11th EUROPEAN BIOSIMILARS CONGRESS

April 26-27, 2018 Rome, Italy

Scientific Tracks & Abstracts
Day 1

Euro Biosimilars 2018

Sessions:

Day 1 April 26, 2018

Current Challenges in Developing Biosimilars | Analytical Strategies for Biosimilars | Biosimilar Companies and Market Analysis | Regulatory Approach of Biosimilars | Intellectual Property Rights | Emerging Biosimilars in Therapeutics

Session Chair
Sakae Tsuda
National Institute of Advanced Industrial Science and Technology, Japan

Session Chair
Kamali Chance
BioSciencesCorp, USA

Session Introduction

Title: **Application of new quality products of type I–III antifreeze proteins and antifreeze glycoprotein**
Sakae Tsuda, National Institute of Advanced Industrial Science and Technology, Japan

Title: **Technical challenges in developing biosimilar antibodies**
Emile Van Corven, Bioceros, Netherlands

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Title: **How to meet FDA requirements for demonstration of interchangeability?**
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Title: **Automated permethylation for glycosylation analysis of biologics using MALDI-TOF-MS**
Archana Shubhakar, Ludger Ltd, UK

Title: **Getting the NHS ready for the biosimilar boom: Shifting attitudes, acceptance and appetites**
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Title: **In the name" of biosimilars: Trademarks issues**
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Title: **An *in-vitro* functional assessment of a biosimilar rituximab and its originator**
Fatemeh Torkashvand, Pasteur Institute of Iran, Iran

Title: **Biosimilar uptake in the MENA region: Strategies and challenges**
Yazan Shaban, Hikma Pharmaceuticals, Jordan

Sakae Tsuda, J Bioanal Biomed 2018, Volume 10
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Application of new quality products of type I–III antifreeze proteins and antifreeze glycoprotein

Sakae Tsuda
National Institute of Advanced Industrial Science and Technology, Japan

A typical ice block is composed of numerous single ice crystals that are created in water during freezing. The crystals grow and merge together to form an ice block, if the temperature remains below 0°C. Type I-III antifreeze proteins (AFPs) and antifreeze glycoprotein (AFGP) accumulate on the surfaces of embryonic ice crystals to inhibit their growth and merging, resulting in an aggregate of tiny ice crystals instead of an ice block. This function of AFP will be useful for the preservation of a variety of water-containing materials such as processed foods, soups, ice creams, noodles, breads, vegetables, seeds, drinks, alcohol, medicines, cosmetics, gels, cells, tissues, and organs. In keeping the size of each ice crystal to a minimum, AFP use may greatly improve the effectiveness of preservation. In addition, fish-derived AFPs bind to the lipid bilayer to prolong the lifetime of cells under hypothermic condition (+4°C), a function that may be applicable to short-term cell preservation or "cell pausing". It should be noted that each AFP and AFGP sample is always a mixture of 2-13 isoforms, which function together far more effectively than any single isoform. We have therefore developed preparation method of quaity products of fish type I-III AFPs and AFGP, and examined their applicability in both industrial and medical fields. An example of application is fabrication of highly porous material using "gelation & freezing method". In this method, we first prepare a solution containing gelatin, ceramic powder, and AFP to be cooled to form a cylindical shape of gel. This AFP-containing gel is then placed on a frozen plate to induce unidirectional freezing. Since AFP binds onto the side (prism plane) of the elongating ice crystals, extremely sharpened and uniformly aligned ice needles are created in the frozen gel. After sintering at 1,000°C, a ceramic containing numerous unidirectionally-aligned dendritic pores is created. The quality products of AFP and AFGP may realize more advanced techniques that have been expected by many great pioneers of this field.

Biography

Sakae Tsuda has completed his PhD at the Hokkaido University (Japan) and Postdoctoral studies at the University of Alberta (Canada). His research background is Biomolecular NMR, which gave him the skills of Biochemistry, Biophysics and Structural Biology. He is a Chief Senior Researcher of National Institute of Advanced Science and Technology, Japan and also a Professor of Hokkaido University. He has published around 110 papers. His current research target is the antifreeze proteins, which have originally been explored from Japanese organisms in the last 20 years.

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Notes:

Emile Van Corven, J Bioanal Biomed 2018, Volume 10
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Technical challenges in developing biosimilar antibodies

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Since originator recombinant proteins are getting off patent, biosimilar molecules are entering the market. Although the overall costs of bringing a biosimilar product to the market is in general much lower than for an originator, the technical challenges to reach biosimilarity compared to originator product are significant. There is also a strong push to bring down the cost of goods to manufacture these products. Strategies will be presented to reach technical proof of similarity of specific antibodies while reducing production costs. These include innovative concepts to increase antibody titers on our CHOBC® platform using our SPOT™ technology and our USP toolbox to modulate relevant post-translational modifications like glycosylation and charge variants. In addition, these include, selection of new Protein A resins to decrease cost of goods while maintaining product quality, the development of high throughput methods, including Multi-Attribute Methods (MAM), to increase efficiency, and the extensive characterization of antibody charge variants (eg oxidation, deamidation, fucosylation, lysine truncation etc.) and disulfide linkage analysis to increase product knowledge.

Recent Publications

1. Van Corven E (2014) Recombinant protein and mAb biopharmaceuticals to become a commodity? Pharmaceutical Bioprocessing. 2(2):107-109

Biography

Emile Van Corven pursued MSc in Biology/Chemistry at Leiden University, Netherlands. He got his PhD in 1987 at Nijmegen University and was a Postdoc Fellow at The Netherlands Cancer Institute in Amsterdam, Netherlands. He is currently the Chief Development Officer at Bioceros, Head of Downstream Process and Analytical Development. He has a track record of more than 25 years in the biopharmaceutical industry: Principal Consultant CMC (Xendo), Director and Global Head of process development and pilot plant GMP manufacturing of vaccines (Crucell/J&J), and development of recombinant proteins (Pharming). He also worked for the Dutch Regulatory Authorities as Head of Control Lab for the Release Of Blood Products/Vaccines, and Head of the Regulatory Group for review of Biotech CMC Dossiers. He has published over 30 peer-reviewed scientific articles, chapters in textbooks, and is Co-inventor of various patents. From 2012-2015, he was a Member of the Editorial Board of *Pharmaceutical Bioprocessing*.

