Tentative Program

3rd International Conference on

Advanced Clinical Research and Clinical Trials

September 20-21, 2017   Dublin, Ireland

Theme: “Exploring Innovations in Clinical Research and Clinical Trials”

**For Available Speaker Slots**
clinicalresearch@pharmaceuticalconferences.org
Featured Speakers

Introduction

**Title:** Need for patient registries for rare disease clinical trials and how to integrate them into the electronic medical record  
*David A Pearce,* Sanford Research, USA

**Title:** Evolving visual analytics for better clinical decisions  
*Dave Anderson,* Syte Logix, Inc., USA

**Title:** Sepsis: Reducing occurrence, and optimizing clinical, pharmaceutical, staff expertise and cost-per-case outcomes  
*Steven H Shaha,* Institute for Integrated Outcomes, USA

**Title:** Challenges in clinical nutritional research: How adaptive design can help?  
*Tanguy Jerome,* Nestle Research Center, Switzerland

**Title:** Evaluation of Swedish integrated Electronic Health Records and register health care data to serve as a reference population in severe asthma clinical trials: The PACEHR study  
*Stefan Franzen,* Register Centre Västra Götaland, Sweden

**Title:** The possibility of the use of single Institutional Review Board (IRB) for multi-site research in China  
*Shuo Chen,* Institute of hematology and Blood Diseases Hospital, China

**Title:** DDI alert think time: Increased alert efficacy and decreased alert fatigue  
*Steven H Shaha,* Institute for Integrated Outcomes, USA

**Title:** Conducting a clinical trial in Mauritius: Legal, regulatory and ethical frameworks  
*Mona Dawood,* Centre International de Développement Pharmaceutique, Mauritius

**Title:** National dermatology radiation oncology registry: A human research registry to collect information from patients referred to radiation oncologists for the management of non melanoma and melanoma skin cancer and difficult to manage inflammatory skin diseases through radiotherapy  
*Lynda Spelman,* Veracity Clinical Research, Australia

**Title:** Methods to enrich clinical trial evidence by real world evidence conceptually explained  
*Mario Ouwens,* Astrazeneca, Sweden

**Title:** Pseudogenes contribute to salmonella typhi pathogenesis in humans  
*Guido C Mora,* School of Medicine, Chile

**Title:** Clinical Research in Mauritius: myths and reality  
*Mona Dawood,* Centre International de Développement Pharmaceutique, Mauritius

**Title:** Detailing key considerations and challenges of EDC in terms of implementation and statistical aspects  
*Liora Bosch,* Omrix a J&J company

**Title:** Possible association of MBL2 gene polymorphism in the occurrence of clinical black water fever in Congolese children  
*Joseph M Bodi,* University of Kinshasa

**Title:** Assessment of validity and reliability of gujarati translation of Penn State Worry Questionnaire (PSWQ) in patients with Generalized Anxiety Disorder (GAD) in comparative clinical trial of *Buspirone & Sertraline* Tablets  
*Hardik R Patel,* Nej Biotech

**Title:** Factors affecting patient participation in clinical trials in Ireland: A narrative review  
*Elaine Walsh,* University College Dublin, Ireland

**Title:** Drug safety study at tertiary care hospital  
*Shiv Kumar Shette*

**Title:** Design of clinical trials of effect on whether preserve Left Colonic Artery (LCA) on the prognosis of patients with laparoscopic resection of Inferior Mesenteric Artery (IMA) in rectal cancer  
*Wenqing Feng,* hanghai Jiaotong University School of Medicine, China
Title: Community-wide interoperability and connectivity for improved outcomes  
Steven H Shaha, Institute for Integrated Outcomes, USA

Title: Rethinking a confirmatory study as adaptive using predictive probability approach and quantile regression models. Its application in clinical trials with CIMAvax-EGF in non small cell lung cancer  
Carmen Valenzuela, Cuban Center of Molecular Immunology, Cuba

Title: Clinical data management: An overview  
Abhijeet Ashu, Bioclinica

Title: Effects of hesperidin supplementation on weight, glycemic control, lipid profile and inflammatory factors in patients with type 2 diabetes: A randomized, double-blind and clinical trial placebo-controlled  
Shahryar Eghtesadi, Azad University

Title: Opportunities, challenges and solutions for pulmonary antibiotic delivery  
Anne Haaije de Boer, Groningen University, The Netherlands

Title: Baseline characteristics of patients with heart failure and preserved ejection fraction at admission with acute heart failure in Saudi Arabia  
Samah Abohammar, King Saud Medical City

Title: Isolation of enterococci, their antimicrobial susceptibility patterns and associated factors among patients attending at the University of Gondar Teaching Hospital  
Amelework Yilema, Ethiopia Public Health Institute

Title: Use of animals in biomedical research  
Narendra Babu Ankem, Chalapathi Institute of Pharmaceutical Sciences, India

Title: Understanding of study endpoints for successful completion of clinical trials  
Madhura Joshi, Lupin Bioresearch Center

Title: Effectiveness of chinese acupuncture on pain relief following surgical removal of impacted third molars: A self-controlled clinical trial  
Joul Kassis, Damascus University, Australia

