Keynote Forum
March 26, 2018

Healthcare & Biosimilars 2018

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Stanley Hong

Celltrion Healthcare, South Korea

Market uptake of mAb biosimilars and their pharmacoeconomics

Many monoclonal antibody biosimilar products are coming on the market since the world first mAb biosimilar, which was Infliximab biosimilar, was approved by EMA and commercialized in 2013. In the beginning of commercialization, there has been lots of resistance from Healthcare Professionals (HCPs) mainly because of their concerns about efficacy and safety. In particular, many HCPs wanted to see more data about the immunogenicity and other side effect profiles. Now, market accessibility of mAb biosimilars has been improved a lot and potential concerns of HCP communities are substantially reducing because much more data about efficacy and side effects including immunogenicity of biosimilar products became available from real world experience as well as additional clinical trials. In terms of pharmacoeconomics, actually huge amount of healthcare budget can be saved from using mAb biosimilars and then the saved budget can be used for the biologic treatment of much more patients and supporting other stakeholders. In another words, the benefit from biosimilars can be distributed back to HCPs. The agenda of this presentation will be development of biosimilars including quality, market accessibility and their pharmacoeconomics.

Speaker Biography

Stanley Hong is a Senior Adviser at the Celltrion Healthcare and has played an important part in its development and success. He was the President of Research and Development at Celltrion, Inc., where he was responsible for the entire R&D including product discovery as well as biosimilar development. His team led the successful development of REMSIMA™, the world's first biosimilar, and gained approval for the product in Korea, Japan, Canada, European Union and USFDA. He was also responsible for the development of other biosimilars in Celltrion and has presented data on biosimilars at national and international medical meetings. He was also the President and CEO of Celltrion Healthcare.

e: seungsuh.hong@celltrion.com

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Sarel Lavy

Texas A&M University, USA

Facility management: Why is looking at projects from a whole life perspective is so crucial in the healthcare industry?

Facility management is considered to be a new and growing profession that: "Encompasses multiple disciplines to ensure functionality of the built environment by integrating people, place, process and technology." This is important for not only architecture, engineering, and construction (AEC) professionals, but also, and even more to owners and users (tenants, vendors, customers, etc.) of these buildings. Decisions made early in the planning and design phases can help conserve an organization's money and resources along its entire service life, but can also have detrimental long-term consequences. In today's world, managing healthcare facilities has become more competitive, relies much more on advanced technologies to operate, focuses on the user experience and safety ("patient-care"), and is more far-reaching (strategic) than in the past. This presentation will discuss about a different perspective on projects one that emphasizes the whole life view of projects, from the early phases of its initiation, all the way to its final stages of renovation, restoration, or demolition.

Speaker Biography

Sarel Lavy is an Associate Department Head Holder of the James C Smith Construction Industry Advisory Council (CIAC) Professorship in Construction Science Co-Editor, Facilities Fellow of the CRS Center for Leadership and Management in the Design and Construction Industry, the Center for Health Systems and Design, and the Center for Heritage Conservation Department of Construction Science College of Architecture Texas A&M University.

e: slavy@arch.tamu.edu

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J Peter Melrose

CHARTSaaS, LLC, USA

Cloud healthcare appliance real-time solution as a service (CHARTSaaS)

Currently, medical mistakes are the third-leading cause of patient deaths in the United States and also a statistically significant cause globally. Given the complexity of medical practice and healthcare delivery, the rapidly increasing volume and variety of relevant information, and the limitations and deficiencies of human cognition; cognitive overload arguably is the root cause of medical mistakes. Therefore, clinical cognitive support is the required remedy for medical mistake mitigation. Because, real-time information technology (IT) is the only cost-effective modality for cognitive support and automatic process management as demonstrated for decades in most industries other than healthcare. Therefore, the author has architected an IT solution named Cloud Healthcare Appliance Real-Time Solution as a Service (CHARTSaaS)©. CHARTSaaS is an internet cloud software integrated development environment (IDE) intended for healthcare provider subject matter experts (SMEs) to design, develop, deploy, operate and optimize IT clinical support applications a.k.a. "apps" with minimal cost or need for IT staff or system support. SMEs simply subscribe to CHARTSaaS, login via the secure portal, and then use the administration (apps and other digital artifacts), Analysis (Bayesian/multi-variate similarity and predictive), Connection (to EHRs and other data/logic sources), Decision (Boolean conditions and actions template), Documentation (access and management), Widget (pre-programmed logic including graphical user interfaces) and Workflow (flowchart with user swim lanes template) features to create and implement apps by using drag-and-drop, text entry, drop-down list selection and other methods not requiring IT technical training. Such apps can run continuously, notify users conditionally and thereby mitigate "failure to rescue" risk.

Speaker Biography

J Peter Melrose has retired from full-time employment in December, 2013, to develop state-of-the-art information technology (IT) tools and methods for medical practice and healthcare delivery. He is a solution-oriented healthcare IT professional and innovative leader, who achieved notable success prior to joining IBM in 2005 by conceiving and directing a broad range of private and public sector healthcare IT initiatives. He has participated in and published about many IT thought leadership and solution innovation projects; and currently he is an independent IT Consultant to healthcare providers, advocating internet cloud-based systems and services, about which he blogs at www.chartsaas.com.

e: jpetermelrose@gmail.com

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Yashwant Pathak

University of South Florida Health, USA

Bio-similar nutraceuticals, herbal drugs and natural medicines: Challenges and solutions

Bio-similar nutraceuticals: The nutraceuticals market is growing significantly. They are forecasting about $176 Billion market size by 2020. The significant increase in the market size is creating pressure on the naturally available ingredients used in nutraceuticals. Hence, people are exploring possibility of using genetically modified materials to be used in place of natural materials. No one has ever studied or reported about the usefulness of this material since these were not available in the early times. This is more challenging in the traditional medicine systems such as Chinese medicine and Ayurvedic medicines. These products, many of which are based on natural plants and have lot of traditional processes before the product reaches the patients. With the advent of genetically modified natural products, will they exactly behave the way the natural products are behaving or different? When you use these genetically modified materials in nutraceuticals, herbal drugs or natural products are you really comparing apples with apples or you are comparing apples with oranges. This presentation will cover the challenges for such products and a need for global standardization process for nutraceuticals and their ingredients.