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Identification and quantification of individual Host Cell Proteins (HCP's) in biosimilars and comparison with originator using SWATH mass spectrometry

Thomas Kofoed
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Regulatory requirements for biosimilars include process related impurities including (HCP) which should be identified, characterized as appropriate, quantified, and compared with the reference products. Here we present a HCP analysis method based on a SWATH (Sequential Windowed Acquisition of All Theoretical Fragment Ion Mass Spectra) LC-MS workflow that is fast, sensitive and provides reproducible identification and absolute quantification of individual HCP's in the purified drug substance. The workflow is generic for vaccines, mAbs (monoclonal antibodies), small therapeutic proteins and protein biopharmaceuticals. We will present this new method for accurate and absolute HCP quantification, and parameters critical for method validation, including reproducibility, linearity, LOD/LOQ and measurement range. Case examples will be shown including comparison between biosimilar and originator product.

Biography

Thomas Kofoed holds a PhD in Chemistry from the University of Southern Denmark, Denmark. He is the Co-Founder and Chief Executive Officer of Alphalyse and has been responsible for general management of Alphalyse since its inception in 2002. He has more than 20 years of experience from the Biotech industry, and previous posts as Head of Proteomics at ACE BioSciences A/S, Denmark, Associated Professor at Copenhagen University, Denmark and Senior Scientist at PNA Diagnostics AS, Denmark.

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R Helena Bustos-Cruz, J Bioanal Biomed 2018, Volume 10
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Bioanalytical methods for biosimilars: An approach

R Helena Bustos-Cruz
Universidad de La Sabana, Colombia

The success of biosimilar development involves demonstrating biosimilarity in terms of quality, security, and efficiency. It is important to establish the bioanalytical principles and methods to allow detailed characterization and to be able to undertake the clinical and non-clinical studies that can verify the security and clinical efficiency and to be granted marketing authorization for biopharmaceuticals. Moreover, to minimize the risk related to biosimilars, immunogenicity studies must be carried out in patients with biopharmaceutical treatment. Thus, the detection and detailed characterization of Antidrug Antibodies (ADAs) will allow for further understanding in relation to the potential impact in terms of the efficiency and safety of the molecule object of study. There is currently no test that provides all the necessary information to be able to define a specific immunogenicity profile. Therefore, the conception of a bioanalytical strategy is necessary: One that sequentially includes the accomplishment of a test panel. Firstly, the most widely accepted methodology includes the accomplishment of a screening test that can assess the capacity of the Ab to bind biotherapeutic proteins. There is then a test to determine the neutralizing (Nab) capacity, the data which will be analyzed in light of the pharmacokinetic/pharmacodynamic parameters, and the magnitude of the biological effect in patients. This test also identifies the risk profile that will allow the rigor in the time parameters for the sampling to be established. These types of immunogenicity studies, which are mostly predictive, require a rigorous validation process to establish an adequate correlation level with clinical results; they also determine feasibility, which allows for the findings to be extrapolated.

Biography

R Helena Bustos-Cruz studied at the University of Tübingen in Germany and carried out her Postdoctoral studies at the Universidad Nacional in Colombia. She is Group Leader of the Therapeutic Evidence Group at the Universidad de La Sabana. She works in Nanobiosensors development for the evaluation and characterization of molecular interaction in biological drugs. She introduced nanobiosensors (surface plasmon resonance and quartz crystal microbalance) as a new research technology in Colombia. Her group works in the field of safety and efficacy for drugs, clinical pharmacology, and pharmacovigilance. Additionally, she participated in elaborating the evaluation guidelines for biosimilars according to the National Institute for the Monitoring of Medicine and Food (INVIMA).

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M Carme Parés Santilari, J Bioanal Biomed 2018, Volume 10
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The Bio Immune(G)ene medicine and the use of miRNAs to regulate the cell

M Carme Parés Santilari
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The microRNAs(miRNAs) are a type of non-coding RNAs molecules that regulates de gene expression in a negative way, this is by downregulating the gene expression mainly at the post-transcriptional level, either by the mRNA degradation process or the inhibition of the translation. It is well known the role that many miRNAs play in the pathogenesis of several diseases as in the inflammation process, several steps of the oncogenesis or the metabolism of several virus and bacteria among many others. One of the main limitations in the use of the miRNAs in treating the diseases is the ability of reaching the target as well of doing so without causing any collateral damage, because it's well-known that one microRNA has the ability to regulate until more than 200 target-genes, and one gene can be influenced by a lot of different microRNA. We propose the BioImmune(G)ene medicine for this purpose: to achieve the cell without harm, our aim is to use all the molecular resources available, especially epigenetic with the microRNA, to restore the cell homeostasis, we only seek to play a regulatory biomimetic role, to give the cell the needed information for its own right regulation. Our experience for the last years in cell regulation has shown the way to fight, for instance, against the deleterious effects of virus or bacteria in the lymphocytes, so often at the background of many autoimmune or allergic diseases, as well as to regulate many other process. To fulfill our purpose, we need some nano-biotechnology to be able to reach our targets, so we introduced very low doses of miRNAs in nano compounds with the aim to promote the regulation of the main signaling pathways disturbed in a given pathology.

Biography

M Carme Parés has completed her MD by the Faculty of Medicine of Pontifical Javeriana University (Bogotá, Colombia) and Posterior Studies in Barcelona-Spain, Master's in Tropical Diseases from the Autonomous University of Barcelona (UAB), and Master's in Homeopathy from University of Barcelona. Her interest for the Immunology and Infectology in the context of Alternative Medicine brought her to follow the work and investigations of Dr. Gilbert Glady, Creator of BI(G)MED and Director of EBMA, the European association for training the medical profession at the BI(G)MED. For the last 8 years she is mainly working at her clinic in Barcelona practicing BI(G)MED and teaching seminars on BI(G)MED.

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Biosimilars in the United States: A progress report and a peek in to the future

Kurt R Karst
Hyman, Phelps & McNamara, PC, USA

The biosimilars industry in the United States is still a nascent one. In 2015, FDA (Food and Drug Administration) approved the first biosimilar biological product, and several other approvals have followed, with more applications for other biosimilar biological products pending at FDA. Although FDA and industry are tackling the scientific and data requirements for FDA to approve a so-called "Section 351(k) application" for a biosimilar biological product, legal issues abound. Whether it is the requirements or the contours of the "Patent Dance" for resolving patent disputes between biosimilars applicants and reference product sponsors, the availability and the scope of 12-year reference product exclusivity, or the appropriate naming convention for biological products, each issue is critical to the success of biosimilars in the United States and to the future of the industry. And with fast-paced litigation, the landscape for biosimilars seems to change on a monthly or weekly basis. This session will explore the ins and outs of current disputes involving the metes and bounds of the patent dance, non patent exclusivity, naming and more, and explain what each dispute might mean for the future world of United States biosimilars.