Title: HCT (Holistic Clinical Trials) and ICT (Integrative Clinical Trials)  
Reza Sanaye

Title: Conducting a clinical trial in Mauritius: Legal, regulatory and ethical frameworks  
Mona Dawood, Centre International de Développement Pharmaceutique, Mauritius

Title: Video-feedback intervention to promote positive parenting adapted to Autism: a randomized controlled trial  
Irina E Poslawsky, University Medical Center Utrecht, The Netherlands

Title: Do more with less: The visualized insight culture  
Debu Moni Baruah, Bioclinica

Title: The effects of sugar cane policosanol on the LDL, HDL, Triglyceride and Total Cholesterol levels of dyslipidemic Patients: A meta-analysis  
Diana-Lynn S Que, Philippines

Title: Effects of low level laser (Diode- 830nm) therapy on human bone regeneration  
Mohammad Nazrul Islam, Shaheed Suhrawardy Medical College Hospital

Title: Development of a generic drug with different pharmaceutical features: A study of the therapeutic equivalence of mometasone nasal spray in patients with seasonal allergic rhinitis (Japanese ceder pollinosis)  
Minoru Gotoh, Nippon Medical School, Japan

For more Speaker Slots & Kindly contact clinicalresearch@pharmaceuticalconferences.org
# Program at a Glance

## Day 1

<table>
<thead>
<tr>
<th>Reception/Registration</th>
<th>08.00-09.00</th>
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<tbody>
<tr>
<td>Time</td>
<td>General Session</td>
</tr>
<tr>
<td>09.00-09.15</td>
<td>Inaugural Address</td>
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<tr>
<td>Least of 3 Keynote/Plenary Talks</td>
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<tr>
<td>09.15-09.45</td>
<td>Keynote/Plenary Talk 1</td>
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<tr>
<td>09.45-10.15</td>
<td>Keynote/Plenary Talk 2</td>
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<tr>
<td>10.15-10.45</td>
<td>Keynote/Plenary Talk 3</td>
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<tr>
<td>Panel Discussions/Group Photo</td>
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<tr>
<td>Coffee/Tea Break 10.45-11.00 (Networking)</td>
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<tr>
<td>11.00-12.40</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>Lunch Break 12.40-13.30</td>
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<tr>
<td>13.30-15.30</td>
<td>6 Speakers (20 Mins Each)</td>
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<tr>
<td>Coffee/Tea Break 15.30-15.45 (Networking)</td>
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<tr>
<td>15.45-17.45</td>
<td>6 Speakers (20 Mins Each)</td>
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## Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Session 1</th>
<th>Session 2</th>
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<tbody>
<tr>
<td>09.00-10.40</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>Coffee/Tea Break 10.40-10.55 (Networking)</td>
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<tr>
<td>10.55-12.35</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>Lunch Break 12.35-13.25</td>
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<tr>
<td>13.25-15.05</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>Poster Sessions</td>
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<tr>
<td>Coffee/Tea Break 15.05-15.20 (Networking)</td>
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<tr>
<td>15.20-17.00</td>
<td>5 Speakers (20 Mins Each)</td>
<td>5 Speakers (20 Mins Each)</td>
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<tr>
<td>Closing Ceremony</td>
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**NOTE:** Program Schedule is subject to change with final allotment of the speaker slots

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For More Details, Visit: [http://clinicalresearch@pharmaceuticalconferences.org](http://clinicalresearch@pharmaceuticalconferences.org)

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http://http://clinicalresearch@pharmaceuticalconferences.org
Conference Highlights

• Innovations in Pre-clinical Research
• Design of Clinical Studies and Trials
• Conducts of Clinical Trials
• Clinical Research and Trials on AIDS
• Clinical Trials on Different Diseases
• Clinical Trials in Developing Countries
• Future of Clinical Trials
• Bioethics and Quality Regulation
• Innovations in Clinical Trials
• Clinical Data Management and Statistics
• Pharmacovigilance and Drug Safety
• Transforming Trial Methodologies
• Clinical and Medical Case Reports
• Biomedical Devices Clinical Research
• GCP Learning and Best Practices
• Risk Management at Research Site
• Current Regulatory Trends in Drug Development
• Oncology Clinical Research
• Clinical Research in Gastroenterology
• Diabetes Clinical Research
Glimpses of Clinical Trials Conferences
TOURIST DESTINATIONS IN DUBLIN

Christ Church Cathedral

Dublin Castle

Dublin Zoo

Leinster House

National Botanic Gardens

National Museum Ireland

St Stephens Green

Tinity College and College Green
Conference Venue
Dublin, Ireland
Proceedings of

2nd International Conference on

Clinical Trials

August 22-24, 2016
Philadelphia, USA
Day 1                  August 22, 2016

Independence A

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/ Sponsorship 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, SerenaGroup, 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 @ Foyer
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, CISCPR, 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 @ Benjamin’s
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
**Workshop**

<table>
<thead>
<tr>
<th>Title: Clinical research site eSource Readiness Assessment tool (eSRA)- A free tool to assist sites in determining if their systems are ready for regulated clinical research data</th>
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</thead>
<tbody>
<tr>
<td>Suzanne Bishop, North American Facilitator for the eClinical Forum, USA</td>
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**Networking and Refreshments @ Foyer**

