# **Tentative Program**

11th International Conference and Exhibition on

## **Pharmacovigilance & Drug Safety**

June 21-22, 2018 London, UK



Interactive Sessions

**Keynote Lectures** 

Plenary Lectures

Workshops

**Exhibitors** 

**B2B**Meetings

## \*\*\*For available speaker slots\*\*\*

pharmacovigilance@pharmaceuticalconferences.org

11th International Conference and Exhibition on

## **Pharmacovigilance & Drug Safety**

June 21-22, 2018 London, UK

**Program at a Glance** 

|                  |  |             | -8. a a. a. a. a          |                           |                              |  |
|------------------|--|-------------|---------------------------|---------------------------|------------------------------|--|
|                  |  |             | Day 1                     |                           |                              |  |
|                  | Reception/Registration   |             | 08.00-09.00               |                           |                              |  |
| Morning Sessions |  | Time        | General                   | Session                   |                              |  |
|                  |  | 09.00-09.15 | Inaugural                 | al Address                |                              |  |
| Ses              | Least of 3 Keynote/Plenary Talks   | 09.15-09.45 | Keynote/Plenary Talk 1    |                           | <b>4</b> 1                   |  |
| ing              |  | 09.45-10.15 | Keynote/Plenary Talk 2    |                           | Da                           |  |
| orn              |  | 10.15-10.45 | Keynote/Plenary Talk 3    |                           | for                          |  |
| Σ                | Panel Discussions/Group Photo  |             |                           |                           |                              |  |
|                  | Coffee/Tea Break 10.45-11.00 (Networking)  |             |                           |                           |                              |  |
| Evening Sessions | 11.00-12.40  |             | 5 Speakers (20 Mins Each) |                           | 19 Speakers for <b>Day 1</b> |  |
| essi             | Lunch Break 12.40-13.30  |             |                           |                           |                              |  |
| g S              | 13.30-15.30  |             | 6 Speakers (20 Mins Each) |                           |                              |  |
| nin              | Coffee/Tea Break 15.30-15.45 (Networking)  |             |                           |                           |                              |  |
| EVE              | 15.45-17.25  |             | 5 Speakers (2             | 0 Mins Each)              |                              |  |
| Day 2            |  |             |                           |                           |                              |  |
|                  |  | Time        | Session 1                 | Session 2                 |                              |  |
| Morning Sessions | 09.00-10.40  |             | 5 Speakers (20 Mins Each) | 5 Speakers (20 Mins Each) | 2                            |  |
| ng Ses           | Coffee/Tea Break 10.40-10.55 (Networking)  |             |                           |                           |                              |  |
| rnir             | 10.55-12.35  |             | 5 Speakers (20 Mins Each) | 5 Speakers (20 Mins Each) | on                           |  |
| Σ                |  |             |                           |                           | 40 Speakers on <b>Day 2</b>  |  |
|                  | Lunch Break 12.35-13.25  |             |                           |                           |                              |  |
| essi             | 13.25-15.05  |             | 5 Speakers (20 Mins Each) | 5 Speakers (20 Mins Each) | Sp                           |  |
| Evening Sessi    | Poster Sessions  |             |                           |                           |                              |  |
|                  | Coffee/Tea Break 15.05-15.20 (Networking)  |             |                           |                           |                              |  |
| Ē                | 15.20-17.00  |             | 5 Speakers (20 Mins Each) | 5 Speakers (20 Mins Each) |                              |  |
|                  | NOTE: Program Shedule is subject to change with final allotment of the speaker slots |             |                           |                           |                              |  |
|                  |  |             |                           |                           |                              |  |

For More Details: pharmacovigilance@pharmaceuticalconferences.org, pharmacovigilance@conferenceseries.net http://pharmacovigilance@pharmaceuticalconferences.org/

## **Conference Highlights**

- Pre-Clinical and Clinical Trials
- Adverse Drug Reactions
- Pharmacovigilance and Risk
   Management
- Good Pharmacovigilance
   Practice
- Pharmacy Practices and its Challenges
- Clinical Trials on Various
   Disorders

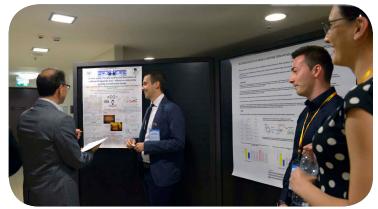
- Biopharmaceutical Sciences
- Diversity in Industrial Clinical
   Trials and Clinical Research
- Case Report in Clinical Trials
- Drug Safety
- Regulatory Affairs
- Clinical Data Base Management
- Clinical Research and Statistics



## Glimpses of Pharmacovigilance 2017





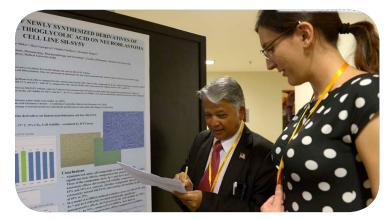










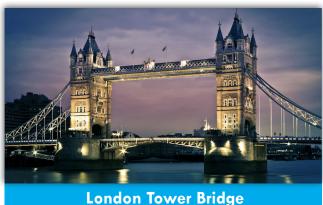


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### Scientific Program

9th International Conference and Exhibition on

## **Pharmacovigilance & Drug Safety**

July 17-18, 2017 Munich, Germany



#### **Conference Series - America**

One Commerce Center-1201, Orange St. #600, Wilmington, Zip 19899, Delaware, USA Toll Free: 1-888-843-8169, P: 702-508-5200, F: +1-650-618-1417

#### **Conference Series - UK**

Kemp House, 152 City Road, London EC1V 2NX, UK Toll Free: +0-800-014-8923

#### Forum 15

conferenceseries.com

## **Opening Ceremony**

#### **Keynote Forum**

Introduction

Title: Impact of the polypill approach in the efficacy and safety of Trinomia®: Post-marketing pharmacovigilance data after three-years

Jorge I Gonzalez Borroto, Grupo Ferrer Internacional, Spain

**Group Photo** 

**Networking & Refreshment Break** 

Title: Risk management life cycle approach – key points

Essam Ghanem, Keyrus Biopharma, Belgium

Sessions: Drug Safety | Pharmacovigilance and Risk Management | Biopharmaceutical Sciences | Adverse Drug Reaction | Good Pharmacovigilance Practice | Clinical Trials on Various Disorders