Recent Publications

1. Kurt R Karst (2017) Patents and exclusivity (Ch. 17) Fundamentals of US Regulatory Affairs, 10th Ed. Regulatory Affairs Professionals Society.
2. Jan Berger, Jeffrey D Dunn, Margaret M Johnson, Kurt R Karst and W Chad Shear (2016) How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management. Am. J. Manag. Care. 22(16 Suppl):S487-S495.
3. Kurt R Karst (2015) FDA's Orange Book and ANDAs: Questioning the Policies and Precedents Surrounding RLD Patent Listings. Respiratory Drug Delivery. 1:59-66.
4. Kurt R Karst (2014) Jumping Legal Hurdles with the US FDA: The Generic Inhaler Challenge. Respiratory Drug Delivery. 1:151-158.
5. Kurt R Karst (2014) Letting the Devil Ride: Thirty Years of ANDA Suitability Petitions under the Hatch-Waxman Act. Wm. Mitchell L. Rev. 40(4):1260-1306.

Biography

Kurt R Karst provides regulatory counsel to pharmaceutical manufacturers on Hatch-Waxman patent and exclusivity, drug development, pediatric testing, and orphan drugs. He helps clients develop strategies for product lifecycle management, obtaining approval, managing post-marketing issues, and defining periods of exclusivity. As the Co-Founder and Primary Author of Hyman, Phelps & McNamara's FDA law blog, he often leads the response to new rules and regulations, sharing his interpretation with the broader legal community. He has co-authored and contributed to several text books, including "*Generic and Innovator Drugs: A Guide to FDA Approval Requirement's"; "Pharmaceutical, Biotechnology*, and *Chemical Inventions"; "Fundamentals of US Regulatory Affairs" and "FDLI's Drug and Biologic Approvals: The Complete Guide for Small Businesses-FDA Financial Assistance and Incentives"*.

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How to meet FDA requirements for demonstration of interchangeability?

Kamali Chance
BioSciencesCorp, USA

There is a great interest from global companies who are developing biosimilars to pursue interchangeability designation for commercialization of their products in the US. An interchangeability designation will not only allow the substitutability at the pharmacy level without the intervention of a health care provider but the first sponsor who is able to garner interchangeability designation will also receive twelve months of marketing exclusivity. This presentation will highlight our current understanding of FDA expectations with regards to demonstrating interchangeability.

Recent Publications

1. Chance K and Reeve R (2016) - Overcoming regulatory and statistical hurdles of biosimilars drug development: designing smarter trials. insight brief: Applied Clinical Trials. Pages. 3-9.
2. Huml R, Chance K et al. (2016) - Challenges with the development of biosimilars in Asia for western markets: an overview and suggested solutions. Therapeutic Innovation & Regulatory Science. 51(2): Page numbers.
3. Goel N and Chance K (2016) Biosimilars in rheumatology: understanding the rigor of their development. Rheumatology. 56(2):187-197.
4. Goel N, Chance K et al. (2015) Operational challenges associated with biosimilar drug development. Journal for Clinical Studies. 7(2):20-27.
5. Goel N and Chance K (2014) The biosimilar landscape: a systematic review of its current status. Arthritis & Rheumatology Journal. 66:S662

Biography

Kamali Chance has a PhD in Nutrition/Nutritional Biochemistry, Master's in Public Health and Regulatory Affairs Certification from Regulatory Affairs Professional Society. She is the CEO & Executive Consultant of KC Biopharma Consulting, LLC, USA. She has an extensive regulatory strategy/ regulatory affairs experience working at a Clinical Research Organization and for pharmaceutical and biotechnology companies. She advises pharmaceutical and biotechnology companies in the development of region specific and/or global regulatory strategy for the development of biosimilars/biologics/drugs. She has authored/co-authored numerous articles on the development of biosimilars and small molecule drugs. Her work experience includes strategic regulatory planning including clinical development plans, preparing and submitting meeting requests to regulators, guiding the client through meeting preparations and attendance at FDA/EMA meetings, regulatory submissions including IND and IND maintenance, ANDA/NDA/BLA/MAA preparations and submissions. She is proficient in performing due diligence assessments for investments and acquisitions for biopharmaceutical/pharmaceutical products.

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Archana Shubhakar et al., J Bioanal Biomed 2018, Volume 10
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Automated permethylation for glycosylation analysis of biologics using MALDI-TOF-MS

Archana Shubhakar[1,3], **Daniel Spencer**[1], **Daryl Fernandes**[1] and **Manfred Wuhrer**[2]
[1]Ludger Ltd, UK
[2]Leiden University Medical Center, The Netherlands
[3]VU University Ámsterdam, The Netherlands

For most therapeutic glycoproteins the glycosylation patterns correlate strongly with the clinical safety and efficacy profiles. In biological tissues these patterns can also correlate with the state of health or disease of the individual. Given this, there is increasing interest in accurately characterizing changes in glycosylation, for example in Quality by Design studies throughout biopharmaceutical development as well as in glycan biomarker discovery for medical diagnostics. Changes in glycosylation patterns can be complex and subtle and the numbers of samples needed to be analysed can be large, ranging from hundreds to thousands. To perform these studies, reliable systems for high-throughput (HT) glycomics are needed. However, despite many advances in glycosylation analysis there are still problems with current technologies, including low sample throughput, long turnaround times, high cost per sample and labour intensiveness. This talk concerns "LongBow" — a system developed at Ludger for reliable HT glycomics. The "LongBow" system is made up of flexible, modular technologies for semi-automated processing of glycans from a variety of clinical and bio-therapeutic samples and analysis by mass spectrometry (MS) and/or ultrahigh performance liquid chromatography (UHPLC). The focus here will be on permethylated N- and O-glycans analysed by matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI-TOF-MS). This automated, HT glycan preparation and permethylation method showed to be robust, convenient and fast and can be applied for biopharmaceutical glycan profiling and clinical glycan biomarker studies.

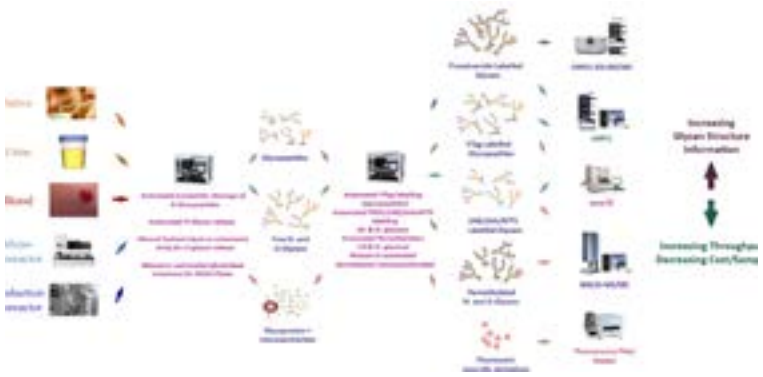

Figure: "LongBow" system developed at Ludger, is made up of flexible, modular technologies for semi-automated processing of glycans from a variety of clinical and biotherapeutic samples.