<table>
<thead>
<tr>
<th>Sessions</th>
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</thead>
</table>

**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**

<table>
<thead>
<tr>
<th>Introduction</th>
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</table>

**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, SerenaGroup, USA |

**Networking and Refreshments @ Foyer**

<table>
<thead>
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**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™ for detection of prostate cancer: Does it have any role in routine clinical practice?**

| Saqib Javed, Leighton Hospital NHS Foundation Trust, UK |

**Workshop**

<table>
<thead>
<tr>
<th>Title: Combating scientific and medical research misconduct and fraud</th>
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| Tamera Norton Smith, Norton Audits, Inc., USA |

**Lunch Break @ Benjamin's**
<table>
<thead>
<tr>
<th>Title</th>
<th>Author/Institution</th>
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<tbody>
<tr>
<td>Using Artificial Intelligence to Measure and Optimize Adherence in Clinical Trials</td>
<td>Gordon Kessler, AiCure, USA</td>
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<tr>
<td>Adverse renal effects of novel molecular oncologic targeted therapies: A review of the FDA Adverse Event Reporting System (FAERS)</td>
<td>Rimda Wanchoo, Hofstra Northwell School of Medicine, USA</td>
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<td>Preliminary in vivo screening of experimentally induced gastric ulcer of Ledebouria Ovatifolia</td>
<td>Eugene Jamot Ndebia, Walter Sisulu University, South Africa</td>
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<tr>
<td>A Modern In-vivo pharmacokinetic (PK) paradigm: Combining snapshot, rapid and full PK approaches to support early drug discovery</td>
<td>Chun Li, Genomics Institute of the Novartis Research Foundation, USA</td>
</tr>
<tr>
<td>Wild leafy vegetable Mormodica foetida, improves metabolic syndrome markers and sperm parameters in diet induced obese male rats</td>
<td>Constance R Sewani-Rusike, Walter Sisulu University, South Africa</td>
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<tr>
<td>Retrospective analysis of clinical pharmacist medication counseling to improve patient medication compliance and patient retention</td>
<td>Joe Martinez, Center Point Clinical Services, USA</td>
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<td>SharePoint development and implementation in a tertiary care center in Lebanon</td>
<td>Ulfat Usta Shanouha, American University of Beirut Medical Center, Lebanon</td>
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<tr>
<td>Reflection of knowledge and concern of ethical principles among biomedical postgraduates: A cross sectional observational study from India</td>
<td>Krishnan Vengada ragava Chary, Saveetha University, India</td>
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<tr>
<td>Magnitude and characteristics of clinical trials in Saudi Arabia: A cross-sectional analysis</td>
<td>Sheraz Ali, King Saud Medical City, KSA</td>
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<tr>
<td>Monitoring long term plasma Ochratoxin A levels of female rats: Fluctuating OTA levels and toxicodynamics</td>
<td>Mehmet Akif Kilic, Akdeniz University, Turkey</td>
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<tr>
<td>Assessment of awareness about ethics committee amongst the research scholars/teachers in government medical colleges of punjab, India</td>
<td>Ramandeep Kaur Brar, Baba Farid University of Health Sciences, India</td>
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<tr>
<td>Emerging role of bioinformatics tools and softwares in evolution of clinical research</td>
<td>Supreet Kaur Gill, Baba Farid University of Health Sciences, India</td>
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<tr>
<td>Gender differences in blood pressure and electrocardiography parameters in response to antihypertensive treatment supplemented with dietary flavonoids</td>
<td>Marina M J Romero-Prado, University of Guadalajara, Mexico</td>
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<tr>
<td>Important considerations for successful Direct-to-Patient study implementation</td>
<td>Joe Martinez, Center Point Clinical Services, USA</td>
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<tr>
<td>Protective effect of Hypericum triquetrifolium Turra on Cyclophosphamide induced cardiotoxicity in rat</td>
<td>Songul Cetik, Mardin Artuklu University, Turkey</td>
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<tr>
<td>Peripheral neuropathy with microtubule inhibitor containing antibody drug conjugates: Challenges and perspectives in translatability from nonclinical toxicology studies to the clinic</td>
<td>Nicola Stagg, Genentech, USA</td>
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Networking and Refreshments @ Foyer

Poster Presentations @ Foyer

| CLTRS001 | Title: Magnitude and characteristics of clinical trials in Saudi Arabia: A cross-sectional analysis | 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 | 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 @ Foyer

**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

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**Awards & Closing Ceremony**

**Lunch Break @ Benjamin's**
**Scientific Program**

**International Conference on**

**Clinical Trials**

**July 27-29, 2015  Orlando-FL, USA**

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<th>July 27, 2015</th>
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**Opening Ceremony**

**Keynote Forum**

**Introduction**

Lee Truax-Bellows  
Norwich Clinical Research Associates Ltd. (NCRA), USA

Edward Greg Koski  
Alliance for Clinical Research Excellence and Safety, USA

**Session Introduction**

**Track 1: Pre-Clinical Research and Conducts of Clinical Trials**

**Track 3: Innovation in Clinical Trials**

**Track 9: Future of Clinical Trials**

**Session Chair:** James J Hickman, University of Central Florida, USA

**Session Co-chair:** Galya Atanasova, University Hospital, Bulgaria

**Title:** Human-on-a-chip systems to direct or possible augment clinical trials  
**James J Hickman,** University of Central Florida, USA