Session Chair: Jorge I Gonzalez Borroto, Grupo Ferrer Internacional, Spain

Session Co-Chair: Essam Ghanem, Keyrus Biopharma, Belgium

**Session Introduction** 

Title: The fundamentals and importance of accurate medical review

Anna Stahl, Otsuka Novel Products GmbH, Germany

Title: Brexit and the pharmaceutical industry

Aaron D Barzey, ADB Medical, UK

Lunch Break

Title: Phytochemical and pharmacological study of volatile fractions from Eucalyptus camaldulensis leaves and their potent effects on isolated aortic and tracheal rings

Dizar A Kheder, University of Zakho, Iraq

Title: Adverse drug reaction: Knowledge and practice of pharmacovigilance by healthcare providers in tertiary institutions in Lagos

Temitope Oyeneye, Drug Consult Pharmacy, Nigeria

Title: Inhibition of APP gamma-secretase: A promising tool for improving brain development in Down syndrome and APP-linked brain disorders

Fiorenza Stagni, University of Bologna, Italy

Networking & Refreshments Break

Title: Pharmacovigilant actions of pharmacist on potassium cyanide Gajendra Singh, Pt. B.D. Sharma University of Health Sciences, India

Title: Good pharmacovigilance practice

Parminder Kaur, RegPak BioPharma Consulting, Netherlands

**Panel Discussion** 

Day 2 July 18, 2017

Forum 15

**Keynote Forum** 

Title: Is the current analysis of MAHs of 'off-label use' constructive?

Anika Staack, MEDICE, Germany

Title: Pharmacovigilance in 2020-future horizons and efficiencies in data acquisition, evaluation and

risk management

Flic Gabbay, TranScrip, UK

**Networking & Refreshments Break** 

Sessions: Good Pharmacovigilance Practice | Drug Safety | Pharmacovigilance and Risk Management

Session Chair: Anika Staack, MEDICE, Germany Session Co-Chair: Flic Gabbay, TranScrip, UK

**Session Introduction** 

Title: How to ensure high quality output in a constantly changing work environment?

Anika Staack, MEDICE, Germany

Title: Efficiency gain in business models for global pharmacovigilance: Automation and burying the silos

Mandar Kelkar, TranScrip, UK

Title: Safepreg papyrus: A scoring system for safer medication use during pregnancy and the evaluation of 1000 drugs

Gamal Hussein, South College School of Pharmacy, USA

Lunch Break

#### **Poster Presentations**

#### Poster Judge: Essam Ghanem, Keyrus Biopharma, Belgium

Title: Screening for the postpartum depression among newly delivered women

Jaya Gurung, Al-Ameen College of Pharmacy, India

Title: Determining the incidence of potential drug interactions in a general hospital not using

PVO2 computerized prescribing; and assessing the influence on prescribers' actions

Saed Amarneh, Laniado Hospital, Israel

Title: Evaluating low-dose Aspirin use in diabetic patients

Wijdan H Ramadan, Lebanese American University, Lebanon

#### Sessions: Regulatory Affairs | Biopharmaceutical Sciences | Adverse Drug Reactions

Title: Under-reporting of adverse drug reactions: A problem that also involves medicines subject to additional monitoring. Preliminary data from a single-centre experience on novel oral anticoagulants

Anna Patrignani, Senigallia Hospital, Italy

Title: Screening for the postpartum depression among newly delivered women

Jaya Gurung, Al-Ameen College of Pharmacy, India

**Networking & Refreshments** 

Title: Pharmacovigilance and the surveillance of adverse drug reactions

Samira Saleh, Future University, Egypt
Title: Overview of pharmacovigilance

Mario Adel Barsoum, Ahram Canadian University, Egypt

**Closing & Award Ceremony** 



## Scientific Program

4<sup>th</sup> International Conference on

# CLINICAL TRIALS

September 11-13, 2017 San Antonio, USA



#### **Conference Series - America**

One Commerce Center-1201, Orange St. #600, Wilmington, Zip 19899, Delaware, USA P: +1-702-508-5200, F: +1-650-618-1417

#### **Conference Series - UK**

Kemp House, 152 City Road, London EC1V 2NX Toll Free: +1-800-216-6499

#### Texas B

#### conferenceseries.com

## **Opening Ceremony**

#### **Keynote Forum**

#### Introduction

Title: The future of the clinical research industry

John P Neal, PCRS Network LLC, USA

Title: The site landscape

Diana L Foster, Society for Clinical Reseaarch Sites (SCRS), USA

Title: Towards more clinically relevant outcome measures in cancer, multi-system syndromes and

patient safety

Ayad Abdul-Ahad, A3 Pharma Counselling Ltd, UK

Title: Novel techniques for improving clinical trial subject retention

Nicki Norris, Symphony Clinical Research, USA

#### Group Photo 10:40-10:45

#### **Panel Discussion**

**Networking & Refreshment Break** 

#### Sessions:

Clinical Research & Clinical Trials | Conducts of Clinical Trials | Clinical Trials on different Diseases | Research and Trials on AIDS / Cancer / Diabetes | Clinical Data Management and Statistics | Innovations & Future of Clinical Trials | CRO/ Sponsorship Clinical Trials | Drug Discovery and Development

Session Chair: Oleg V Tcheremissine, Carolinas HealthCare System, USA

Session Chair: Sarah Attwood, IntegReview IRB, USA

Session Introduction

Title: Developing an Alzheimer's clinical trial network with the Carolinas healthcare system, a large fully integrated health care system

Oleg V Tcheremissine, Carolinas HealthCare System, USA

Title: Current events in pre-approval access in the United States

David Vulcano, HCA Healthcare, USA

Title: Spontaneous hyphema in patient proned for acute respiratory distress syndrome

Valerie G Sams, San Antonio Military Medical Center, USA

Title: A new class of distribution-free models in analysis of adverse events in drug safety

Richard Entsuah, Merck Research Laboratories, USA

Title: Management of clinical trial agreements

JoAnn Pfeiffer, Arizona State University, USA

Title: Utilizing emerging virtual care methods to improve access to behavioural health services within

the ambulatory care setting

Manuel A Castro, Carolinas HealthCare System, USA

#### **Panel Discussion**

**Lunch Break** 

Title: Final revisions to the common rule- How will this affect human subject protection?