Recent Publications

1. Ventham N T et al. (2016) Integrative epigenome-wide analysis demonstrates that DNA methylation may mediate genetic risk in inflammatory bowel disease. Nature Communications. 7:13507.
2. Dotz V et al. (2015) Mass spectrometry for glycosylation analysis of biopharmaceuticals. TrAC Trends in Analytical Chemistry. 73:1-9.

3. Ventham N T et al. (2015) Changes to serum sample tube and processing methodology does not cause inter-individual variation in automated whole serum n-glycan profiling in health and disease. PloS One. 10(4):e0123028.
4. Shubhakar A et al. (2015) High-throughput analysis and automation for glycomics studies. Chromatographia. 78(5-6):321-333.

Biography

Archana Shubhakar obtained her Master's Degree in Biochemistry from Bangalore University in India. She worked in the public relations sector for a few years and gained experience in people skills. Currently, she is a Scientist at Ludger (UK) and has been an integral part of the development team, taking new glycobiology products from initial research to final product launch for several years. Her research involvement and accomplishments have been the implementation and development of high throughput analysis and robotization for N-glycan release, glycan derivatization and analysis using a number of orthogonal analytical platforms. As, Ludger is a consortium member of the European and UK funded projects she is also involved in market research, communication with other consortium members and project coordination/management of research projects and grants. She is pursuing her PhD in collaboration with the Department of BioAnalytical Chemistry at Vu University, Amsterdam, The Netherlands under the supervision of Dr. Daryl Fernandes and Prof. Dr. Manfred Wuhrer. Her PhD thesis is entitled "Method development for the discovery of glycosylation biomarkers of inflammatory diseases".

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Getting the NHS ready for the biosimilar boom: Shifting attitudes, acceptance and appetites

Theo Christie
National Institute for Health Research, UK

The biosimilars market is going to heat up considerably over the next three years - but is the NHS ready for the biosimilars boom? The NIHR Clinical Research Network (NIHR CRN) - the research delivery arm of the NHS - offers a unique insight into the biosimilar landscape in the UK. The NHS deals with over 1 million patients every 36 hours. It is therefore a huge user and thus purchaser all categories of medicines. In this context/to most, biosimilars are a no-brainer. With the promise of a smaller price tag than original biologics, they have the potential to deliver NHS cost-savings and help ensure the sustainability of public healthcare systems, whilst also broadening access to healthcare so that greater numbers of patients can be treated with cutting edge biologic medicines. What's not to like? But as with anything new, there are always early skeptics. Our industry partners in the past have voiced a lack of interest and willing from invesitgators to conduct biosimilar research. The NIHR CRN launched it's biosimilar offer almost 1 year ago and can now report that the tide has turned and attitudes and acceptance in relation to biosimilars in the UK are changing. The NIHR CRN is an independent, government-funded organisation, which has devised an offer to industry centered around support for biosimilar research. We can show you a range of perspecitves from clinicians and company case studies to show how this tide is turning and that the UK is open for business to biosimilar research.

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"In the name" of biosimilars: Trademarks issues

Roberto Valenti
DLA Piper, Italy

Biosimilars in Europe are typically branded differently from the reference drug, however the non-proprietary names of European biosimilars are identical to those of their reference drug. More specifically, biosimilars are named according to the degree of "similarity" if compared with the biologics. When the physico-chemical differences stay in the range defined by EMA, they take the same INN (International Nonproprietary Names) of biologics; when the range is exceeded, it is necessary to create a new INN. The situation is different in USA, where the FDA requires - for all biologic products – that a randomly-generated suffix is added to the INN in all cases. This presentation is aimed at addressing the consequences of the different policies in Europe and USA with regard to the branding of biosimilars on the industry, and on the development of the market.

Biography

Roberto Valenti is a partner at DLA Piper Italy. He focuses on IP litigation, including matters relating to trademarks, copyrights, designs, unfair competition and misleading and comparative advertising. He also has experience dealing with IP non-contentious matters, such as drafting licence and transfer agreements relating to trademarks, copyrights and designs, with a special focus in the life science sector. With a PhD in Intellectual Property, University of Pavia, in the last 7 years, he has been the Chairman of the Life Science Working Group of the American Chamber of Commerce in Italy. He is commended in the WTR 1000: The World's Leading Trademark Professionals 2017. Chambers Europe, Chambers Global, The Legal 500 EMEA and a number of client surveys have identified him as a leading individual in the IP field, with particular reference to the Life Science arena. He is listed as Acritas Star™ Lawyer 2017.

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Fatemeh Torkashvand et al., J Bioanal Biomed 2018, Volume 10
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An *in-vitro* functional assessment of a biosimilar rituximab and its originator

Fatemeh Torkashvand[1], **Behrouz Vaziri**[1] and **Amirhossein Saadatirad**[2]
[1]Pasteur Institute of Iran, Iran
[2]AryoGen Pharmed, Iran

This study described the functional characterization of a biosimilar rituximab and its originator. Functional characterization contained of a series of bioassays: Surface Plasmon Resonance (SPR) assays for Fc receptors binding analysis, Complement-Dependent Cytotoxicity (CDC) and Antibody-Dependent Cell-Mediated Cytotoxicity (ADCC) assays. With regard to binding of Fc to Fc gamma receptors mediates ADCC and CDC, complete affinity study of these receptors can increase the knowledge about the acceptable range of amount of these Critical Quality Attributes (CQAs). A widespread functional characterization package displayed that biosimilar rituximab has similar biological properties as originator rituximab; also the cell-based bioassays confirmed this.

Biography

Fatemeh Torkashvand is an Academic Member in the Biotechnology Research Center at Pasteur Institute of Iran. She received her Bachelor's degree in General Biology from Buali Sina University, and her Master's degree in Cellular and Molecular Biology from the Khatam University. She has completed her PhD in Pharmaceutical Biotechnology from Pasteur Institute of Iran, in 2016. She has started her activities as an Assistant Professor at Pasteur Institute of Iran from 2017. Her research interests include Protein Chemistry, Biopharmaceuticals Characterization and Quality by Design (QbD) in Biopharmaceutical Development.