**Title:** Improved estimation of area under the ROC curve using ranked set sampling  
**Jingjing Yin,** Georgia Southern University School of Medicine, USA

**Coffee Break**

**Title:** Inference and sample size determination for clinical trial with rare events and potential misclassification  
**James Stamey,** Baylor University, USA

**Title:** Dental pulp stem cells mobilized with granulocyte colony-stimulating factor for total pulp regeneration: Phase 1 clinical trial  
**Misako Nakashima,** National Center for Geriatrics and Gerontology, Japan

**Title:** Trisenox disrupts MDM2-DAXX-HAUSP complex and degradation of MDM2 in acute promyelocytic leukemia cells  
**Sanjay Kumar,** Jackson State University, USA

**Title:** Fraud and misconduct of clinical trials  
**Rucha Majmundar Mehta,** GCP Freelance Monitor and Mentor, India
Title: Assessment tools for myocardial infarction risk  
Galya Atanasova, University Hospital, Bulgaria

Title: Data management in pharmacovigilance  
Ajay Francis Christopher, Baba Farid University of Health Sciences, India

Session Chair: Loon-Tzian Lo, Union Health Associates, USA

Title: Improving participation among older African Americans in clinical research: Interim results from a randomized controlled faith-based intervention to increase clinical trial screening and enrollment rates  
Paula M Frew, Emory University School of Medicine, USA

Title: Leveraging technology to optimize clinical study design process  
Anvita Karara, Carnegie Mellon University, USA

Title: Framework model of Transcranial electrical stimulation (TES) research trials to clinical protocol recommendation  
Iman Ghodrati Toostani, University of Sao Paulo, Brazil

Title: Behavioural intervention to increase physical activity in adults with coronary heart disease in Jordan  
Eman Alsaleh, University of Nottingham, UK

Upstream therapeutic strategies of Valsartan and Fluvastatin on hypertensive patients with non-permanent Atrial Fibrillation (VF-HT-AF): Study protocol for a randomized controlled trial  
Wenwei Qi, Tianjin Medical University, China

Workshop

Title: Workshop on MedDRA and WHO DD terminology  
Samina Qureshi, PSI International Inc., USA

Panel Discussions

Day 2  July 28, 2015

Title: The future of clinical trial conduct demands a quality system approach: Are you ready?  
Lee Truax-Bellows, Norwich Clinical Research Associates Ltd. (NCRA), USA

Track 4: Transforming Trials Methodologies: Clinical Studies  
Track 5: Molecularly Targeted Trials: Comparative Approach  
Track 6: Challenges and Advancement in Breast Cancer Trials: Case Study  
Track 8: Business development in Clinical Trials

Session Chair: Helen Snooks, Swansea University Medical School, UK
Session Co-Chair: Rania Abdelmonem Mostafa Khattab, Cairo University, Egypt

Title: Improving quality, efficiency and financial performance: A holistic approach in clinical trial and research administration  
D C Saha, Resource Development Corporation, USA

Title: Using electronic routine linked health records in HTA of interventions in emergency care  
Helen Snooks, Swansea University Medical School, UK

Title: A study of the prevalence and association of ocular chlamydial conjunctivitis in women with genital infection by Chlamydia trachomatis, Mycoplasma genitalium and Candida albicans attending outpatient clinic in Egypt  
Rania Abdelmonem Mostafa Khattab, Cairo University, Egypt

Title: The effectiveness of a home-based interactive e-health educational intervention for middle-aged coronary heart disease (CHD) adults in improving total exercise, adherence rate, exercise efficacy and outcomes: A study protocol for a randomized controlled trial  
Eliza M L Wong, Chinese University of Hong Kong, China

Title: Effect of intravenous glutamine supplementation in trauma patients receiving enteral nutrition: A prospective, blinded, randomized, placebo-controlled clinical trial  
Ruqaiya M Al Balushi, United Arab Emirates University, UAE

Title: Assessment of MIC by E test of ocular antibiotics used for treatment of patients with keratitis and postoperative ocular infections  
Maha Haggag, Research Institute of Ophthalmology, Egypt
Title: Evaluation of patients with dry eye disease for the presence of conjunctival Chlamydia trachomatis and ureaplasma urealyticum infection
Maha Mohssen Abdelfattah, Research Institute of Ophthalmology, Egypt

Poster Presentations

Special Session by Fang Gao Smith, University of Birmingham, UK

Session Chair: Fang Gao Smith, University of Birmingham, UK
Session Co-Chair: Joyce Yeung, University of Birmingham, UK
Title: How to handle a multi-center randomized control trial with premature termination
Fang Gao Smith, University of Birmingham, UK
Title: Study of postoperative delirium in elderly patients undergoing hip fracture surgery
Ting Li, Wenzhou Medical University, China
Title: Patient recruitment and consent in difficult populations
Joyce Yeung, University of Birmingham, UK
Title: Functional near infrared spectroscopy (fNIRS) to identify pain in children
Yifei Jiang, Cincinnati Children's Hospital Medical Center, USA
Title: Bridging the research gap: An overview of training placements for collaboration fellows
Teresa Melody, Heart of England NHS Foundation Trust, UK
Title: Power of clinician trainees in clinical research
Joyce Yeung, University of Birmingham, UK