Speaker Biography

Yashwant Pathak completed his education M.S., Ph.D. in Pharmaceutical Technology from India and EMBA and MS Conflict Management from Sullivan University, USA. He is Associate Dean for Faculty Affairs at the newly launched College of Pharmacy, University of South Florida. Tampa, Florida. With extensive experience in academia and industry, he has over 150 publications research papers, abstracts, chapters and reviews, 7 books in Nanotechnology and drug delivery systems, 6 in Nutraceuticals and several books in cultural studies. His areas of research include drug delivery systems, nanotechnology applications in pharmacy and Nutraceuticals. He has travelled extensively over 80 countries and is actively involved with many Pharmacy colleges in different countries.

e: ypathak1@health.usf.edu

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Umesh Sharma

Mayo Clinic Health System, USA

Attitudes and behaviour of nursing staff toward in-patient rounding by hospitalists

Historically, medicine and nursing has had a hierarchical and patriarchal relationship, with physicians holding monopoly over knowledge-based practice of medical care, thus impeding inter professional collaboration. Power gradient prevents nurses from demanding cooperative patient rounding. We surveyed attitudes of nursing staff at our tertiary care community hospital, before and after implementation of a patient-centered interprofessional (hospitalist-nurse) rounding process for patients. We obtained a baseline Nursing Staff survey of about 90 nurses working at Mayo Clinic Health System, Franciscan Healthcare in La Crosse, Wisconsin. Survey questions were used to assess baseline attitudes and satisfaction with current model of in-patient rounding. Starting March 19th 2012, the "patient-centered in-patient rounding plan" was implemented by every hospitalist staff for next 3 months. After the implementation period, attitudes and satisfaction of nursing staff towards Hospitalist rounding and communication were reassessed using the same surveys. There was a substantial improvement in nursing staff satisfaction related to the improved communication (7%-54%, p<0.001) and rounding (3%-49%, p<0.001) by hospitalist providers. Patient-centered rounding also positively impacted nursing workflow (5%-56%, p<0.001), nurses' perceptions of value as a team member (26%-56%, p=0.0018) and their job satisfaction (43%-59%, p=0.103). Patient-centered rounding positively contributed to transforming the hospitalist–nurse hierarchical model to a team-based collaborative model, thus enhancing inter professional relationships.

Speaker Biography

Umesh Sharma, MD, MBA, FACP, FHM is currently serving as Consultant at Department of Hospital Medicine, Mayo Clinic Health System; Assistant Professor of Medicine at Mayo Clinic College of Medicine; Chair of Division of Community Hospital Medicine, Mayo Clinic Health System (Jan 2014 to date) and; Regional Chair of Department of Hospital Medicine, Mayo Clinic Health System, South-East Minnesota practice (Aug. 2016 to date). He also served as Chair of Department of Hospital Medicine, Mayo Clinic Health System, Franciscan Health Care, La Crosse, WI (Jan 2012 to July 2016). His roles include: Leading clinical integration of Hospital Medicine departments across various sites in Mayo Clinic Health System in WI, MN; dissemination of Mayo Clinic's corporate strategies and rearrange community division of hospital medicine's priorities and resources to ensure sustainable competitive advantage; strategic consulting, including identifying and solving current state challenges, planning and implementation of projects to achieve an integrated future state model for Community Division of Hospital Medicine and; work-force planning: physician recruitment, contracting, on-boarding, etc. He has completed his Master of Business Administration from University of Massachusetts, Amherst, Isenberg School of Business in May 2015; Residency: Internal Medicine, Weill Medical College of Cornell University at St. Barnabas Hospital, Bronx, NY July 20, 2003 to July 20, 2006; MBBS (Bachelor of Medicine & Surgery), Byramjee Jeejeebhoy Medical College, University of Pune, Pune, India July 1993 to Jan. 1999.

e: Sharma.umesh@mayo.edu

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Meerambika Mahapatro

National Institute of Health and Family Welfare, India

Domestic violence, women's health and the sustainable development goals: Global target, national response and future directions