Sarah Attwood and Melanie Flores, IntegReview IRB, USA

Title: Exploration of common pet peeves within the sponsor/CRO relationship

Chris Chan, FibroGen, Inc., USA

Title: Insurance considerations for global clinical trials

Brian M Toglia, Tanner-Ibbotson, Inc., USA

Titile: Using interactive 3D visualization for rapid discovery of "hidden" outliers and correlations in

clinical trial studies

Michael Zeitlin, Aqumin LLC, USA

Title: Re-inventing the entry-level clinical research coordinator

Lauren E Ballina, Clinical Research Fastrack, USA

Title: Equipoise: The guiding ethical principle pertaining to randomized clinical trials

Scott Gelfand, Oklahoma State University, USA

#### **Panel Discussion**

**Networking & Refreshment Break** 

Title: Cancer metastasis: Enactment of the script for human reproductive drama Xichun Sun, Virginia Commonwealth University School of Medicine, USA

Title: Effective eCRF designing - Data management approach

Mohsin Shaikh, Axiom Real-Time Metrics, Canada

Title: Dexamethasone as a ropivacaine adjuvant for ultrasound-guided interscalene brachial plexus

block: A randomized, double-blinded clinical trial

Thiago Mamoru Sakae, University of Southern Santa Catarina, Brazil

#### **Panel Discussion**

#### **Special Session**

Title: An open dialogue with sites about streamlining the startup process

David Vulcano, HCA Healthcare, USA

Diana L Foster, Society for Clinical Research Sites (SCRS), USA

Colleen Hoke, Objective Clinical, USA

JoAnn Pfeiffer, Arizona State University, USA

#### **Panel Discussion**

#### Day 2 September 12, 2017

#### **Texas B**

#### **Keynote Forum**

#### Introduction

Title: Choosing the right trials and technologies to support research entity goals

Colleen Hoke, Objective Clinical, USA

Title: Liver let die-Challenges and opportunities in developing interventions for fatty

liver disease (NAFLD/NASH)

Clayton Dehn, Clinical Trials of Texas, USA

Title: Global challenges in conducting clinical trials

Milan Satia, Ethicare Clinical Trial Services, India

Title: Streamlining clinical trial conduct in a national healthcare system towards

pragmatic cardiovascular clinical trials

Jacob Joseph, Harvard Medical School, USA

#### **Panel Discussion**

**Networking & Refreshment Break** 

**Sessions:** 

Drug Discovery and Development | Clinical Research & Clinical Trials | Clinical Study Designs |
Research and Trials on AIDS / Cancer / Diabetes | Globalization of Clinical Trials | Outsourcing in
Clinical Trials | Medical and Clinical Case Reports | Pharmacovigilance and Drug Safety

Session Chair: Colleen Hoke, Objective Clinical, USA

Session Chair: Richard Entsuah, Merck Research Laboratories, USA

**Session Introduction** 

Title: Research on connective tissue rehabilitation: A meta-analysis

F Buck Willis, Galveston Clinical Research Foundation, USA

Title: Trial promoter: A web-based tool for boosting the promotion of clinical research through social media

Katja Reuter, University of Southern California, USA

Title: Integration of clinical study data to support trial simulation activities

Raj Bandaru, Sanofi Pharmaceuticals, USA

Title: More is not better: The result from a US government sponsored multi-center randomized international

clinical trial to prevent tuberculosis in HIV/AIDS population

Jing Bao, National Institutes of Health, USA

Title: Primary outcome is not significant, now what?

Geraldine E Baggs, Abbott Nutrition Research and Development, USA

Title: A high prescision gait analysis system for in community monitoring of patients with neurological and musculoskeletal disorders

Hamid Najafi, Sensoplex, Inc., USA

#### **Panel Discussion**

**Lunch Break** 

Title: Innovations from a family medicine department engaged in clinical trial research

Lindsay Lowe, Carolinas HealthCare System, USA

Title: Innovation starts with people: A new paradigm in workforce development

David Vulcano, HCA Healthcare, USA

Title: PVG and drug safety- pharmacovigilance in India and emerging markets: An industrial perspective

Ujwala V Salvi, Nucleon Therapeutics, LLP, India

Title: The good, the bad, and the unknown of executing clinical trials in Mexico and Latin America

Sergio Guerrero, Clinical Research Center in Mexico, Mexico

Title: Conceptual progress in the management of sickle cell pain from individualized trial and error approach to a specific pharmacologic precision medicine

Samir K Ballas, Thomas Jefferson University, USA

Title: Best strategies to recruit and enroll elderly blacks into clinical and biomedical research

Lennox Graham, Howard University, USA

#### **Panel Discussion**

**Networking & Refreshment Break** 

Title: Bangladesh: Can be a potential new hub for global CROs for global clinical trials

Wasif Ali Khan, International Centre for Diarrhoeal Disease Research, Bangladesh

Title: Old chemicals, now as potential life savers against ischemic and reperfusion injuries

Myoung-Gwi Ryou, Tarleton State University, USA

Title: The effect of progressive resistance exercises (PRE) with knee flex device made by researcher to increase muscular power and ROM after knee arthroplasty

Bijan Goodarzi, Islamic Azad university, Iran

#### Workshop

Title: Current state of statistical methods in handling missing data in clinical trials

Richard Entsuah, Merck Research Laboratories, USA

| Poster Presentations |   |  |  |  |
|----------------------|---|--|--|--|
| CLTRS 001            | Title: Long-term effect of policosanol on the functional recovery of non-cardioembolic ischemic stroke patients: a one year study |  |  |  |
|                      | Julio C Fernandez, National Centre for Scientific Research, Cuba  |  |  |  |
| CLTDS 000            | Title: Clinical efficacy of Echinops echinatus extract in the treatment of liver enlargement                                      |  |  |  |
| CLTRS 002            | Muhammad Akram, The University of Poonch, Pakistan  |  |  |  |
| CLTDC 000            | Title: Lipid-lowering and antioxidant effects of policosanol in diabetic patients: a pilot study                                  |  |  |  |
| CLTRS 003            | Julio C Fernandez, National Centre for Scientific Research, Cuba  |  |  |  |
| CLTRS 004            | Title: Epidemiology and risk factor for hyperlipidemia in Pakistan  |  |  |  |