Workshop

Title: Country, culture and gender dynamics in research and clinical trial agreement and contract negotiations
D C Saha, Resource Development Corporation, USA

Panel Discussions

Day 3

July 29, 2015

Hall - 3

Workshop

Title: Handling and processing safety reports from clinical trials and spontaneous origin
Ajay F Christopher, Baba Farid University of Health Sciences, India

Track 2: Risk Management and Data Outsourcing: Organizational Aspect
Track 7: Adaptive and Randomized Trials: CRO and Sponsors Partnership
Track 10: Bioethics and Quality Regulation

Coffee Break

Session Chair: Samina Qureshi, Drug Safety Surveillance, PSI International, Inc., USA
Session Co-Chair: Ruqaiya M Al Balushi, United Arab Emirates University, UAE
Title: Developing a model to enhance patient involvement in designing and conducting research: Views of patients, academics and organisational staff
Helen Snooks, Swansea University Medical School, UK
Title: Psychological interventions with cardiac patients
Petra Bagdi, National Center for Spinal Disorders, Hungary
Title: Comparing the efficacy, tolerability and easy administration of dihydroarthemisinin, piperaquine, artemate, sulfamethoxypyrazine and pyrimethamine against sulphadoxine-pyrimethamine for preventing malaria in children: A randomized phase III trial in Ghana
Margaret Kweku, University of Health and Allied Sciences, Ghana
Title: Nutrient composition of soya bean meal and soy protein isolate and their effects on the growth performance and haematological parameters of albino rats
Oluwatoyin Aletor, The Federal University of Technology, Nigeria
Overview of the clinical trials control in Egypt
Azza Saleh Radwan, Ministry of Health, Egypt

Video Session

Title: Role of clinical trial treatment in determination of the chronic illnesses that went on to be of unknown etiologies and used to be treated symptomatically
Abbas Alnaji, Al-Sadir Medical City, Iraq

Lunch Break
| P-01 | Title: Health promoting activities of β-cryptoxanthin  
      Hoyoku Nishino, Kyoto Prefectural University of Medicine, Japan |
| P-02 | Title: Introducing the PRIDAL model for linking routine health and identifiable patient reported data in HTA  
      Helen Snooks, Swansea University Medical School, UK |
| P-03 | Title: A project of evaluation the effects of a rheumatoid arthritis self-management program: A randomized controlled trial  
      Su-Hui Chen, Chang Gung University of Science and Technology, Taiwan |
| P-04 | Title: Importance of clinical research training to nurses for wider roles in clinical research- A study  
      Ramandeep Kaur Romana, Baba Farid University of Health Sciences, India |
| P-05 | Title: Shockingly high rates of Smokers in Saudi youths and their parents: High incidences of dental caries fluorosis and oral cancers among smokers- An eye opening community health survey  
      Ibrahim Khalil AL Ibrahim, University of Hail, Saudi Arabia |
| P-06 | Title: Development of a heart failure self-management program: Design of a randomized controlled trial  
      Jung-Hua Shao, Chang Gung University, Taiwan |
| P-07 | Title: Implementation of a predictive risk tool in primary care: a qualitative study of understanding and engagement among practitioners  
      Helen Snooks, Swansea University Medical School, UK |
| P-08 | Title: Understanding patients perspective on clinical research in Indian population  
      Kaushal Kapadia, Texila American University, USA |
| P-09 | Title: Unique eCRF – A wave of the clinical trial future  
      Supreet Kaur Gill, Baba Farid University of Health Sciences, India |
| P-10 | Title: Comparison the cytotoxic effects of anticancer drug liposomal lyophilized formulation LLF OR-2011 and OR-2011 substance from nitrosourea class  
      Basel Albassett, Peoples Friendship University, Russia |
| P-11 | Title: Scope and barriers in clinical trials of herbal drugs  
      Ramandeep Kaur, Baba Farid University of Health Sciences, India |
| P-12 | Title: Regulatory transparency: Technical, legal and ethical aspects of access to clinical trials report – Brazilian approach  
      Varley Dias Sousa, University of Brasilia, Brazil |
| P-13 | Title: Comparative immunohistochemical analysis of Beclin-1 & MDM-2 in benign & malignant Ameloblastomas  
      M A El-Barrawy, Alexandria University, Egypt |
Proposals are invited for organizing Symposia/Workshops at Conference Series LLC Conferences or Conference Series LLC will sponsor small events at your universities in related areas under the title of your own. These proposals can be sent to respective conference mail ids.
Day 1  October 27, 2014

Registrations

Hall 4

Opening Ceremony

Keynote Forum

**Introduction**
K C Singhal  
NIMS University, India

John Barber  
Dr. Reddy's Laboratories, UK

K C Singhal  
NIMS University, India  

Coffee Break @ Hall 4

Prakash V Diwan  
Anurag Group of Institutions, India

J Vijay Venkatraman  
Oviya MedSafe Pvt. Ltd., India

Track 1: Pharmacovigilance and its Challenges
Track 2: Role of Clinical Trials
Track 3: Clinical Trials on Diseases