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Biosimilar uptake in the MENA region: Strategies and challenges

Yazan Shaban
Hikma Pharmaceuticals, Jordan

Biosimilars medications represent a new challenging frontier for the MENA (Middle East and North Africa) region healthcare landscape. While the region is suffering from political and economical challenges, the need for cost savings promised by the introduction of biosimilar medications has become of great interest to policy makers in the region. In spite of this, misconceptions about the biosimilar approval pathways, lack of robust regulatory frameworks, varying drug purchasing regulations and ongoing debate regarding switching, interchangeability and extrapolation is hindering these products from acheiving their maximum potential. Companies who want to enter the biosimilar business have to implement a diverse and complicated strategy to navigate through this turbulent landscape.

Biography

Yazan Shaban has graduated in 2008 with a Bachelor's Degree in Pharmacy from the University of Jordan, Jordan and in 2014 has completed his MBA degree from the German Jordanian University, Jordan. Since 2008, he has worked in varying positions in the Pharmaceutical Industry having worked for Ipsen Biopharmaceuticals Inc, MSD and Jansenn. As a Brand Manager for Biosimilars in Hikma Pharmaceutical, he has been responsible for launching Remsima in the MENA region as the first monoclonal antibody biosimilar to be approved by MENA authorities.

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Scientific Tracks & Abstracts
Day 2

Euro Biosimilars 2018

Sessions:

Day 2 April 27, 2018

Current Challenges in Developing Biosimilars | Analytical Strategies for Biosimilars | Biosimilar Companies and Market Analysis | Legal Issues and BPCI Act | Biologic Drugs | Biological Medicine | Biowaiver Biobetters | Biosimilar Market and Cost Analysis

Session Chair
Roberta Bursi
InsilicoTRIALS, Italy

Session Chair
Oleksandr Kukharchuk
ReeLabs Pvt. Ltd., India

Session Introduction

Title: ***Insilico*TRIALS democratizes simulations in healthcare**
Roberta Bursi, InsilicoTRIALS, Italy

Title: **Similar effects of peptides and proteins from animal venoms and of human Ly-6 proteins on nicotinic receptors**
Victor Tsetlin, Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry RAS, Russia

Title: **Identification of biosimilarity in early process development and clone screening**
Thomas Zahel, Exputec GmbH, Austria

Title: **Analysis of the pharmacological intervention and cognitive development through technology in the treatment of autism**
Eraldo Martins Guerra Filho, Recife Center for Advanced Studies and Systems, Brazil

Title: **Influence of fetal placenta extract on growth of experimental solid tumors**
Oleksandr Kukharchuk, ReeLabs Pvt. Ltd., India

Title: **Innovative, cost effective solution for self-administration of bio-similar drugs**
Menachem Zucker, E3D Elcam Drug Delivery Devices, Israel

Title: **Meeting the challenges of gaining marketing approval of biosimilars across the globe**
Cecil Nick, PAREXEL International, UK

Title: **Using organ-specific progenitor cells extracts in regenerative medicine**
Padma Priya Anand Baskaran, ReeLabs Pvt. Ltd., India

Title: **Applications and advantages of gold nanoparticles as X-ray contrast agent**
Mohammed H Alwan, Al Nahrain University, Iraq

Title: **Understanding the nocebo effect that can help in optimizing treatment outcomes with biosimilars**
Mourad F Rezk, Medical and Scientific Affairs, Switzerland

Roberta Bursi, J Bioanal Biomed 2018, Volume 10
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11th EUROPEAN BIOSIMILARS CONGRESS

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*Insilico*TRIALS democratizes simulations in healthcare

Roberta Bursi
*Insilico*TRIALS, Italy

Computer simulations are considered standard technology in many industries like Automotive, Engineering and Aeronautics, but they are generally poorly established in the healthcare sector. At the same time, pharmaceutical and medical device companies are facing the challenges of exponential growth of research and development costs, of high attrition rates and of inefficient development processes. Since more than a decade, the US Food and Drug Administration agency has indicated Modeling and Simulation as a technological solution which can help to contain development costs and which can enable data-driven decisions and the optimization of development plans. *Insilico*TRIALS is the first web-based, cloud-based platform that provides healthcare companies and researchers with easy-access and ready-to-use computational models to perform simulations for pharmaceutical and medical device development and approval processes. The features of the platform ensure that no highly-specialistic knowledge is required to run the models, leading to a democratization of the simulations. Individualized simulations and post-processing are performed in public or private cloud, to streamline the design and development process. Users can securely share their data models with project partners, simulation parameters, and results through the digital library. Use case examples pertaining the pharmaceutical area of biologics including, but not limited to an estimation model for colloidal interactions and protein aggregation propensities will be presented and discussed.

Biography

Roberta Bursi has obtained her PhD in Computational Chemistry at the University of Southern California, Los Angeles, USA. She is a Biopharmaceutical Professional with twenty years experience in modeling and simulation implementation and deployment across research and development organizations of medium- and large-sized multinational pharma companies aiming at delivering innovative medicines to patients. She is the author of more than 30 peer-reviewed scientific publications, inventor of 4 patents and Project Management Professional (PMP) certified by the Project Management Institute, USA. She is currently the Vice President Model Informed Drug Discovery Development at *Insilico*TRIALS LLC.

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Similar effects of peptides and proteins from animal venoms and of human Ly-6 proteins on nicotinic receptors

Victor Tsetlin
Shemyakin-Ovchinnikov Institute of Bioorganic Chemistry RAS, Russia

In the frames of the organized conference the term "biosimilar" is apparently most applicable to compounds which in principle should be identical but, especially if produced by heterologous expression in different laboratories, may differ in the degree of purification or other properties which are difficult to control. On the other hand, of great interest is "biosimilarity" as a manifestation of similar biological activity produced by compounds of absolutely different structure. In the proposed lecture it will be illustrated by interaction of various naturally-occurring and designed/ synthesized compounds with various subtypes of nicotinic acetylcholine receptors (nAChRs). The similarity in the effects of various compounds appears when they attach roughly at the same binding site at the nAChRs. α-Neurotoxins from snake venoms have played a crucial role in earlier isolation of muscle-type nAChRs and at present are a good pharmacological tool for identifying muscle-type and neuronal α7 nAChRs. Their binding site is situated in the receptor ligand-binding domain (LBD) at the interfaces between the subunits, as earlier shown by "wet" biochemistry and then confirmed by the X-ray analysis. Another class of sophisticated tools for research on nAChRs are α-conotoxins, neurotoxic peptides from *Conus* marine snails which not only allow to distinguish muscle nAChRs from the neuronal ones, but also help to identify individual subtypes of neuronal receptors. α-Conotoxins as such or as modified forms are considered as promising drugs, in particular those selective for the α9 nAChR may give new analgesics. The deviations from "biosimilarity" might arise if some of the structurally similar compounds have additional targets: for example, we found that α-cobratoxin, a classical blocker of muscle and neuronal α7 nAChR can also inhibit certain subtypes of GABA-A receptor and weak inhibitory activity against this receptor was manifested by several α-conotoxins. Some activities, when measured by one method may be similar, but differ when tested by another method. For example, α-cobratoxin, such α-conotoxins as PnIA analogs and Ly-6 proteins ws-Lynx1 and SLURP-1 (these proteins have the same three-finger folding as α-cobratoxin) inhibit ion currents in the α7 nAChR (with the affinity decreasing in this series) according to electrophysiology experiments, while radioligand analysis revealed that α-cobratoxin and α-conotoxins bind to the orthosteric site in the receptor, but the Ly-6 proteins attach in the allosteric one.

