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21 - 22 March 2019 | Porto

3rd Annual

BIOSIMILARS AND BIOLOGICS

D E S

C R I P

T I O N



KEY LEARNING POINTS

On 21 & 22 March 2019, Porto will host the 3rd BioTech Pharma Summit: Biosimilars & Biologics 2019. This year's flagship event will gather top EU, US, Asia and global regulators, officials, healthcare actors as well as industry leaders, to foster open exchange and debate on the role of the biosimilars & biologics medicines sector.

The BioTech Pharma Summit: Biosimilars & Biologics 2019 is the leading event to continually stay on the pulse of the biosimilars' ever-changing market and convenes key stakeholders including biosimilar and innovator pharmaceutical manufacturers, payers, providers and patient advocates addressing timely challenges and best practices for biosimilar product success.

- Interchangeability strategy in Biosimilar clinical trial
- Innovations in Biologics Drugs, Biosimilars and Biobetters
- Educational Materials on Biosimilars
- Biosimilar development in emerging markets
- CMC Analytical Comparability: Methods & Strategies for Biologics, Biosimilars & Biobetters
- Prognosis for the Global Biologics market in an era of transformative new technologies
- Critical Analytical Characterization Steps for Biosimilarity Assessment
- Process Development for Biosimilars - Industry challenges
- Biosimilars development and impact on clinical practice
- Pricing and reimbursement considerations for Biosimilars
- Commercial challenges and opportunities - strategies to develop Biosimilars & Biologics
- Relationship between originators' patents in the field of biologics
- Understanding the current regulatory approval standards

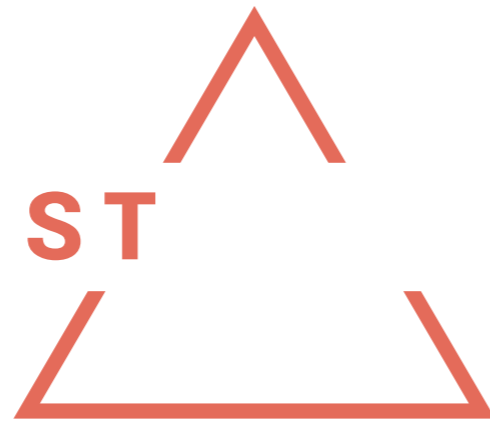
W H O S H O U L D A T T E N D

The **BioTech Pharma Summit (EPM Group)** are exclusive events designed for senior level attendees from leading **Pharmaceutical, Biopharmaceutical, Biotechnology, Diagnostics, CRO** and Solution Provider companies, along with highly esteemed members of academic and government institutions.

Chief Executives, Executive Directors, Vice Presidents, Heads and Team Leaders and Managers including:

- Biologics/Biotechnology/Biogenics
- Biopharmaceuticals
- Business Development
- Chief Scientific Officer
- Clinical Immunology
- Commercial Affairs
- Drug and Safety Assessment
- Drug Safety & Risk Management
- Intellectual property
- Legislation and Policy Advice
- Manufacturing Market
- Strategy Marketing & sales
- New Product Development
- Pharmacovigilance
- Preclinical and Clinical Development
- Pricing and Reimbursement
- Health Economics
- Principal Scientist
- Process Control and Analytical Technologies
- Quality Affairs/Quality Control
- Regulatory Affairs
- Regulatory Compliance
- Legal Affairs
- R&D

SPEAKERS LIST



BRENDA GOMES VALENTE
Health Surveillance and Regulation Specialist at ANVISA

BR



EMILE VAN CORVEN
Chief Development Officer at Bioceros

NL



JUSTIN STEBBING
Professor of Cancer Medicine and Oncology at Imperial College London

UK



FERNANDA ALEIXO
Director Policy & Market Access at Mylan

PT



NED POJSKIC
Leader, Pharmacy & Health Provider Relations at Green Shield Canada

CA



SUZETTE KOX
Secretary General IGBA (International Generic and Biosimilar medicines Association)