Session Chair: Barna Ganguly, Pramukhswami Medical College, India
Session Co-Chair: Anju Gopan, ICON Clinical Research, India

Multi center trials and monitoring
Anju Gopan, ICON Clinical Research, India
Challenges of pharmacovigilance programme in our set up
Barna Ganguly, Pramukhswami Medical College, India
Detection and evaluation of drug safety signals in post marketing phase
Neha Vala, Lambda Therapeutics Research Ltd., India

Lunch Break @ Hall 4

Workshop on Pharmacovigilance of drugs of Indian system of medicine
K C Singhal, NIMS University, India

Coffee Break @ Hall 4

Data analytics in pharmacovigilance
Amit Srivastava, Infocorp Software Solutions, India
Pharmacovigilance in India and emerging markets: An industry perspective
Shashidhar Swamy, Wockhardt Limited, India
Role of pharmacovigilance in drug development
Prabhakar Reddy Veerareddy, Palamuru University, India
Role of pharmacovigilance in health regulation
Ayesha Rubina, Rajiv Gandhi University of Health Sciences, India

Coffee Break @ Hall 4

Artificial neural network: A data mining tool in pharmacovigilance
Prithviraj Chakraborty, Bengal College of Pharmaceutical Sciences and Research, India
Pharmacovigilance and it's challenges
Anant Khot, Amrita Institute of Medical Science, India
Clinical application of a computerized system for physician order entry with clinical decision support to prevent adverse drug events in long-term care
Gayatri Devi C, Nizam's Institute of Medical Sciences, India
Retrospective analysis on adverse drug reactions induced by antibiotics in a tertiary care centre
A Renuka Saravana Selvan, Sri Ramachandra Medical College & Research Institute, India
Pharmacovigilance - A wake up for healthcare professionals and the public
Sagar D Kadam
Hon. Shri Babanrao Pachpute Vichardhara Trusts (HSBPVT's) Group of Institutions College of Pharmacy, India
<table>
<thead>
<tr>
<th>Title</th>
<th>Author/Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghrelin as a biomarker for nutritional and inflammatory status in patients on maintenance hemodialysis</td>
<td>Vanitha Rani N, Sri Ramachandra University, India</td>
</tr>
<tr>
<td>An overview of the recent advances in the treatment of Parkinson's disease</td>
<td>Shwetha E S, Rajiv Gandhi University of Health Sciences, India</td>
</tr>
<tr>
<td>Recent advances in breast cancer therapy</td>
<td>Bhanu Priya B, Mysore Medical College and Research Institute, India</td>
</tr>
<tr>
<td>A retrospective study of Eclampsia in a tertiary care center</td>
<td>Mary Rohini Pentareddy, Mediciti Institute of Medical Sciences, India</td>
</tr>
</tbody>
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### Day 2 | October 28, 2014 | Hall 4

**Track 4: Adverse Drug Reactions**
- Using pharmacodynamics and pharmacokinetics during clinical practice to avoid drug overdose
  Jamal Tashkandi Fanzca, Umm Al-Qura University, KSA
- European risk management plans- Current experience of the generics sector
  John Barber, Dr. Reddy’s Laboratories, UK
- Recent trends in clinical trial including pharmacogenomics approaches for drug development and rational therapy
  R Manavalan, Annamalai University, India
- Role of pharma industries in the improvement of pharmacovigilance system
  Pranjali Bordoloi, Lambda Therapeutics Research Ltd., India
- Why do we need Pharmacovigilance in India?
  Ratinder Jhaj, All India Institute of Medical Sciences, India

**Coffee Break @ Hall 4**

**Session Introduction**

- Knowledge, attitude and perceptions/practices of patients in India towards Adverse Drug Reaction (ADR) reporting
  Mala Kharkar, Patkar and Varde College, India
- Current developments in pharmacovigilance from the regulator's perspective: A risk management, master file and dictionary evolution (REMS, PSMF and xEVMPD/IDMP)
  Mohammad Wasif Khan, YES Regulatory Healthcare Services India Pvt. Ltd., India
- Current evidence on the effect of DPP-4 inhibitor drugs on mortality in type 2 diabetic (T2D) patients: A meta-analysis
  Raja Chakraverty, Bengal College of Pharmaceutical Sciences and Research, India
- Early identification and prevention of drug-to-drug interactions in a tertiary care hospital
  Radhika Soanker, Nizam’s Institute of Medical Sciences, India
- End of the blockbuster model - What next?
  Sreethar D, Manipal University, India
- Study on variations of theophylline plasma concentrations with respect to time of administration
  Mahvash Iram, Ameen College of Pharmacy, India

**Lunch Break @ Hall 4**

**Session Chair: Sreethar D, Manipal College of Pharmaceutical Sciences, India**
**Session Co-Chair: Jamal Tashkandi Fanzca, Umm Al-Qura University, KSA**