#### **Day 3 September 13, 2017**

Muhammad Akram, Government College University, Pakistan

#### **Texas B**

#### **Sessions:**

Clinical Research & Clinical Trials | Clinical Trials on different Diseases | Globalization of Clinical Trials | Future of Clinical Trials | CRO/ Sponsorship Clinical Trials | Outsourcing in Clinical Trials | Pharmacovigilance and Drug Safety | Post-marketing Surveillance

Session Chair: Jing Bao, National Institutes of Health, USA

**Session Introduction** 

Title: Future visions in clinical trials: The role of artificial intelligence and how it changes clinical research

Kim Walpole, Trials.ai, USA

Title: Clinical coding for clinical data management professional

Mohsin Shaikh, Axiom Real-Time Metrics, Canada

#### Workshop

Title: Advantages and challenges conducting clinical trials in China

Jing Bao, National Institutes of Health, USA

#### Panel Discussion

**Networking & Refreshment Break** 

Title: The role of corruption and unethical behaviour in precluding the placement of industry sponsored clinical trials in Sub-Saharan Africa: Stakeholder views

Efe Egharevba, Glasgow University of Health & Wellbeing, UK

Title: Efficacy of combined versus open and closed kinetic-chain exercises on selected physical performance indices and health-related quality of life of individuals with knee osteoarthritis

Oladapo Michael Olagbegi, Rhodes University, South Africa

Title: Antidepressant like effect of Citronellyl Acetate in mice

Luciana Kelly Ximenes, Federal University of Ceara, Brazil

Title: New pattern clinical study of adverse drug reaction to ART may lead to chase drug discovery in anti-retroviral drug towards zero adverse drug reaction

Rahul Hajare, Rajgad Dnyanpeeth's College of Pharmacy, India

Title: Clinical evaluation of the use of enrofloxacin against Staphylococcus aureus clinical mastitis in sheep

Victor Ngu Ngwa, University of Ngaoundere, Cameroon

Title: The challenges of Clinical trials in developing nations: Ethiopian perspectives

Etsubdink Abera Aboye, St. Paul's Hospital Millennium Medical College, Ethiopia

#### **Panel Discussion**

Title: A network-based pharmacology study of the potential hepatotoxicity of two common hepatoprotective chinese herbal medicines

Ming Hong, The University of Hong Kong, China

Title: Vector surveillance of Zika virus/JE in selected high risk areas of India

Nasreen Akhtar, National Institute of Malaria Research, India

Title: Designing a bayesian adaptive phase 2 proof of concept trial for BAN2401, a monoclonal antibody for the treatment of early Alzheimer's disease

Chad J Swanson, Eisai, Inc.

Title: Detailing key considerations and challenges of EDC in terms of implementation and statistical aspects

Liora Bosch, Omrix a J&J company, Israel

Titile: The role of palliative care in Phase 1 Oncology clinical trial participants

Amanda M Brock, University of Pennsylvania, USA

Title: Precision and accuracy of the new XPrecia Stride mobile coagulometer

Francesco Piacenza, National Institute of Health and Aging, Italy

#### **Panel Discussion**

#### **Award & Closing Cermony**



1341st Conferences

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Journal of Cancer Science & Therapy Open Access

Joint Conference
Proceedings of

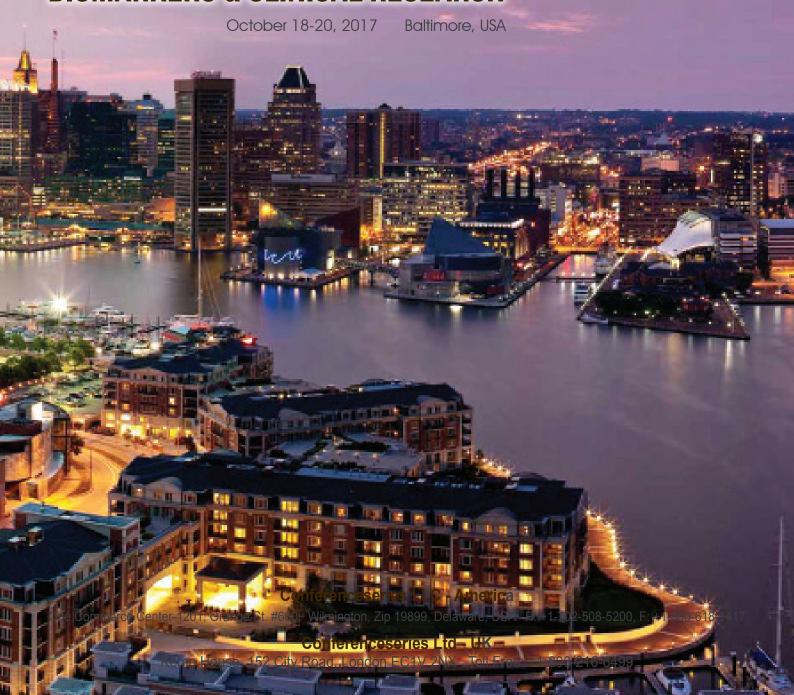
25th World Congress on

## **CANCER SCIENCE AND THERAPY**

8

10th World Congress on

## **BIOMARKERS & CLINICAL RESEARCH**



#### **Conference Hall**

#### conferenceseries.com

## **Opening Ceremony**

#### **Keynote Forum**

#### Introduction

Title: Molecular surrogates of histologic activity in crohn's disease

Frédéric Baribaud, Johnson & Johnson, USA

Title: Genomic approaches in modern biotechnology - From discovery translation to

implementation

David Dongliang Ge, Apostle Inc, USA

Title: Integrated biomarker strategies in immuno-oncology

Kamala K Maddali, Cancer Genetics Inc, USA

#### **Panel Discussion**

#### **Networking & Refreshment Break**

Title: Non-invasive quick, early diagnostic method and individualized safe, effective treatment of various cancers and their metastasis using highly sensitive electromagnetic field resonance phenomenon between 2 identical molecules or cancer tissues Yoshiaki Omura, New York Medical College, USA