Recent Publications

- Dutertre S, Nicke A and Tsetlin V I (2017) Nicotinic acetylcholine receptor inhibitors derived from snake and snail venoms. Neuropharmacology. 127:196-223.
- Kudryavtsev D S, Shelukhina I V, Son L V, Ojomoko L O, Kryukova E V et al. (2015) Neurotoxins from snake venoms and α-conotoxin ImI inhibit functionally active ionotropic γ-aminobutyric acid (GABA) receptors. J Biol. Chem. 290(37):22747-22758.
- Kasheverov I E, Chugunov A O, Kudryavtsev D S, Ivanov I A, Zhmak M N et al. (2016) High-affinity α-Conotoxin PnIA analogs designed on the basis of the protein surface topography method. Sci. Rep. 6:36848.
- Tsetlin V I (2015) Three-finger snake neurotoxins and Ly6 proteins targeting nicotinic acetylcholine receptors: pharmacological tools and endogenous modulators. Trends Pharmacol. Sci. 36(2):109-123.

Biography

Victor Tsetlin has got PhD and DSci degrees in Chemistry (1973, 1987) at the Shemyakin-Ovchinnikov Institute; now Head of the Department of Molecular Basis of Neurosignaling; Professor (1996) and Corresponding Member of the Russian Academy of Sciences (2006). He received the following awards: Russian State Prize in Science and Technology (1985), and the Humboldt Prize (1992). He is an Invited Scientist at the Uppsala University, Imperial College (London), Institute of Protein Research (Osaka), Free University (Berlin). He is a Member of the Advisory Board of FEBS J (2000-2011), Biochem. J. (2013-present). He has published over 200 papers: in *PNAS, Neuron, Nature Str. Mol. Biol., J. Biol. Chem., J. Neurochemistry, TIPS, Sci. Rep., Neuropharmacology*.

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Using organ-specific progenitor cells extracts in regenerative medicine

Padma Priya Anand Baskaran, Oleksandr Kukharchuk, Andrii Kukharchuk, Abhijit Bopardikar, Rohit Kulkarni and **Sunil Pophale**
ReeLabs Pvt. Ltd., India

Proliferation and differentiation of stem cells requires a specific microenvironment – "stem cells niche". For *in vivo* modulation of organ-specific niches during SCs transplantation could be useful Fetal Tissue Extracts (FTEs). In the stage of organogenesis microenvironment in each of the organs must be specific and stable enough to generate constant signal for the final differentiation of organ-specific progenitor cells. The purpose of this study is to test and validate this hypothesis. We investigated the content and concentrations of growth factors in FTEs of various organs; and studied the efficacy of FTEs in liver cirrhosis and chronic non-healing wounds patients who did not respond to stem cells treatment. Transplantation of prenatal hepatoblasts, hematopoietic stem cells, and 3 weeks of daily fetal liver extracts injections showed effectiveness in 75% of this liver cirrhosis cases that is characterized by significant decrease of liver fibroscan density, decrease of portal hypertension and ascites, decrease or normalization of biochemical markers of liver damage. Connective tissue metabolism showed increase of fibrinolytic and collagenolytic activity. In patients with chronic non-healing wounds who do not have any improvement after previous stem cells treatment, administration of FTEs (skin, muscle) activated the wound epithelialization with completely healing of Thus, FTEs obtained from the stage of incomplete organogenesis can be useful for *in vivo* modulation of organ-specific niches for transplanted stem cells.

Biography

Padma Priya Anand Baskaran completed her MSc Biotechnology from Saint-Petersburg State Chemical Pharmaceutical Academy (Russia). She has her research experience, and history of working in the hospital & health care industry. She is skilled in Stem Cells Therapy protocol from preparation to treatment and has established efficacy of stem cells in clinical research. She has 15 scientific publications to her credit. Her field of interest includes: Ageing, Prenatal Stem Cells, Exosomes, 3D Progenitor Cell Cultures, and Stem Cell Niche Modeling.

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Analysis of the pharmacological intervention and cognitive development through technology in the treatment of autism

Eraldo Martins Guerra Filho
Recife Center for Advanced Studies and Systems, Brazil

Autism is a mental disorder of neurodevelopment in which there occurs a break in the fundamental processes of socialization, communication and learning. These disorders are collectively known as disorders of development. Which the multidisciplinary approaches are effective for not only the issue of education and socialization, but mainly the social question and the attempt to establish etiologies and clinical well defined, capable of accurate prognostications and therapeutic approaches, effective. Understand what pharmacological interventions are most widely used in Brazil as: Risperidona, an antipschycotic atypical, followed by benzodiazepines (Tranquilizers Sedatives) and of the heterocyclic compounds (other antipsychotics or neuroleptics) associated with the use of technology. Can contribute to better results in the treatment and cognitive development of autism. The technology adopted was the Cangame, by the various services offered as: personalization and customization of content, monitor the entire stage of life of autistic (children through adult), scheduling activities and preparation of monitoring reports. This intervention seal can contribute to better outcomes in the treatment and cognitive development of the autistic. For such a survey and survey data found in the literature and in oturas research, together with the tests and aplciabilidade technology. are the target of this research, with the aim of promoting new studies and processes that can reduce time and cost in relation to the treatment and learning of autistic.

Biography

Eraldo Guerra has completed his Master Science Computer at the age of 36 years from C.E.S.A.R (Center for the Study of Advanced Systems of Recife) and It has more than 40 awards in innovation, entrepreneurship, technology for health, two awards from the United Nations in 2017 and participated in the BID. He is an expert in distance education by SENAC, research professor of the Faculty São Miguel. Has published articles in several countries and participates in a number of initiatives of research and development enterprise.