**Study of self-reported Adverse Drug Reactions and factors influencing it among HIV/AIDS patients on antiretroviral therapy**
- Sandeep B, Raichur Institute of Medical Sciences, India
- PV requirements in non ICH regions
  Shoba Rajagopal, Norwich Clinical Services, India
- Pattern of Adverse Drug Reactions (ADRs) among patients admitted in a tertiary care teaching hospital
  Balaji Vasu, S.S. Institute of Medical Sciences & Research Centre, India
- A study on analysis of fixed drug combinations widely prescribed in India
  S Bettina Lavanya Magdaline, Sri Ramachandra University, India
- A case of corticosteroid induced cushing’s syndrome reported to a tertiary care teaching hospital
  Sirisha Goli, Nizam’s Institute of Medical Sciences, India
- Role of risk management in pharmacovigilance
  Manjunath H, JJM Medical College, India
- Evaluation of the role of nephrotoxic drugs in contrast induced nephropathy
  Sirisha Annavarapu, Kamineni Institute of Medical Sciences, India
- Impact of educational intervention on pharmacovigilance and adverse drug reaction reporting among the prescribers and nurses in a tertiary care teaching hospital of northern India
  Sukhpreet Singh, Era’s Lucknow Medical College & Hospital, India

**Coffee Break @ Hall 4**
Cutaneous drug reactions reported in a dermatology outpatient clinic of a tertiary care hospital
Swathi Ratnam, Rangaraya Medical College, India
Study of efficacy, Adverse Drug Reaction and compliance of anti-retroviral drugs in a tertiary care hospital
Chitra Karuppiah, Andhra Medical College, India
Herbal medicine use and the emerging concern for ADR monitoring
Prashanth D, JJM Medical College, India
National pharmacovigilance programme
Geetha Shashidhar, S S Institute of Medical Sciences, India

Hall 4
Poster Presentations 1 @ Hall 4
Poster Presentations 2 @ Hall 4

Day 3 October 29, 2014
Hall 4

Track 8: Clinical Research and Statistics
Track 9: Strategies for Growth in Pharma Environment
Track 10: Good Pharmacovigilance Practice and Pharmacoepidemiology
Track 11: Case Report in Clinical Trials
Session Chair: Shakila Srikumar, Quest International University Perak, Malaysia
Session Co-Chair: Gunjan Jain, Oracle Health Sciences, India

Session Introduction
Translation of pharmacogenomics into clinical practice of personalized psycho-therapeutics
Shakila Srikumar, Quest International University Perak, Malaysia
In vitro and In vivo leaf extracts of Gymnema sylvestre involve the protective effects and development of metabolic syndrome in high-fat diet-fed rats
Bakrudeen Ali Ahmed, University of Malaya, Malaysia
Clinical research - Present status & future challenges: Applying new technologies for cost effectiveness, high data quality and patient safety
Gunjan Jain, Oracle Health Sciences, India
Frequency of ABO blood group and Rh-D factor among the donor population of Warangal
Morem Nagaraju, Vaagdevi College of Pharmacy, India

Coffee Break @ Hall 4

Evaluating the rationality of claims made in drug promotional literature in west Chennai
Pavithira Sekar, Sri Ramachandra University, India
Title: The Role of pharmacovigilance in biosimilars
Imran Maniary, JJM Medical College, India
A case report on suspected calcium channel blocker induced hypothyroidism
Pruthvi D, Osmania Medical College, India
Review of the softwares used in pharmacovigilance and clinical trials
Apoorva B M, S.S Institute of Medical Science and Research Centre, India
Prescribing patterns of antimicrobials in diabetic foot ulcer in a tertiary care hospital
Ramadi Prameela, Andhra Medical College, India
A prospective observational study of drug induced contact dermatitis in patients attending tertiary care hospital
Priyank Shah, SKN Medical College and General Hospital, India
Honey plus coffee versus systemic steroid in the treatment of persistent post-infectious cough: A randomised controlled trial
Homa Gharaie, Ministry of Health and Medical Education, Iran

Lunch Break @ Hall 4

Young Researchers Forum
Panel Judges: Homa Gharaie, Ministry of Health and Medical Education, Iran
Panel Judges: Shakila Srikumar, Quest International University Perak, Malaysia
Rosuvastatin improves endothelial dysfunction in ankylosing spondylitis
Nidhi Garg, Punjabi University, India
Neuroprotective effect of Withania Somnifera root extract incorporated organic tea in Parkinsonism
Ananya Bagchi, IIT Kharagpur, India
Assessment of endogenous biochemical composites emphasizing drug interaction of cardiovascular combined dosage formulation in marketed product
Rakesh Das, Jadavpur University, India
Endothelial function and endothelial progenitor cells in ankylosing spondylitis
Inderjeet Verma, Punjabi University, India
A randomized, open label, controlled, single centre study to evaluate the efficacy and safety of Lagenaria siceraria fruit juice in patients diagnosed with cardiovascular disorders
Sameer D Kulkarni, Birla Institute of Technology & Sciences, India
Management of anemia among hemodialysis patients in a tertiary care hospital: A cost of illness study
Uday Venkat Mateti, Manipal College of Pharmaceutical Sciences, India

Anti-inflammatory activity of modified compound mediated through enzyme-inhibition
Mohini Phanse, Modern College of Pharmacy, India