Title: An empirical assay for assessing genomic sensitivity and for improving cancer diagnostics

Diana Anderson, University of Bradford, UK

Title: Translational approach to detect biomarkers bedside

Srinivas Pentyala, Stony Brook Medical Center, USA

Title: Cancer genomic biomarkers in human malignancies

Jianhua Luo, University of Pittsburgh, USA

## Panel Discussion Group Photo

Lunch Break

Title: Perioperative use of NSAID might prevent early relapses in breast and other

Cancers: An upstream approach

Michael Retsky, Harvard School of Public Health, USA

#### **Panel Discussion**

#### Sessions:

Biomarkers | Cancer Biomarkers | Novel Approaches to Cancer Therapeutics | Molecular Biomarkers | Biomarkers for Immuno-Oncology | Biomarkers in Clinical Research & Development | Biomarkers and Drug Discovery | Cancer Metastasis | Cancer screening & Diagnostics Session | Tumor & Cancer Immunology | Biomarkers and Pathology | Biomarkers for Disorders

Session Chair: Diana Anderson, University of Bradford, UK

Session Chair: Jianhua Luo, University of Pittsburgh, USA

**Session Introduction** 

Title: Water channel AQP5 is a potential novel biomarker of diabetic nephropathy

Wenzheng Zhang, Albany Medical College, USA

Title: SIRT1 and Chk1 inhibition as novel therapeutic strategies in melanoma

A-Lien Lu-Chang, University of Maryland, USA

Title: Cancer and personalized medicine: Advances and conundrums in cancer therapy: A perspective on

how to Improve foresightedness and pioneer cancer treatment innovations

**Sherry A Bradford**, AccuTheranostics, USA

Title: Key molecules associated with the development of nodular gastritis due to Helicobacter pylori infection in children

Tamaki Ikuse, Juntendo University Graduate School of Medicine, Japan

#### **Panel Discussion**

**Networking & Refreshment Break** 

Title: Cancer metastasis: Enactment of the script for human reproductive drama

Xichun Sun, Virginia Commonwealth University, USA

Title: Paraneoplastic antigens as biomarkers for surveillance and prediction of recurrence in ovarian cancer

Michael A Tainsky, Wayne State University School of Medicine, USA

Title: Nanofibers with unique adaptive and invasive properties for enhanced tumoral retention and anticancer drug delivery

Vanessa Bellat, Weill Cornell Medicine, USA

Title: CS1 (CD319) is an effective immunotherapeutic target for multiple myeloma

Porunelloor A Mathew, University of North Texas Health Science Center, USA

Title: The efficacy of Gasdermin gene family for tumor marker in colorectal cancer

Hajime Orita, Shizuoka Hospital-Juntendo University, Japan

Title: Sam68 regulates colon tumorigenesis by genotoxic stress-induced NF-kB activation

Kai Fu, Johns Hopkins University, USA

#### **Video Presentations**

Title: Early detection of ovarian cancer

**Tijen Atacag**, Near East University, Turkey

Title: Chronic inflammation and mucus hyper secretion — the factors responsible for various respiratory diseases including throat and lung cancers

Manikonda Prakash Rao, Osmania University, India

#### **Panel Discussion**

#### Day 2 October 19, 2017

**Conference Hall** 

#### **Keynote Forum**

Title: Regulatory considerations for In Vitro diagnostics in oncology

Soma Ghosh, Food and Drug Administration, USA

Title: Mate-Pair Sequencing (MP-Seq) as a powerful clinical tool for the management of

cancer patients

David I Smith, Mayo Clinic, USA

Title: The predictive safety testing consortium: Qualification of translational safety

biomarkers for use in drug development

John Michael Sauer, University of Arizona College of Medicine, USA

#### **Panel Discussion**

**Networking & Refreshment Break** 

Title: Pre-clinical and clinical studies in COPD and cardiovascular areas and the role of biomarkers

Nikolai V Ivanov, Philip Morris International Research & Development, Switzerland

Title: Tackling heterogeneity in advanced cancers with personalized combination therapeutics

Lowe Leroy, Lancaster University, UK

#### **Panel Discussion**

#### Session:

Biomarker Discovery | Radiation Oncology | Cancer Clinical Trials | Cancer Diagnostics & Diagnostic Market | Targeted Cancer Therapy | Verification & Validation | Personalized Medicine and Data Analysis | Cancer Research | Clinical Research | Clinical Trials | Translational Biomarkers & Diagnostics |

Session Chair: Frédéric Baribaud, Johnson & Johnson, USA

Session Chair: David I Smith, Mayo Clinic, USA

Session Introduction

Title: In silico approach to biomarker discovery and precision medicine applications pertaining to medical devices

Yelizaveta (Lisa) Torosyan, Food and Drug Administration, USA

Title: Serum biomarkers in cancer patients treated with checkpoint inhibitors

Peter Schulz-Knappe, Protagen AG, Germany

Title: AlphaLISA high throughput screen discovers a novel small-molecule inhibitor to target protein arginine methyltransferase 5 in pancreatic and colorectal cancers

Tao Lu, Indiana University School of Medicine, USA

#### **Panel Discussion**

Lunch Break

Tittle: Detection of gene mutations in gastric cancer tissues by sequencing panel

Tomoaki Ito, Shizuoka Hospital-Juntendo University, Japan
Title: Focused ultrasound enhanced delivery in solid tumors
Victor Frenkel, University of Maryland School of Medicine, USA

Title: Clinical plasma biomarker development for Major Depressive Disorder (MDD)

Alexander M Buko, Human Metabolome Technologies, USA

Title: Aberrant genome duplication as both a cause and a cure for cancer

Melvin L DePamphilis, National Institute for Child Health & Human Development, USA

#### **Panel Discussion**

#### Networking & Refreshment Break

Title: FDA/CDRH perspectives on imaging biomarkers: Technical performance and analytical validation