Domestic violence (DV) is a global issue and a serious public health problem, affecting women of different cultures and regions across the world. Evidence suggests that there is a close association between DV and women's health. In India, approximately 37% women are assaulted by their husband and family. More than 30% of women worldwide have experienced either or both physical and sexual violence. Although the healthcare system is often the first point of contact for victims for treatment, support and care for injuries and other health problems; women who are experiencing or have experienced violence make higher use of health-care services still there is an inadequacy of healthcare response towards them. The Sustainable Development Goals (SDG) place an important thrust on the prevention of violence against women and girls. SDGs offer an opportunity to achieve the commitments on the prevention of violence against women and girls. This is the first time that a global development agenda has addressed all forms of violence against women and girls, as well as violence against children. However, there is global and national challenges as in several countries to create integrated response to addresses the legal systems, customary laws and societal norms that foster systematic discrimination against women, poor translation of action plan into practice and implementation and in some countries the health systems are not experienced (equipped) to tackle the problem of violence with health promotion perspective. Therefore, an integrated system approach for intervention is needed to promote collective response. The paper aims to propose a suitable model for prevention of domestic violence based on the existing intervention programmes and empirical research. Observations and evidences based on existing intervention projects analyzed with reference to existing literature and described as to how they have been applied in various settings with different population groups to bring the most viable solution for reducing the prevalence and the harmful consequences of domestic violence. The proposed Five "R" integrated model is developed that health sector can adopt and respond to domestic violence which has five nodes or phenomena. These are rescue, recovery, rehabilitate, resilience and reform. All these five phenomena are conceptually defined and substantiated by an example and learnings from the initiative. India is trying implementation of such model that improves effectiveness, efficiency and accountability of the State and the society by promoting community-led initiatives. The proposed operational paradigm also elaborates the role of healthcare providers at the institutional level and at community level. These models ultimately suggest importance of understanding collaborative and convergence between social networks, community cohesion and the state. In addition, it suggests that community resources, cultural actions and low-budget interventions prove to postulate for a sustainable change. It suggests that specific indicators on violence against women should be included in health information and surveillance systems to monitor the progress in achieving SDG. Education and Capacity Building of Health Professionals, implementation of guidelines and protocols for routine screening, assessment of dangerous level, safety planning and documentation along with the health-care providers' attitudes towards DV and towards survivors is required for responding to intimate partner violence and sexual violence against women. Advocacy and political will is important to ensure that the health sector plays its role in addressing violence against women.

Speaker Biography

Meerambika Mahapatro is a Social Epidemiologist who is interested in understanding the influence of social contextual determinants, especially policy determinants on health, particularly among vulnerable populations (i.e., women and children with abuse). She is also interested in the methodologies involved in social-behavioral interventions to promote healthy behavioral changes and enhance community well-being. Her research interests include health policies and standard guideline practice related to gender abuse/violence, sexual violence and mental health. She has been the Principal Investigator of various research projects and received grants from WHO, ICMR, NIHFW, MOHFW, and Uttarakhand State govt.

e: meerambika.mahapatro@gmail.com

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Gimol Thomas George

Florida Atlantic University, USA

Improving physician-patient relationship by enhancing medical students' interpersonal and communication skills through small group activities

Improved physician-patient relationship is an integral part of medical practice. When treating patients, physicians need to fulfill various roles in their daily clinical activities such as educators, counselors, advocates, and many other interpersonal tasks. In order to succeed in these roles, physicians must be excellent communicators. Physicians develop many skill sets during undergraduate medical education. This study focuses on effective methods to enhance medical students' interpersonal and communication skills through small group activities. The various small group activities in the first and second years of the medical curriculum include Problem-Based learning (PBL), Inquiry (IQ) Cases, Student-Led Inquiry (SLIQ) Cases, Clinical Skills, Science of Clinical Practice and Clinical Learning Group. Eight students are assigned to each group and an experienced facilitator is assigned to facilitate the activities. Prior to the beginning of the activities, facilitators are required to attend faculty development sessions. In addition, facilitators meet weekly with course directors to discuss student progress and concerns. Several methods are used to assess students' interpersonal and communication skills in these small group activities. Some of the assessment methods are verbal peer feedback at the end of each session, mid-block and final facilitator narrative feedback, narrative self-assessment and narrative peer feedback. Since students receive vigorous training on interpersonal and communication skills and are assessed numerous times in the first two years of the medical curriculum, the number of students with inappropriate interpersonal and communication skills in the clinical year (3rd) is extremely minimal. The small group activities give students an effective platform to enhance their interpersonal and communication skills, which are critical for practicing physicians in the contemporary health care system.

Speaker Biography

Gimol Thomas George, a Harvard Macy Scholar, is currently employed at the Charles E. Schmidt College of Medicine (CoM), Florida Atlantic University (FAU) as an Assistant Professor of Integrated Medical Science and the Director of Program Evaluation and Assessment. Prior to joining FAU CoM, she worked at Nova Southeastern University College of Dental Medicine as the Director of Assessment & Educational Specialist as well as the Director for Effective Teaching, Learning and Assessment Methodology course in the Postdoctoral Program. She has been affiliated with several universities in various capacities, including serving as a Ph.D. Thesis Advisor/Examiner. During her academic career, she earned a Doctoral Degree in Education with a specialty in Human Resources Development. She has been published internationally and has received various awards and recognitions for her contributions in academia.

e: georgeg@health.fau.edu

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Beat Flühmann

Vifor Pharma Ltd., Switzerland

Nanomedicines: An emerging regulatory challenge

Today, up to 23 nanomedicines are approved and approximately 50 are in clinical development. In the past, first follow-on products also referred to as nanosimilars have entered the European market through the generic approval pathway. But upon substitution, significant differences have been observed in clinical practice raising doubt about their therapeutic equivalence. Today, leading regulatory authorities such as FDA and EMA as well as the regulatory science community are aware of these challenges and discuss regulatory requirements. Particularly, demonstration of pharmaceutical equivalence and bioequivalence prerequisites for generic approval according to 505(j), is extremely difficult if not impossible. While nanomedicines share lots of communalities such as heterogeneity, complexity, and the large molecular size with biologics, they are synthetic products and therefore, not eligible for the 505(k) biosimilar pathway. Hence, today generic manufacturers seeking for regulatory approval of follow-on products face challenges due to the nature of these nanomedicines and lack of an appropriate regulatory pathway following the principle of similarity. Based on data from the introduction of biosimilars in Europe, we estimate potential health care expenditure savings of EUR 280 million in France, Germany, Italy, Spain and UK, and USD 2'002 million in the US for the year 2020 from an approval pathway for nanosimilars. The biosimilar legislation that has successfully facilitated patient access to save and cost-effective medicine could serve as a model for a yet to establish nanosimilar approval pathway.

