagar D Kadam, Babbanrao Pachpute Vichardhara Trust’s Group of Institutions, India

12:30-12:55
Title: The regulation of allogeneic human cells and tissue products as biomaterials
Kazuo Yano, Tokyo Women’s Medical University, Japan

Lunch Break 12:55-14:00

14:00-14:25
Title: Pharmacovigilance: State of pharmacovigilance in developing countries: Lomie’s hospital (East Region / Cameroon) in regard to the harmonization of new European reglementations of pharmacovigilance
Carolle Laure Matene Kpoumie, ONMC, Paris

Workshop

14:25-15:25
Title: Lean, six sigma and ISO and their applications in clinical trials/research
Pramod Wable, Daiichi Sankyo Development Ltd, UK

15:25-15:50
Title: Challenges and issues in pharmacovigilance of herbal medicines in India
Mahek Arora, Amity University, India

Panel Discussions

 Networking & Refreshment Break 15:50-16:05

16:05-17:05
Poster Presentations

PC 01
Title: The influence of co-prescribed GABA-ergic drugs on anti-depressant compliance in patients with depression: A prospective study in a South African private healthcare cohort
Martha Susanna Lubbe, North-West University (NWU), South Africa

PC 02
Title: The importance of pharmacovigilance, now and in the future
Michelle perry, Aspen Pharmacare Trading Limited, Ireland

PC 03
Title: Effect of Stachys mialhesi de noe on the inflammation induced by hyperhomocysteinemia in cardiovascular diseases
Sakina Zerizer, University of Constantine, Algeria

PC 04
Title: Uncommon serum creatine phosphokinase and lactic dehydrogenase increase during diosmin therapy: Two case reports
Giulia Milano, University of Genova, Italy

PC 05
Title: An observational study of cutaneous adverse drug reactions in a teaching hospital
Deepti Chopra, Hamdarb Institute of Medical Sciences and Research, India

PC 06
Title: Attitude and awareness of adverse drug reaction reporting by health professionals in seven hospitals in the holy city of makkah, kingdom of Saudi Arabia
Naif Al Hazmi, Bradford University, KSA
### Track 5: Pharmacokinetics and Pharmacodynamics

Session Chair: Subodh Bhardwaj, Arable Corporation, USA
Session Co-Chair: Doaa A Ghareeb, Alexandria University, Egypt

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<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker &amp; Affiliation</th>
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<tbody>
<tr>
<td>10:00-10:25</td>
<td>Medication administration errors in pediatric ward: An observational study</td>
<td>Zayed Alsulami, Alkhairj Military Industries Corporation Hospital, KSA</td>
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<tr>
<td>10:25-11:25</td>
<td><strong>Workshop</strong> Title: Potential molecular mechanism of <em>Berberis Vulgaris</em> extract, berberine and berberine chitosan nanoparticles in Alzheimer treatment</td>
<td>Doaa A Ghareeb, Alexandria University, Egypt</td>
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<tr>
<td>11:40-12:05</td>
<td>Hydroxychloroquine in patients with inflammatory and erosive osteoarthritis of the hands (OA treat): Study protocol for an on-going randomized controlled trial</td>
<td>Pascal Klaus, Charite - Universitätsmedizin Berlin, Germany</td>
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<td>12:05-12:30</td>
<td>Rapid, accurate and simple microfluidic device based on fluorescent read-out immunoassay for the determination of oral anticoagulants compounds in treated patients</td>
<td>J Pablo Salvador, CIBER-BBN, Spain</td>
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**Networking & Refreshment Break 11:25-11:40**

**Lunch Break 12:30-13:30**

**Award Ceremony**

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Title: Pharmacokinetic-model based microfluidic multi-organ-on-a-chip for testing whole-body response to xenobiotic compounds

**Jong Hwan**, Hongik University, South Korea

Title: Sakina Zerizer, University of Constantine, Algeria

**Martha Susanna Lubbe**, North-West University (NWU), South Africa