Daniel M Krainak & Robert Ochs, Food and Drug Administration, USA

Title: Hepatocellular carcinoma 2017: MR and MSCT imaging

Janio Szklaruk, UT MD Anderson Cancer Center, USA

Tittle: The study of the markers of mood disorder with gastrointestinal cancer patients

Satoshi Tokuda, Shizuoka Hospital-Juntendo University, Japan

Title: Clinical constellation of the utility of the p87 biomarker for cancer

Martin Tobi, Central Michigan University College of Medicine, USA

Title: Identification of phenanthridinone based inhibitors of BRD2-BD2 bromodomain by structure-based drug discovery approach

Padmanabhan Balasundaram, National Institute of Mental Health and Neuro Sciences, India

Title: Anticancer activity of polyphenolic acetates mediated by calreticulin transacetylase in lung cancer

Vishwajeet Rohil, Vallabhbhai Patel Chest Institute, India

Title: Combination of mass spectrometry-ELISA platforms for Alzheimer blood biomarkers

Weiming Xia, Boston University School of Medicine, USA

#### **Panel Discussion**

Day 3 October 20, 2017

#### **Conference Hall**

#### **Keynote Forum**

Title: Tumor genomic sequencing to guide treatment

George Vasmatzise, Mayo Clinic, USA

Title: Ab-proteases as unique biomarkers and biopredictors to monitor chronic

inflammation of autoimmune origin at subclinical and clinical stages

Sergey Suchkov, I M Sechenov First Moscow State Medical University, Russia

Title: Immunobiomarkers for immunotherapy in non-small cell lung carcinoma

Qing Kay Li, Johns Hopkins Medical Institutions, USA

#### **Panel Discussion**

**Networking & Refreshment Break** 

#### Sessions:

Biomarkers & its Diseases | Cancer Cell Biology | Cancer Drugs | Precision Medicine & Cancer Therapy | Functional Genomics and Cytogenetic Biomarkers | Omics Technologies in Biomarkers Discovery and Validation | Techniques to Maximize Biomarker Identification | Biomarkers and Pharmacology |

Session Chair: Vasmatzis George, Mayo Clinic, USA

Session Chair: Qing Kay Li, Johns Hopkins Medical Institutions, USA

**Session Introduction** 

Title: Dysregulation of apoptosis-regulating miRNA by curcumin sensitizes kidney cancer cells to TRAIL induced apoptosis

Ismael Obaidi, Conway Institute, Ireland

Title: Proteomics-based biomarker discovery through data mining

Umashanger Thayasivam, Rowan University, USA

Title: Bacterial nucleases as signal-amplifying biomarkers for infectious disease diagnostics

James O McNamara, The University of Iowa, USA

Title: Human MicroRNA miR-888 cluster is a novel oncogenic network in the prostate involved in cancer progression pathways

Aurora Esquela Kerscher, Eastern Virginia Medical School, USA

Title: Cytoglobin expression in transplanted pancreatic islets improves insulin production by enhanced oxygen supply and protects from cell death in diabetes

Bhuvarahamurthy Venugopal, University of Madras, India

Title: MERTK promotes resistance to irreversible EGFR TKIs in NSCLCs expressing wild-type EGFR

Dan Yan, Emory University, USA

Title: Angiogenic properties of NSC-70 (UKRAIN/NSC-631570)

Wassil Nowicky, Ukrainian Anti-Cancer Institute, Austria

Title: Nanotechnology platform for personalized cancer treatment

Shyam Mohapatra, University of Soiuth Florida, USA

Title: Organelle genome polymorphisms: A molecular epidemiology tool for differentiation of cyclospora cayetanensis isolates during foodborne outbreaks

Hediye Nese Cinar, Food and Drug Administration, USA

Title: Oxidative stress induced NRF2 regulation in BxPC-3 pancreatic cancer cells and identification of therapeutic targets

Hem D Shukla, University of Maryland, USA

Title: Stem cell factors and markers: Biomarkers for bladder cancer detection and target therapy

Mohammad Obaidul Hoque, Johns Hopkins University, USA

Title: Biomarkers of hypoglycemia in human breath and sensor development

Mangilal Agarwal, Indiana University, USA

Title: Current regulatory trends and applicability of biomarkers in drugs, biologics and devices: A US

**FDA Outlook** 

Nina Mezu-Nwaba, Food and Drug Administration, USA

#### **Panel Discussion**

**Networking & Refreshment Break** 

#### **Video Presentations**

Title: Serum SAA2 protein as a diagnostic biomarker for egyptian Hepatocellular Carcinoma patients associated with HCV Infection

Erin Awad Rezk Sharkawy, Cairo University, Egypt

Title: Biomarker of adult human neurogenesis enables studies of aging and depression

Mirjana Maletic-Savatic, Baylor College of Medicine, USA

#### **Poster Presentations**

Title: Non-interventional, retrospective and anonymized data base study on breast tumors

P 01 for markers predictive of risk of recurrence

Kamuju Suryahari & Immadi Sreevallika, Clinical Trials, India

Title: Derivation of a unique body surface area (BSA) formula for calculation of relatively

P 02 safe doses of dog and human anticancer drugs

Saganuwan Alhaji, University of Agriculture, Nigeria

Title: Specificity of biogenic selenium nanoparticles for prostate cancer chemoprevention

P 03 with reduced risk of toxicity

Praveen Sonkusre, CSIR - Institute of Microbial Technology, India

#### Panel Discussion

**Award Ceremony** 

Thanks Giving & Closing Ceremony





702<sup>nd</sup> Conference

## Scientific Program

## 6th Pharmacovigilance Congress

September 28-30, 2016 Toronto, Canada



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#### **Meighen Room**

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## **Opening Ceremony**

#### **Keynote Forum**

Introduction

Title: Pharmacovigilance and compliance of drugs labeling information with the 2015 FDA lactation guidelines

Gamal Hussein, South College School of Pharmacy, USA

**Group Photo** 

Networking & Refreshments Break

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

Title: The use of laser therapy in dermatology(Benign pigmented lesions)

Ossama Roshdy, Alexandria University, Egypt

Lunch Break

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

Session Chair: Sutapa Bandyopadhyay Neogi

Session Introduction

Title: Tablet splitting of psychotropic drugs for patients with dementia: A pharmacoepidemilogic study in a Brazilian sample