Speaker Biography

B Flühmann is a Pharmacist by training and holds a PhD in Molecular Biology from ETH Zürich, Switzerland on "Structural analysis and characterization of cell surface receptors" and a MBA of the University of St. Gallen Switzerland. He is working in various positions in the field of Pharmaceuticals and Functional Nutrition. He has been leading a global multidisciplinary research and development team at Roche/DSM nutritional products developing novel compounds for the prevention and treatment of diabetes. At Vifor Pharma Ltd., he has been acting as Global Brand Director defining global strategic product plans across all functions (medical, marketing, market research, regulatory, life cycle management, logistics) and ensuring the operational execution. In his current position at Vifor Pharma Ltd, he is Global Lead of Non-Biological Complex Drugs with a main interest in regulatory aspects of nanomedicines. He is a Steering Committee Member of the Non-Biological Complex Drugs Working Group hosted at Lygature a non-for-profit organization. The mission of the Non-Biological Complex Drugs Working Group is to work on appropriate and harmonized science-based approval and post-approval standards for Non-Biological Complex Drugs to ensure patient benefit and safety.

e: Beat.Fluehmann@viforpharma.com

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Vijaya Iragavarapu-Charyulu

Florida Atlantic University, USA

Chitinase-3-like-1 protein (CHI3L1) expressed during allergic pulmonary inflammation alters lung microenvironment accelerating breast cancer metastasis

Metastasis is the primary cause of death in women with breast cancer. Elevated serum levels of a glycoprotein known as chitinase-3 like-1 protein (CHI3L1) has been correlated with poor prognosis and shorter survival of patients with cancer and inflammatory diseases (Jensen, Johansen, and Price 2003b). CHI3L1 is known to be expressed in solid tumors such as breast (Johansen et al. 2003). Inflammation plays a pivotal role during tumor progression and metastasis. Since previous studies showed that CHI3L1 modulates inflammation, we determined the role of CHI3L1 in the context of pre-existing inflammation and metastasis. Using triple negative model of breast cancer, we demonstrated that CHI3L1 alters the cellular composition and inflammatory mediators in the lungs of mice with pre-existing pulmonary inflammation leading to the establishment of a metastatic niche. We found that CHI3L1 deficient mice with pre-existing inflammation had decreased pro-inflammatory mediators, and significant reduction in tumor volume and metastasis compared to wild type controls. Pre-existing inflammation and CHI3L1 may be driving the establishment of a pre-metastatic milieu in the lungs and aiding in the establishment of metastasis. We show that CHI3L1 levels are increased at both the "pre-metastatic" and "metastatic stage" and that tumor cells, splenic, alveolar and interstitial macrophages, and myeloid derived population produce CHI3L1. Thus, CHI3L1 may be one of the more promising prognostic markers for recurrent breast cancer (Johansen et al. 1995), metastatic breast cancer (Jensen, Johansen, and Price 2003b) and advanced breast cancer (Coskun et al. 2007). Therefore, understanding the role of CHI3L1 in inflammation during tumor progression could result in targeted therapies for breast cancer patients.

Methods: 8-12 week-old female BALB/c mice and CHI3L1 knockout mice were used in all studies. Allergic pulmonary inflammation was induced in mice using an established ragweed sensitization aerosol challenge model (Shibata et al. 2000). Mice with established pulmonary inflammation were implanted with luciferase transfected 4T1 mammary tumor cells and monitored for tumor progression by *in vivo* imaging. Excised pulmonary tissue was formalin-fixed and H & E histological analysis was done to assess metastasis, inflammatory cellular infiltrates and pulmonary architecture. Flow cytometric analysis of alveolar and interstitial fluid was performed using antibodies specific.

Results & Discussion: It is well established that inflammation within the tumor microenvironment fosters tumor growth and metastasis. Growth of tumors in 4T1 ragweed mice was higher compared to the 4T1 saline control mice. Furthermore, survival in 4T1 ragweed mammary tumor mice was decreased compared to the 4T1 saline controls.

Speaker Biography

Vijaya Iragavarapu-Charyulu obtained her Ph.D. in Microbiology and Immunology from University of Miami, Miami, Florida. She is an Associate Professor in Biomedical Sciences Department where she has been conducting breast cancer research. She is also invested in the educational mission of College of Medicine. She is a Co-director of the Fundamentals of Biomedical Sciences course at FAU.

e: iragavar@health.fau.edu

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Henry M Haire

Florida Atlantic University, USA

Hospital follow-up at a resident primary care clinic decreases readmission rates

Background: Hospital Readmissions are a multifaceted problem that greatly impact health care quality and costs. Interventions such as follow-up and discharge planning improvements have shown variable levels of success in decreasing readmissions. This study examines the impact of resident-based clinics on adiacent hospital readmission rates.

Objective: Our study examined if outpatient follow-up at a resident-run primary care clinic after hospitalization decreases future utilization of inpatient and emergency care.

Methods: This quality improvement project utilized a pre-post analysis of all patients with a hospital admission and subsequent follow—up at an internal medicine resident outpatient clinic begun in July 2014 to assess total number of admissions. ER visits, and cumulative hospital days before and after establishing outpatient care in the resident clinic. Randomly selected non-clinic patients admitted to the hospital within that timeframe were also assessed in a pre-post manner and then also compared with patients seen in the resident clinic.

Result: The total number of eligible patients seen at the residency outpatient clinic was 326, 155 insured and 171 uninsured, and all patients eligible were included in this study (100%). Patients seen in the resident clinic had a significant decrease in number of readmissions and length of stay from pre-clinic to post-clinic dates. Uninsured clinic patients also demonstrated a decreased use of emergency room Services. The non-clinic population did not demonstrate any Statistically significant Changes during the timeframe.