Adverse drug reactions of herbal medicines used for the treatment of life style disorders - An overview
Bhavana Bhat, Manipal College of Pharmaceutical Sciences, India

Effect of Gymnema sylvestre on pharmacokinetics and pharmacodynamics of Pioglitazone in diabetic rats
Shravan Kumar, JNTUK, India

Development and validation of new rp-HPLC method for ceftibuten in bulk and its pharmaceutical dosage form
Varaprasad Adepu, JNTUK, India
Scientific Program
2nd International Conference and Exhibition on Pharmacovigilance & Clinical Trials
November 18-19, 2013   Hilton San Antonio Airport, TX, USA

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**Keynote Forum**

**Introduction**

**Walter Schwerdtfeger**
Federal Institute for Drugs and Medical Devices, Germany

**Keith A. Wesnes**
Northumbria University, UK

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**Track 1: Pharmacovigilance and its Challenges**

**Track 2: Role of Clinical Trials**

**Track 3: Clinical Trials on Diseases**

**Track 4: Adverse Drug Reactions**

**Session Chair:** Xiaodong Feng, California Northstate University, USA

**Session Co-Chair:** Rama Krishna Raparla, Vaageswari Institute of Pharmaceutical Sciences, India

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### Session Introduction

**Title:** Portuguese pharmacovigilance system

*Maria Teresa Herdeiro,* Universidade do Porto, Portugal

**Title:** Pain management, reducing pain, avoiding adverse events, and reducing diversion

*Rob W. Hutchison,* Texas A&M University System, USA

**Title:** The extent of pharmacovigilance awareness among pharmacy senior students of Centro Escolar University, Manila, Philippines

*Mary Jane C. Cruz,* Centro Escolar University, Philippines

**Title:** Clinical trials pharmacy service

*Eugenia Hong,* The Royal Melbourne Hospital, Australia

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**Title:** Assessing cancer risks associated with DPP 4 inhibitors: Role of FAERS in cancer

*Xiaodong Feng,* California Northstate University, USA

**Title:** Extent of under reporting of adverse drug reactions (ADRs) in India: Evaluation using logistic regression analysis (LRA) model

*Suresh Bowalekar,* PharmaNet Clinical Services Pvt. Ltd., India

**Title:** A prospective study on adverse drug reactions and signal detection

*Sivanandy Palanisamy,* KMCH College of Pharmacy, India

**Title:** Immunosuppressive effects of mesenchymal stem cells versus corticosteroid in experimental model of arthritis

*Marwa Elhussiny Younnis,* Cairo University, Egypt

**Title:** Sample size in clinical trial

*Pratyay Pratim Datta,* Hi-Tech Medical College and Hospital, India

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Coffee Break @ Texas Foyer

Cocktails Sponsored by Journal of Pharmacovigilance @ Rio Grande
Day 2  November 19, 2013

Track 5: Pharmacokinetics and Pharmacodynamics
Track 6: Pharmacy Practices and its Challenges
Track 11: Case Report in Clinical Trials

Session Chair: Jayshree Mishra, Texas A&M Health Science Center, USA
Session Co-Chair: Keith A. Wesnes, Northumbria University, UK

### Session Introduction

- **Title:** Renal excretion of Apricitabine: Ex vivo and In vivo studies  
  **Mariana Babayeva,** Touro College of Pharmacy, USA
- **Title:** Herb and drugs interactions in oncology  
  **Tanawan Kummalue,** Mahidol University, Thailand
- **Title:** Pharmacovigilance major problem is counterfeit drugs  
  **Sravankumar Gunda,** India

### Coffee Break @ Texas Foyer

- **Title:** The effect of pharmacist entrepreneurs’ managerial competencies on the performance of selected independent community pharmacy establishments in metro manila, Philippines  
  **Nelson T. Tubon,** University of Santo Tomas, Philippines
- **Title:** Role of regulatory affairs in pharmacovigilance: Marketing authorizations and new pharmacovigilance legislation in EU: important changes, challenges and options  
  **Nathalia Valkova,** Salvis Pharma Ltd, Bulgaria
- **Title:** Effect of Gymnema sylvestre leaf extract on development of diabetic induced in rats  
  **Rama Krishna Raparla,** Vaageswari Institute of Pharmaceutical Sciences, India

### Lunch Break @ Lone Star West

- **Title:** Improving the bioavailability of the drugs in GI tract by modulating the epithelial targets  
  **Jayshree Mishra,** Texas A&M Health Science Center, USA
- **Title:** Monitoring the drug toxicity of antineoplastic chemotherapy in children with cancer  
  **Ioan Magyar,** University of Oradea, Romania
- **Title:** Study on chitosan-poly vinyl alcohol gauze encapsulated with transexamic acid for hemostasis  
  **Abhishekkumar Ramasamy,** India

### Poster Presentations @ Austin

### Award Ceremony

Cocktails Sponsored by **Journal of Clinical Trials @ Rio Grande**

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**Venue**

Dublin, Ireland

**Important Dates**

- Abstract submission opens: October 24, 2016
- Registration opens: November 07, 2016
- Early bird registration: January 16, 2017
- On spot registration: September 20, 2017