Patricia Medeiros-Souz, Universidade de Brasília, Brazil

Title: Nucleoside drug safety improvement via pronucleotide approaches

Zhihong Xu, South College, USA

Title: Blockade of the NMDA receptor in developing cortex induces autophagy-mediated death of migrating cortical GABAergic interneurons: an ex in vivo and in vivo study in GAD67-GFP mice

Bruno J Gonzalez, Normandy University/Inserm NeoVasc, Rouen, France

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

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

#### **Keynote Forum**

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

Sessions: Pharmacy Practice & its Challenges

Session Introduction

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-Disubstituited -5-Mercapto -1, 2,4-Tiazoles

Melanya A. Samvelyan, Yerevan State University, Armenia

#### **Young Research Forum**

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

Title: Survey on counterfeiting of Amoxicillin and Amoxicillin + Clavulanic acid marketed in lubumbashi

Pierrot Mwamba T, University of Lubumbashi, Congo

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

Title: Over-the-counter (OTC) products withdrawn from the united states due to the inclusion of undeclared prescription ingredients in the past 15 years

Maame Twum, South College School of Pharmacy, USA

Title: Targeting population for AST: previous allergy history and Cephalosporin skin test positivity

Dong-Yoon Kang, Seoul National University Hospital, Korea

| Dong-Yoon Ka | ng, Seoul National University Hospital, Korea   |
|--------------|---|
|              | Lunch Break:  |
|              | Poster Presentation Session   |
| 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 $\Gamma$ -Lactones and biological studies of the obtained compounds Tariel V Ghochikyan, Yerevan State University, Armenia   |
| PVC03        | Title: Radical scavenging activity and phytochemical constituent of <i>Tulipa Systola Stapf</i> Mohammed Farhad Ibrahim, University of Salahaddin, Iraq  Title: Prenatal exposure to alcohol impairs the long term integration of GABA interneurons and the |
| PVC04        | 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   |
| 1 7 600      | Branka Janicijevic, Institute for Anthropological Research, Croatia  Title: Epidemiologic study based on Adverse Drug Events in patients visiting Emergency Department:   |
| PVC09        | A retrospective Observational Study in Three University Hospital  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:  |

|                  | Networking & Refreshments Break: |
|------------------|----------------------------------|
| Panel Discussion |                                  |
| Award Ceremony   |                                  |
|                  |                                  |

# Day 3 September 30, 2016 Algonquin Room A B2B Meetings @ 10:00-10:45 Networking & Refreshments Break: Academic Research Meetings @ 11:00-13:00 Lunch Break: Panel Discussion Award Ceremony Thanks Giving Ceremony

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## **Scientific Program**

2<sup>nd</sup> International Conference on

# Clinical Trials and Therapeutic Drug Monitoring

August 22-24, 2016 Philadelphia, USA



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#### **Independence A**

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## **Opening Ceremony**

#### **Keynote Forum**

#### Introduction

Title: Patient centricity - A patient's perspective

Michael Bernstein, Clinical Supplies Management Inc., USA

Title: Why conferences and continued training really matter

Jody Ehrhardt, Ehrhardt Clinical Research, USA

Title: Phase II clinical trials using formulations of compounds derived from tea plant for

restoration of salivary function and treating herpes labialis

Stephen Hsu, Augusta University, USA

#### **Sessions:**

Pre-Clinical Research | Conducts of Clinical Trials | Clinical Study Designs | Innovations in Clinical Trials | Clinical Data Management and Statistics | CRO/ Sponsorhip and Future of Clinical Trials | Clinical Trial Supply Management

Session Chair: Entsuah Anthony Richard, Merck & Co., Inc., USA Session Co-Chair: Suyu Liu, The UT MD Anderson Cancer Center, USA

**Session Introduction** 

Title: Preclinical and clinical research in wound healing and hyperbaric medicine

Thomas E Serena, Serena Group, USA

Title: A mixture model using likelihood-based and Bayesian approaches for identifying responders and non-responders in longitudinal clinical trials

Entsuah Anthony Richard, Merck & Co., Inc., USA

**Networking and Refreshments** 

Title: The Burden of Therapy©\* [BOTh©\*]. A novel method to evaluate the impact of therapeutic agents on patient safety

Ayad K Abdul-Ahad, BOTh Analytics GmbH, Germany

Title: A framework for investigating scientific and medical research misconduct and fraud

Tamera Norton Smith, Norton Audits, Inc., USA

Title: Establishing a standard practice to communicate trial results to study volunteer

Jill McNair, CISCRP, USA

Title: Regulatory and compliance considerations for Direct-To-Patient (DTP) distribution of clinical trial material

Michael Bernstein, Clinical Supplies Management Inc., USA

Title: Wound healing characteristics treated by two newly developed amino acid-based biodegradable polymers in burn and incision porcine wound models

Chih-Chang Chu, Cornell University, USA

**Lunch Break** 

Title: Bayesian Decision-Optimal Interval (BOIN) designs for Phase I clinical trials

Suyu Liu, The UT MD Anderson Cancer Center, USA

Title: The importance of subject recruitment and retention to clinical trial success

Jody Ehrhardt, Ehrhardt Clinical Research, USA

Title: Good pharma scorecard-A reform strategy to drive improvement clinical trial transparency

Jennifer Miller, NYU Langone Medical Center, USA

Title: Re-engineering the clinical development process

Anvita Karara, Carnegie Mellon University, USA

Title: Clinical research site eSource Readiness Assessment tool (eSRA)- A free tool to assist sites in determing if their systems are ready for regulated clinical research data

Suzanne Bishop, North American Facilitator for the eClinical Forum, USA

**Networking and Refreshments** 

Sessions

Title: Low temperature plasmas at atmospheric pressure towards new pharmaceutical products in medicine

N Merbahi, University of Toulouse, France

Title: High patient satisfaction rating for clinical medication counseling services when provided by clinically trained pharmacists

Joe Martinez, Center Point Clinical Services, USA

Title: Functional identification of a CRF-DA microcircuit in mice with relevance to drug abuse

Kyle Gobrogge, Tufts University, USA

**Title: Big data analytics – Clinical integration and visualization Ankit Lodha**, University of Redlands - School of Business, USA