Conclusion: Resident-run primary care clinics may be a useful intervention to prevent hospital readmissions for patients and thus substantially reduce costs and penalties that might be imposed.

Speaker Biography

Henry M. Haire, M.D., FACP, B.A., M.S., serves as the inaugural Medical Director of the FAU Medicine Resident Clinic and Associate Professor of Integrated Medical Sciences In the Charles E. Schmidt College of Medicine. Dr. Haire has extensive clinical experience as an Internist and nephrologist in private practice in Fort Walton Beach Florida and developed the Watson Clinic Kidney Center as well as served as a Medical Director of multiple entities. These included Medial Director of Advanced Home Health, Watson Clinic Kidney Center, Senior Health Care Center, Dialysis Services of Florida, Renal Care Group and NW Florida Humana Health Insurance. He has had extensive experience in multiple health care systems, including Kaiser Permanente, FoundCare, Community Health Center, Redington Medical Primary Care, Charis Health Center, and was the owner of Nephrology Associates of NW Florida. He has held many positions including Chief of Staff and Chief of Medicine at Fort Walton Beach Medical Center and currently is the Chairman of the Education Council for the Palm Beach County Medical Society and on the Board of Directors. He is an active member in multiple national societies and is a Fellow of the American College of Medicine and is a member of the American Medical Association Florida Medical Association, American Society of Nephrology, and emeritus member of the Florida Society of Nephrology.

e: hhaire@health.fau.edu

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Rodica Olteanu

Colentina Clinical Hospital, Romania

Inflectra-Our experience on immunogenicity (Case series)

Biosimilars represent a new tendency in the treatment of many immune-mediated inflammatory diseases, including psoriasis. Regulatory requirements for approval of biosimilars are different from those of originators and rely mostly upon the evidence generated from bioequivalence studies and in particular from RCT, as an important part of it. In our study, case series, we tried to correlate the immunogenicity (measured with ELISA method: Antidrug antibodies and drug level) on eight patients on Inflectra (Infliximab biosimilar), treated more than eight months in our Dermatology Clinic. Our goal was to determine the evolution of the inflammatory markers (ESR, PCR) together with the evolution of PASI, PASI50 and PASI90 on a case series of eight patients for eight months. We were also capable to evaluate the possible correlations between these indices and immunogenicity. We found an interesting fact that from these eight patients, two had sub-therapeutically drug level but not anti-Infliximab antibodies. One of these two patients had also elevated inflammatory markers and the other one has gained more than 10kgs. Peculiar is also the finding that the third patient developed anti-infliximab-antibodies as well as sub-therapeutically trough level of Infliximab. Two months later, we evaluate the same parameters and we found no anti-infliximab antibodies and therapeutically through level. There is some discussion in the literature regarding the transient anti-drug antibodies and therefore the need to repeat them when positive and mainly when the clinical appearance does not explain the paraclinical findings. Our study concluded that, even on small clinical trial you can find valuable information that can help to tailor the treatment for the patient.

Speaker Biography

Rodica Olteanu is a Dermatologist and Medical Director of Colentina Clinical Hospital, Bucharest, Romania. She has received her PhD on lupus research in 2007, in collaboration with Hamburg University. She is involved in autoimmunity and immunogenicity of biologics and biosimilars and published more than 100 papers in lupus and psoriasis. She is Alumni EADV Club rewarded, winner of many international grants, Member in EADV Project Committee, AAD, GRAPPA, EuSCLE, SRD, ILDS Member and Member in Editorial Board of SRD and LAJPPA. She has completed her educational training by participating at Master Class on Psoriasis- Barcelona, Center for Excellence in Psoriasis-Vienna, Pearls in Lisbon and Bucharest-as Invited Speaker and also at Harvard. She supports the idea of a collaborative work group of specialists in different areas for autoimmune diseases also with patient's participation and she intent to create an Autoimmune Diseases Center in Colentina Hospital.

e: rodicaolteanu@hotmail.com

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Todd Lester

BioAgilytix, USA

Recommendations for the development and validation of neutralizing antibody assays in support of bio-similar assessment

The American Association of Pharmaceutical Scientists (AAPS) biosimilar focus group on nonclinical and clinical assays has developed a manuscript to guide the industry on best practices and testing strategies when developing neutralizing antibody (NAb) assays for biosimilar programs. Establishing that there are no clinically meaningful differences in immune response between a proposed product and the originator product is a key element in the demonstration of bio-similarity. It is critical to collect, evaluate and compare the safety and immunogenicity data from the clinical pharmacology, safety, and/or efficacy studies especially when the originator drug product is known to have potential for immune-mediated toxicity. In this presentation, a comprehensive review and recommendations on assay formats, critical reagents, approaches to method development, and validation of the neutralizing antibody assays will be discussed.

Speaker Biography

Todd Lester is the Bioanalytical Project Manager in BioAgilytix, oversees and leads all technical aspects of BioAgilytix's bioanalytical studies including design, interpretation, analysis, documentation, and reporting. He is a seasoned Biotech/Pharmaceutical Project Management Professional with broad GxP expertise. He is well-versed in the regulations and filing requirements for FDA and EMA, particularly regarding biosimilar development and the related immunogenicity assessment strategy and data interpretation. He has completed his BS in Biological Sciences from Cornell University and is a licensed Project Management Professional (PMP) with the Project Management Institute (PMI).

e: todd.lester@bioagilytix.com

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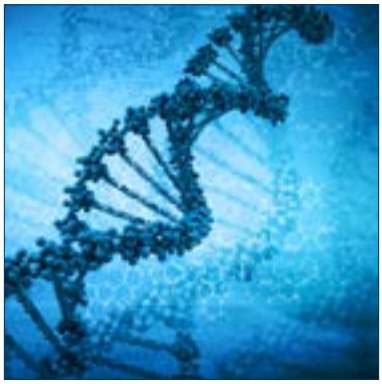

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Sylvain Bertel

Clermont Auvergne University, France

A hybrid algorithm for a health care supply chain problem

It deals with the reorganization of a French dental care hospital using a modeling approach by multiple incremental processes. This work is a part of a double complexity (algorithmic and systemic) in the implementation of tools for the hospital supply chain. For this purpose, several formal multicriteria models have been made. We have developed a hybrids algorithm to solve large instances. They will subsequently help for the dialogue with the various stakeholders of the dental hospital chain for its reorganization.