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Influence of fetal placenta extract on growth of experimental solid tumors

Oleksandr Kukharchuk, Andrii Kukharchuk, Abhijit Bopardikar, Anand Baskaran Padma Priya, Rohit Kulkarni and **Sunil Pophale**
ReeLabs Pvt. Ltd., India

Tumor growth and metastasis are dependent on the degree of neovascularization in the tumor bed. Vascular Endothelial Growth Factor (VEGF) is a key angiogenic factor, frequently utilized by tumors to switch on blood vessel growth. Eriksson A et al (2002) showed that Placenta Growth Factor (PlGF-1) antagonizes VEGF-induced angiogenesis when both factors are co-expressed in murine fibrosarcoma cells. During the organogenesis, apoptosis of the primary cells of the embryo is extremely intense. It is possible that placental factors regulate this apoptosis. The purpose of study is to analyze influence of fetal placenta extracts (FPEs) on solid experimental tumors growth and caspases activity in tumor tissues. Experiments accomplished in 330 rats. Subfascial transplantation of tumor cells were performed. FPEs injected on the 7th day after tumor transplantation. After FPEs administration the growth curve of sarcoma 45 plotted on the line of negative polynominal relativity with time; growth of carcinoma had negative linear relativity from the time that evidences about the rapid regression of the tumor mass. Dynamic of Lymphosarcoma growth also characterized by negative polynomial time-related dependence. After administration of FPEs in carcinoma tissue the level of conjugated diene raised by 40%, malondialdehyde level increased twice. Simultaneously, sharp decrease in superoxide dismutase and γ-glutamyl transpeptidase activity observed; in carcinoma tissue activity of caspase-3 exceeded control by 47%, activity of effector caspase-8 by 2.4 times. FPEs induced apoptosis in the tissues of experimental tumors and block angiogenesis due to rapid necro-apoptosis and regression of tumor mass had occurred.

Biography

Oleksandr Kukharchuk, MD is the Research Director of ReeLabs Pvt. Ltd. He has guided research and clinical study in HM of Ukraine: in experiments and clinical study, to determine effectiveness of transplantation of stem cells, tissues of fetal and extra-fetal material and tissue therapy by Filatov in immune and onco-pathological process, pancreo- and colonogenic peritonitis, ageing and dysfunction of reproductive system. He is the author of the book "*Stem cells: Experiment, Theory, Clinic. Embryonic, mesenchymal, neural, hematopoietic stem cells*". He was the Director of the Coordination Centre for Transplantation of Organs, Tissues and Cells of the Ukraine Health Ministry.

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Innovative, cost effective solution for self-administration of bio-similar drugs

Tsachi Shaked and **Menachem Zucker**
E3D Elcam Drug Delivery Devices, Israel

The purpose of this presentation is to identify and present a cost-effective method and devices to self-administration of biosimilar drugs and molecules while keeping the entire process safe and easy to use. Disposable auto-injectors have their advantages of safe and simplicity but pose an additional cost of materials to a bio-similar drug/molecule. Reusable auto injectors are more cost effective, but the ones in the market are complicated, are not easy to use and not completely safe. In this presentation we will present a new, innovative, method for easy and safe yet cost-effective way for self-administration of biosimilar drugs/ molecules. These innovative devices might be a perfect partner with the biosimilar drug as they are not only cost effective, safe and easy to use, but also have a lower environmental impact of plastic parts and trash. We will discuss mechanical auto-injectors and electronic auto-injectors while in both the only disposable part is the cassette that holds the PFS (Progression-free survival) with the drug inside.

Biography

Tsachi Shaked graduated in Master's in Business Administration with expertise in Marketing from Bar-Ilan University in Ramat-Gan, Israel. He is a Chief Marketing Officer at E3D (Elcam Drug Delivery Devices) a subsidiary of Elcam Medical. As part of the company's portfolio, he is deeply involved with the development of the new version of drug delivery devices that includes connectivity and electronic applications. He is with the company from 2006.

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Meeting the challenges of gaining marketing approval of biosimilars across the globe

Cecil Nick
PAREXEL International, UK

This presentation addresses the challenges sponsors face in developing biosimilars for the global market amidst a myriad of varying regulatory requirements. Differences in approach between CHMP and FDA will be considered with respect to the impact of variances in the regulatory frameworks and conflicting quality and clinical data requirements. Consideration will then be given to the need for inclusion of local patients in order to gain regulatory marketing approval as is the case for example in China, Japan, Russia and India. Also in some regions there is the need compare the biosimilar against reference product sourced from specific regions at the quality and sometimes the clinical level. The timings for clinical trial approval and potential for interaction with regulatory authorities in order to seek feedback on the suitability of the proposed development program will also be discussed.

Biography

Regulatory affairs professional for over 30 years. Has particular expertise in monoclonals and biosimilars, having worked on over 20 such programs, engaged in over 50 interactions and meetings with regulatory agencies in the EU, US, Canada, Australia, Mexico, Brazil and supported 6 submissions in the EU and US. He has also participated extensively in Industry and International meetings on the subject. Prior to joining PAREXEL, Cecil served as Regulatory Manager at Novo Nordisk Ltd. Fellow of TOPRA and has been a guest lecture at Cardiff University MSc in Clinical Research and Greenwich University MSc in Pharmaceutical Sciences courses and Biotech Module leader for the TOPRA MSc course. He was on the editorial panel of SCRIP Clinical Research and has authored many articles on regulatory and clinical development issues. Holds BSc (Hons) in Biochemistry from the University of Cape Town.

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Identification of biosimilarity in early process development and clone screening

Thomas Zahel
Exputec GmbH, Austria

Biosimilar development is seeking to identify clones and manufacturing process conditions that are most likely to yield similar quality profiles as the originator product. However, during clone screening and process development, sufficient repetitions of experiments is not feasible in order to perform scientific and statistically sound bioequivalence analysis according to FDA guidelines. Although sample size of biosimilar experiments of a specific clone at a specific process condition is limiting, data is usually rich in redundant critical quality attributes (CQAs). Taking advantage of that situation, we want to present a novel multivariate statistical approach to identify lead clones and optimal process conditions that will later on increase the chance of passing bioequivalence assessment. Moreover, we want to present a successful implementation of a biosimilarity software application that helps operators to identify biosimilar clones and process conditions and even enables them to take counter actions within their process development. This ultimately leads to a more robust and data driven process development of biosimilars.

Biography

Thomas Zahel has completed his PhD in Applied Statistics for Biopharmaceutical Development and Manufacturing at Vienna Technical University, Austria. Since 2014, he is leading an innovation group devloping novel multivariate statistical methods for biosimilarity testing and process validation at the data science and software company Exputec, located in Vienna, Austria.