#### **Panel Discussion**

#### Day 2

#### August 23, 2016

#### **Independence A**

#### **Keynote Forum**

Introduction

Title: Golden Era of Research

Tamera Norton Smith, Norton Audits, Inc., USA

Title: Medical heroes science museum initiative: An innovative approach to patient education

Jill McNair, CISCRP, USA

Title: The power of translational research Thomas E Serena, Serena Group, USA

**Networking and Refreshments** 

#### **Sessions:**

Clinical Research and Trials on Diabetes/ AIDS / Cancer | Clinical Trials on Different Diseases and Medical Devices | Clinical Trials (Countries/Continents) | Therapeutic Drug Monitoring and Drug Quantification | Innovations in Clinical Trials

Session Chair: Ayad K Abdul-Ahad, BOTh Analytics GmbH, Germany Session Chair: Joao Paulo Tardivo, Faculdade de Medicina do ABC, Brazil

**Session Introduction** 

Title: Virucidal capacity of novel ProtecTeaV sanitizer formulations containing lipophilic Epigallocatechin-3-Gallate (EGCG)

Stephen Hsu, Augusta University, USA

Title: Response-Adaptive Randomization urn designs in clinical trials

Annalisa Piccorelli, University of Wyoming, USA

Title: Photodynamic therapy to treat diabetic foot infection

Joao Paulo Tardivo, Faculdade de Medicina do ABC, Brazil

Title: Histoscanning<sup>™</sup> for detection of prostate cancer: Does it have any role in routine clinical practice?

Saqib Javed, Leighton Hospital NHS Foundation Trust, UK

#### Workshop

Title: Combating scientific and medical research misconduct and fraud

Tamera Norton Smith, Norton Audits, Inc., USA

**Lunch Break** 

Title: Using Artificial Intelligence to Measure and Optimize Adherence in Clinical Trials

Gordon Kessler, AiCure, USA

Title: Adverse renal effects of novel molecular oncologic targeted therapies: A review of the FDA Adverse Event Reporting System (FAERS)

Rimda Wanchoo, Hofstra Northwell School of Medicine, USA

Title: Preliminary in vivo screenning of experimentally induced gastric ulcer of Ledebouria Ovatifolia

Eugene Jamot Ndebia, Walter Sisulu University, South Africa

Title: A Modern *In-vivo* pharmacokinetic (PK) paradigm: Combining snapshot, rapid and full PK approaches to support early drug discovery

Chun Li, Genomics Institute of the Novartis Research Foundation, USA

Title: Wild leafy vegetable Mormodica foetida, improves metabolic syndrome markers and sperm parameters in diet induced obese male rats

Constance R Sewani-Rusike, Walter Sisulu University, South Africa

Title: Retrospective analysis of clinical pharmacist medication counseling to improve patient medication compliance and patient retention

Joe Martinez, Center Point Clinical Services, USA

Title: SharePoint development and implementation in a tertiary care center in Lebanon

Ulfat Usta Shanouha, American University of Beirut Medical Center, Lebanon

**Networking and Refreshments** 

Title: Reflection of knowledge and concern of ethical principles among biomedical postgraduates: A cross sectional observational study from India

Krishnan Vengada ragava Chary, Saveetha University, India

| Poster Presentations |  |  |  |  |
|----------------------|--|--|--|--|
| CLTRS001             | Title: Magnitude and characteristics of clinical trials in Saudi Arabia: A cross-sectional analysis  |  |  |  |
| CLIKSOOI             | Sheraz Ali, King Saud Medical City, KSA  |  |  |  |
| CLTRS002             | Title: Monitoring long term plasma Ochratoxin A levels of female rats: Fluctuating OTA levels and toxicodynamics                             |  |  |  |
|                      | Mehmet Akif Kilic, Akdeniz University, Turkey  |  |  |  |
| CLTRS003             | Title: Assessment of awareness about ethics committee amongst the research scholars/teachers in government medical colleges of punjab, India |  |  |  |
|                      | Ramandeep Kaur Brar, Baba Farid University of Health Sciences, India   |  |  |  |
| CLTRS004             | Title: Emerging role of bioinformatics tools and softwares in evolution of clinical research   |  |  |  |
| CLIK3004             | Supreet Kaur Gill, Baba Farid University of Health Sciences, India   |  |  |  |

#### **Panel Discussions**

Day 3 August 24, 2016

#### **Independence A**

#### **Sessions:**

Bioethics and Quality Regulation | Pharmacokinetics and Pharmacodynamics | Toxicogenomics Challenges and Applications | Pharmacovigilance and Drug Safety

Session Chair: Nicola Stagg, Genentech, USA

**Session Introduction** 

Title: Gender differences in blood pressure and electrocardiography parameters in response to antihypertensive treatment supplemented with dietary flavonoids

Marina M J Romero-Prado, University of Guadalajara, Mexico

Title: Important considerations for successful Direct-to-Patient study implementation

Joe Martinez, Center Point Clinical Services, USA

Title: Protective effect of Hypericum triquetrifolium Turra on Cyclophosphamide induced cardiotoxicity in rat

**Songul Cetik,** Mardin Artuklu University, Turkey

Title: Peripheral neuropathy with microtubule inhibitor containing antibody drug conjugates: Challenges and perspectives in translatability from nonclinical toxicology studies to the clinic

Nicola Stagg, Genentech, USA

**Networking and Refreshments** 

Title: Proposal of supervised data analysis strategy of plasma miRNAs from hybridisation array data with an application to assess hemolysis-related deregulation

**Elena Landoni**, University of Milan, Italy

Title: Clinical research during the Ebola virus disease outbreak in guinea: Lessons learned and ways forward

Abdoul Habib Beavogui, Rural Health of Maferinyah, Guinea

Title: Use of investigative sites in Central & Eastern Europe (CEE) for successful clinical studies

Jeffrey Blum, EastHORN Clinical Services, USA

Title: Determination of glyceryl trinitrate and its two main metabolites in human plasma using a new sensitive gas chromatography method

Mohammadreza Sattari, Tabriz University of Medical Sciences, Iran

**Awards & Closing Ceremony** 

**Lunch Break** 

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