Speaker Biography

Sylvain Bertel has been working as Assistant Professor of Computer Sciences and Production Engineering at Clermont-Ferrand Management School (Clermont Auvergne University) since 2002. His research deals mainly with building models in optimization method with genetic algorithms and the use of discrete event simulation methods. He applies his modeling in the field of industrial enterprises, financial supply chain management, human resources management and health care systems. Before integrating the academic world, he worked in an IT service company.

e: sylvain.bertel@uca.fr

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Y Leon Guo

National Taiwan University, Taiwan

Precision medicine in prevention: Predicting atopic diseases

A group of prevalent conditions in children, atopic dermatitis (AD), asthma, and allergic rhinitis (AR) are chronic disorders resulting in adverse quality of life in patients and their family due to prolonged and repeated symptoms. The prevalences of these atopic diseases have increased in the past two decades worldwide, including in Taiwan. Atopic diseases are multi-factorial diseases, that genetic and environmental factors contribute to the development. However, environmental factors probably play a more important role than genetic in the rapidly increased prevalences in the past few decades. Exposed to allergens and air pollutants, infection, stress, etc. were all reported to associate with occurrence of atopic diseases. Predictive models for estimating the risk probability of AD and asthma were proposed based on analysis of follow-up study of birth cohorts in Taiwan, taking into account of hereditary and environmental factors. The predictive models were further improved after taking into account biomarkers, genetic polymorphisms, and maternal mental health during pregnancy. Using this precision medicine approach, we can identify high-risk children and potentially develop environmental preventive strategies.

Speaker Biography

Y. Leon Guo is currently an professor at National Taiwan University College of Medicine Department of Environmental and Occupational Medicine, Taiwan

e: leonguo@ntu.edu.tw

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Radwan Ahmed

PIONEERA HealthCare Group, Egypt & Herriot Watt University, UK

Biosimilars marketing strategies: Insight into the future of potential growth and key challenges

What does experience in the Eu and US so far can tell us about the opportunities and challenges in Biosimilars? While Biosimilars' growth potential looks extremely attractive, winning is not as simple as it might look at the first sight. Biosimilars hold a great potential for stakeholders. The opportunities are estimated at approximately $100 billion of biologics to lose patent protection in the Eu and US over the next few years. Although the European experience to date is reasonably good, additional challenges to the new launches of Biosimilars should be considered. Companies should craft a clear marketing strategy and incorporate the lessons learned from previous successes and failures. Past events in the biosimilar global market place could provide valuable insights into future success. In fact, it could provide an interesting reference for the next waves of Biosimilars.

Speaker Biography

Radwan Ahmed is the Chairman and CEO of PIONEERA Healthcare Group. He is also an Adjunct Professor of Management at Edinburgh Business School; Herriot Watt University in the UK. He has over 25 years of experience within the Pharmaceutical sector, including ethical pharmaceuticals, OTC, generics and strategic management consultation. His experience was gained at French, German, Japanese, Swiss and British multinational pharmaceutical companies. He was the Marketing Director of Novartis, Regional Marketing Director of Otsuka and GSK. He has received his Master and Doctoral degrees from Middlesex University in London. He also holds a first degree in Pharmacy and Pharmaceutical Sciences from Cairo University.

e: ahmed.radwan@pioneerahc.com

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Md Abu Zafor Sadek

University of Dhaka, Bangladesh

Growth potential of biosimilars in emerging countries

In view of the global changes in disease pattern, reduced health budget, patent expiry of some high valued products and side effects of chemical drugs, global pharmaceutical giants are concentrating on biotech products among which anticancer, cardiovascular, antidiabetic, antiasthmatic, antiarthritic products are especially important. However, developing a biotech product involved huge cost which is possible only by research based top companies. Realizing the fact, many pharmaceutical companies tried to imitate the original biotech products after patent expiry and became successful which bring a breakthrough in terms of health cost. These imitated products are termed as biosimilar products. Although the history of biosimilars started at European Union (EU) in 2006 with single product, but currently it has been recognized everywhere in the world and EU have highest 19 biosimilar products. United States Food and Drug Administration (USFDA) was little conservative with biosimilars; nevertheless, they approved the first biosimilar 09 years after EU approval and presently they have three biosimilars which are playing significant role in price cutting of branded biologics. They also have so many biosimilars under pipeline. Emerging economies especially China and India are very aggressive with biosimilars. Considering easy regulation, cheap labor and related cost factors they are in little advantageous than others. Under Pharmaceutical Benefits Scheme, Australian government is promoting biosimilars and they already approved 09 biosimilars. Japan, Korea, Canada, South Africa are also encouraging biosimilars. However, it is worth mentioning that in spite of enormous potentiality and rapid growth till to date biosimilar market is insignificant compared to total pharmaceutical market and success of biosimilars will depend on the acceptance by the physicians, treatment cost reduction, trust on manufacturer, proper information, drug substitution, efficacy, safety etc. Considering present stumpy growth in pharmaceuticals, geographical location, economic growth, drug policies, expertise etc., emerging economies may be an impressive hub for rapid growth of biosimilar products. Therefore, this study will concentrate to determine the growth potential of biosimilars in emerging countries.