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Applications and advantages of gold nanoparticles as X-ray contrast agent

Mohammed H Alwan, Logean Q Al Karam and **Auns Q Al Neami**
Al Nahrain University, Iraq

X-ray medical imaging is one of the most important imaging techniques because of its low cost and reachable technique. But it has poor ability to depict soft tissues and small details between soft tissues at the borders of interference. This limitation was overcome by using iodine-based contrast agent but this chemical compound has limitations for use due to its toxicity and side effects. Ten years ago, a new variant contrast agent of medical X-ray imaging was discovered, developed and understudy to date. The new variance factor is gold nanoparticles, which may overcome these limitations because of its excellent properties, where the biological distribution of these particles is higher than iodine compounds. The interaction between bones and soft tissue is more apparent, stay longer at the targeted site which allows for a longer imaging time and all of the above factors enhance the X-ray diagnostic ability. This study consists of the synthesis of gold nanoparticles, animal preparation (which includes a selection of animal type, housing, preparing the tumor and tumor implantation), intravenous administration of gold nanoparticles to infected mice then X-ray imaging was taken by conventional X-ray unit. The resulted X-ray images demonstrated that gold nanoparticles were attractive to move towards tumor site through the general circulation and spent more time at the tumor site (inverse the iodine contrast agent) which allows for a longer time of imaging, lower levels of toxicity and side effects. All of the mentioned factors lead to enhancement of X-ray diagnostics (i.e. obtained X-ray images contain the site of abnormality, two dimensions abnormality map, extra details of bone-soft tissue interference and high contrast level)..

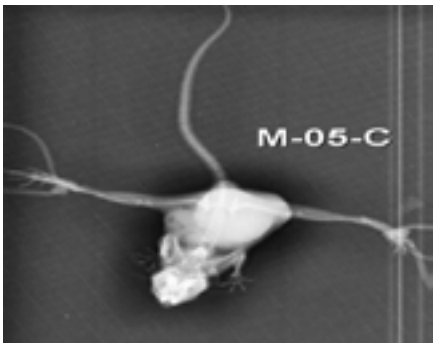

Figure: The figure shows enhancement of the X-ray images abilities in the reorganization of abnormal soft tissue and increase of the overall resolution level of the image based on the usage of gold nanoparticles as contrast agent.

Recent Publications

1. E Boisselier and D Astruc (2009) Gold nanoparticles in nanomedicine: preparations, imaging, diagnostics, therapies and toxicity. Chemical Society Reviews. 38(6):1759-1782.
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3. S Ahn, S Y Jung and S J Lee (2013) Gold nanoparticle contrast agents in advanced X-ray imaging technologies. Molecules. 18(5):5858-5890.
4. Cole L E et al. (2015) Gold nanoparticles as contrast agents in X-ray imaging and computed tomography. Chemical Reviews. 10(2):321-341.
5. J F Hainfeld et al. (2006) Gold nanoparticles: a new X-ray contrast agent. British Journal of Radiology. 79(939):248-253.

Biography

Mohammed H. Alwan has completed his Bachelor degree from Baghdad University/ Iraq in 2004 then studied for M.Sc degree in Al-Nahrain University/ Iraq in 2015. He spent ten years serving as Biomedical Engineer at the Ministry of Health institutes/ Iraq started at 2005 in Al-Karamaa general Hospital and in Ibn-Al-Bitar Center for Cardiac and Vascular Diseases and Al-Sadr General Hospital then at 2015 in the Middle Euphrates center for oncology at Al-Najaf health directorate.

Logean Qadri Al-Karam in Al-Nahrain University/ College of Engineering/ Biomedical Engineering Department. B.Sc. in Material Engineering / University of Technology, 2000. M.Sc. in Material Science / subspecialty in the Polymers 2008. Training in Department of Materials Engineering, Auburn University, Auburn, AL, USA. Hands-on laboratory experience in synthesis and characterization of ceramics, nanoparticles and ceramic polymer hybrid composites under of Dr. Z. Y. Cheng in 2013, PhD in Material Science/ subspecialty in Nanotechnology, 2014. Teaching in the following subjects now: Materials Science, Biomaterials, Physics, Application of Medical Engineering. The important publishing researches about (7) researches.

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Understanding the nocebo effect that can help in optimizing treatment outcomes with biosimilars

Mourad F Rezk
Medical and Scientific Affairs, Switzerland

Many theories have tried to explain the well-known placebo effect of some inactive ingredients as an outcome of patient's expectations. The expanded use of generics and now the increasing use of biosimilars have brought a new definition to the attention of clinicians who tend to describe the correlation between negative expectations or negative communications with negative subjective treatment outcomes as the nocebo effect, a phenomenon that can cause the induction or the worsening of symptoms by sham or active therapies may account for some adverse events (AEs) reported by patients following treatment. Nocebo responses may occur as unintended result of the requirement for healthcare professionals to explain possible complications and side effects when initiating treatment. Misleading or over negative communications may set negative expatiations at the patients' level which may ultimately trigger negative perceptions of treatment outcomes and a tendency to overreport adverse events and to withdraw from treatment regimens. Proper fact-based explanations by health care professionals coupled with strategies to reassure and engage patients upon initiating or switching to a biosimilar are key in ensuring better treatment outcomes and sustainability on biosimilars to ensure broader access for patients to complex biologics and reduce the financial burden on health care systems.

Recent Publications

1. Rezk M F and Pieper B (2017) Treatment outcomes with biosimilars: be aware of the nocebo effect. Rheumatol Ther. 4(2):209-218.
2. Declerck P and Farouk Rezk M (2017) The road from development to approval: evaluating the body of evidence to confirm biosimilarity. Rheumatology. 56(suppl_4):iv4-iv13.
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5. Thakur K, Biberger A, Handrich A and Rezk M F (2016) Perceptions and preferences of two etanercept autoinjectors for rheumatoid arthritis: a new European union-approved etanercept biosimilar (Benepali®) Versus Etanercept (Enbrel®) - findings from a nurse survey in Europe. Rheumatol Ther. 3(1):77-89.

Biography

Mourad F Rezk is the Global Head of Medical Affairs for Biogen's biosimilars portfolio He is an MD with more than 25 years of industry experience in medical affairs and R&D roles. Along the course of the last 10 years, he has been quite involved in evolving the understanding of the biosimilars role in improving access to high quality biologics and has been frequently invited as a Speaker to international congresses on biosimilars and has also published a sizable number of publications addressing different biosimilars scientific topics.

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