Speaker Biography

Md. Abu Zafor Sadek is serving as a Senior Additional Manager, Product Management at Renata Limited, one of the top tier pharmaceutical companies of Bangladesh. Being graduated in Pharmacy from Khulna University, he has started his career at Orion Pharmaceuticals Limited as Product Executive. Thereafter, he has completed his MBA in International Business from Dhaka University. He has more than 11 years' career in Pharmaceutical Management with excellent track record. His area of interests includes launching time demanded new products, brand management, strategy formulation, business opportunity identification, international business, training, presentation skills etc. In addition to his regular job, he is pursuing for Doctor of Business Administration (DBA) Degree on "Growth Potential of Biosimilars Products in Bangladesh" from the Institute of Business Administration (IBA), University of Dhaka- the leading business school of the country. He has 05 publications in different local and international journals including International Journal of Business and Management, Canada. His article namely "Persuade of Marketing Mix in Choosing Biological Products by Specialists Doctors" is going to be published very soon. He has presented biosimilars and other topics at different conferences across the world including 5th European Biosimilars Congress, Valencia, Spain and 2nd Biosimilars Asia-Pacific Summit, Singapore. He is also involved in writing health column for the leading Bangladeshi newspapers.

e: azs_sohel@yahoo.com

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Priscilla Ream

Bronson Commons, USA

Hospital housekeepers - Partners to prevent and control healthcare associated infections

Hospital Housekeepers (HH) are the responsible for cleaning, disinfecting, and are the final personnel to process medical waste in healthcare environments - practices proven to be essential to prevent and control healthcare associated infections (HAIs). Studies have shown that HH have poor education/ training, and other factors that increase their risk of being exposed to workplace hazards such as biological risk. Ineffective waste management, along with increasing the risk for HH injuries, can also increase the risk for accidents with biological material among healthcare workers, and people without presumed risk. HH should be treated as the important partners they are to prevent and control HAIs and consequently improve patient safety and the quality of healthcare services provided to clients. That being said, they should have appropriate training, access to information to prevent injuries, access to vaccines like HBV prior to exposure, appropriate PPE, and in the case of a work-related exposure incident, the same treatment as a healthcare worker would receive. The healthcare team should also receive continuing education about waste management to avoid improper waste segregation.

Speaker Biography

Priscilla Ream is a Brazilian nurse and received her BSN in 2011, her MSN in 2014 by Federal University of Goias, Brazil. She has experience in Practical Nursing, Nursing Research, Infection Control, and Epidemiology – mostly acquired as a member of the Nursing Faculty Research Group at the Federal University of Goias: Center for Studies and Research in Nursing Infection Prevention and Control Related to Health Care (NEPIH) between 2009-2015. During undergraduate, she participated in an internship in the Infection Control Commission in the Faro Hospital, Algarve, Portugal. To expand her international experience as a nurse, in 2016 she received her RN license in the USA, and currently works as RN in the State of Michigan. She has publications in the area of accidents with biological material and wound treatment, and serves as a reviewer for Journals while enhancing her international nursing career.

e: prisf_enf@yahoo.com.br

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Janice Nahra Friedel

Iowa State University, USA

The global health care worker crisis: Where will we get our nurses?

The American nursing shortage: A reflection of the global healthcare worker crisis. This presentation highlights the American nursing shortage, the context for the shortage; efforts to recruit and retain nurses to the workforce; government, industry, foundation, and k-20 educational institutions efforts to increase the number of qualified individuals pursuing nursing careers. The presenter will begin by sharing innovative strategies and programs developed by a few higher education institutions to increase the number of nursing graduates. This interactive session will engage the participants in sharing the strategies and programs that their institution has taken to increase the number of nursing program graduates.

Speaker Biography

Janice Friedel is an Associate Professor at the School of Education, Iowa State University. She has 28 years of experience in community colleges in Iowa and Kentucky. She has served in a variety of executive level community college positions in Iowa and Kentucky, including the community college presidency, and as the State Administrator for a system of community colleges and the State Director for career and technical (vocational) education for secondary and post-secondary education. She is past Chair of the National Council of State Directors of Community Colleges, and past Member of the Executive Board of the National State Directors for Career and Technical Education. Her current research interests center on higher education public policy, community college leadership development, the community college mission and governance, career and technical education, the economic benefits of community college attendance, and dual/concurrent enrollment.

e: jfriedel@iastate.edu

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Kiminobu Sugaya

University of Central Florida, USA

Small molecule drug therapy to increase neurogenesis in Alzheimer's disease

Despite decades of investigations in both basic and clinic, the cause of Alzheimer's disease (AD) still remains unknown. Current problem of developing AD research is that many treatments are focusing AD hallmarks, amyloid plaque and neurofibrillary tangles, and they have been very effective in AD animal models but never be successful showing any significant effect in clinical trials. Thus, establishment of an effective treatment in a model, which represents pathophysiology of AD is needed. Previously, we were able to show improved cognitive function of aged, memory-impaired animals through the implantation of human neural stem cells (NSCs), which produced much excitement throughout the research world and the overall medical community; given the implication that this could lead to a cure for all neurodegenerative diseases, including AD. However, when we transplant NSCs to a transgenic animal model produces Amyloid-β (Aβ) plaque formation in the brain by expressing familial AD mutant amyloid precursor protein (APP), mimicking the pathological condition of AD, we did not find any new neuronal development formed from the donor cells. This indicates that transplantation of NSCs by itself may not be a cure for AD. Here, we show that the combination drug therapy of Phenserine (reduce APP level) and NBI-18 (increase endogenous NSCs) increased neurogenesis and significantly improved memory in the transgenic AD mouse model. This combination therapy could bring us an effective treatment for AD. I will further discuss the use of iPS cell to confirm the efficacy of this therapy *in vitro* 3D human AD brain model.

Speaker Biography

Kiminobu Sugaya is a Professor of Medicine, the Head of Neuroscience and the Chair of Multidisciplinary Neuroscience Alliance, Burnett School of Biomedical Sciences-College of Medicine University of Central Florida.

e: ksugaya@mail.ucf.edu

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Amal I Khalil

King Saud bin Abdul-Aziz University for Health Sciences, Saudi Arabia

Nurse's knowledge, attitudes and practices versus patient's perspectives on the use of seclusion and physical restraint: Evidence based on psychiatric clinical practices

The overall goal of this speech was to support the evidence based on clinical psychiatric nursing, regarding the elimination of seclusion and restraint practices in inpatients' psychiatric wards. This was done by conducting two studies: The first was conducted with an objective of investigating the nurses' knowledge, attitudes and practices towards the use of seclusion and physical restraints; the second study however, was aimed to investigate the psychiatric inpatients' experiences and suggestions regarding seclusion and restraint practices. The data was therefore collected in 2 phases from two different settings, between October 2014 and June 2015. Firstly, 37 nurses (52.8%) of whom were male had moderate knowledge and attitude, yet a strong intent to use physical restraints. There was therefore, no significant correlation between nurses' practice, knowledge and attitude scores. It was noted that 33.3% of the respondents preferred using both restraints and seclusion. The male gender was correlated with a higher use of physical restraints r=−341, while the use of seclusion had a positive significant correlation with nurses' level of education r=465, and a negative association with the other demographics. The second study explored the patient's perceptions regarding their obligation to be in either physical restraints or seclusion. The results revealed that the majority (60.9%) of the participants perceived that S/R application is neither necessary nor benefical in treating their dificulties. Hence, the frequency of restraint among the study participants ranged between zero and eight times, while the seclusion frequency ranged between zeros to twenty times. Consequently, and based on the results from both studies and other findings done in the same field, there was an evidence that nurses' inadequate level of knowledge on the physical and psychological effects of restraints and seclusion impact their performance and attitude in caring with psychiatric patients. Therefore, an in-service training program on procedure, indication, and negative consequences of restraints and seclusion is highly suggested to limit the frequency of its use amongst psychiatric patients. Moreover, the recommendations of this study are supported by literature. According to Balas and Boren (2000), leaders and clinicians in the research setting need to understand the relationship between an organization's culture of safety and patient outcomes, as well as how nurses' qualifications and certification can influence executives to lead working environment improvements. In addition, and even more important, future researches need to address how research findings and evidence can be translated to become the new standard of nursing practices. Likewise, the recommendation is parallel with the necessary request of psychiatric patients, which is to eliminate seclusion and restraint by supporting the use of less intrusive, preventative, and evidence-based interventions in behavioral emergencies that aid in minimizing aggression while promoting patients' safety.

Speaker Biography

Amal I Khalil is an Assistant Professor of Psychiatry and Mental Health Nursing at the Menoufyia University in Shebin-alkom, Egypt. Currently, she is working at King Saud bin Abdul-Aziz University for Health Sciences, College of Nursing, Jeddah, where she was awarded many times for her teaching activities, community and social contributions. She was nominated as a Reviewer to the *Journal of Horizon Research Publishing*, USA, *International Journal of Nursing and Clinical Practices* and *International Journal of Research in Nursing*. She has many publications and presented many research papers both nationally and internationally. In addition to teaching and research, she had worked as a Psychotherapist at a private practice and has membership in APNA (American Psychiatric Nurse Association), Family and Child Safety program related to National Guard Health Affairs, Saudi Arabia, and KAFA institution for smoking and addiction management.

e: khalilam@ngha.med.sa

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Aaron Damien Barzey

ADB Medical, United Kingdom

EU biosimilar regulation and the possible effect of Brexit on biosimilar medicines

The European Union (EU) has led the way for the global expansion of the biosimilar market for 15 years and is the global leader in the review and approval of biosimilar medicines and biosimilar regulation via the London based European Medicines Agency (EMA). Other countries, such as Australia, work side by side with the regulations and guidance produced from the EMA, and institutions, such as the World Health Organisation, have periodic meetings in London to discuss biosimilar medicines. Because, the United Kingdom is about to leave the EU on 29th March 2019 and the EMA and all its staff will have to relocate to remain in the EU as a result. All biosimilar products will need to be re-registered to one of the remaining 27 countries and there is the very real risk that this relocation will see losses in talented staff as well as hinder the approval and maintenance of biosimilar medicines.

Speaker Biography

Aaron Damien Barzey has been working in the Pharmaceutical Industry, covering Medical Affairs, Pharmacovigilance, Regulatory Affairs and Compliance, in multiple countries and multiple companies. At GSK, he was the Global Labelling Lead for the orphan drug 'ofatumumab'. He was responsible for the company core datasheets, labelling strategy, EU labelling negations and oversaw the product launch in emerging markets. His major accomplishment was leading the launch of Arzerra for the treatment of chronic lymphatic leukaemia across the EU, Australia and other countries. In 2015, he started his own regulatory consultancy, ADB Medical, providing ad-hoc support or project specific guidance to various companies. In 2016, he was chosen as the Pharmaceutical Industry SME to discuss the possible impact of Brexit on the pharmaceutical industry, which included debating with Nigel Farage live on national television and to discuss further on live on UK TV with Piers Morgan and Susanna Reid.

e: abarzey@adbmedical.com

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