BE



NIKOLAI BRUN
Chief Medical Officer. Director of Division at Danish Medicines Agency

DK



CATE LOCKHART
Program Director at Biologics and Biosimilars Collective Intelligence Consortium

US



JOÃO GONÇALVES
Group Leader/ Principal Investigator at iMed-The Research Institute for Medicines

PT



RODEINA CHALLAND
Director at Challand Biosimilar Consulting

UK

 Chairperson - DAY 2



BARBARA VALENTE-SINGER
Chief Medical Officer at Fresenius-Kabi SwissBioSim

CH



JOSÉ MARONA
Resident of Rheumatology Centro Hospitalar de Lisboa Ocidental, EPE - Egas Moniz Hospital

PT



ROMAN IVANOV

Vice President,
Research &
Development
at BIOCAD

RU



LORRAINE FINCHAM

Commercial Research
Initiative Manager
at NIHR National
Institute for Health
Research

UK



**FRANCOIS-XAVIER
FRAPAISE**

Principal at F.-X.
Frapaise Consulting

FR



STEINAR MADSEN

Medical Director at
Norwegian Medicines
Agency

NO



ANNA ROSE WELCH

Chief editor
at Biosimilar
Development

 Chairperson - DAY 1

US



RAHUL PADHYE

Vice President and
Head, Business
Development &
Licensing at Cipla
Limited

IN



GILLIAN WOOLLETT

Senior Vice President
at Avalere Health

US





**SCIENTIFIC
AGENDA**

08:30 Registration and Welcome Coffee

09:10 Opening of the BioTech Pharma Summit with the President of INFARMED, [Maria do Céu Machado](#)**THE FUTURE OF BIOSIMILARS**09:20 **Biosimilar global development: after >10years are we closer ?**By [Barbara Valenta-Singer](#) - Chief Medical Officer Biosimilar at Fresenius-Kabi SwissBioSim

- > FDA - EMA: how to explain and address different expectations for Equivalence margin, Confidence Interval, clinical endpoints, Reference products
- > Why has interchangeability still not taken up?
- > How does the practice of settlement interfere with the proposed benefits in case of interchangeability?

10:00 Speed Networking

10:20 **Advancing Biosimilars in MENA/GCC**By [Rodeina Challand](#) - Director at Challand Biosimilar Consulting Ltd

- > Biologic/ Biosimilar uptake
- > Regulatory status
- > Challenges
- > Opportunities

11:00 Morning Coffee & Networking Break

REGULATORY LANDSCAPE & PATENT PROTECTION11:30 **Danish experience with switching treatments for patients on to Biosimilar products - regulatory initiatives**By [Nikolai Brun](#) - Chief Medical Officer, Director of Division at Danish Medicines Agency

- > Denmark has championed the active switching of patients onto Biosimilar medicines
- > This review will address the experience in Denmark, and the potential pitfalls and benefits of forcing a hard switch regimen through a population

12:10 **Panel Discussion: Progress in the regulatory landscape for biosimilars**Moderated by [Suzette Kox](#) - Secretary General at IGBA (International Generic and Biosimilar medicines Association)

Panelists: [Maria do Céu Machado](#) - at INFARMED | [Brenda Gomes Valente](#) - at ANVISA | [Nikolai Brun](#) - at EMA/DKMA | [Gillian Woollett](#) - at Avalere Health

13:00 Business Lunch

CLINICAL TRIALS AND REAL-WORLD EVIDENCE14:00 **Enabling an NHS research-ready workforce to embrace the biosimilars boom**By [Lorraine Fincham](#) - Commercial Research Initiative Manager, NIHR

- > Learn how the UK analysed, identified and addressed challenges of embracing the biosimilar boom in the NHS
- > Hear UK experiences of creating an educational resource for the research-ready workforce
- > Understand how a network approach was a crucial component of the solutions proposed

14:40 **Global Comparator Product for Biosimilar Development and Waiving of Bridging Studies**By [Suzette Kox](#) - Secretary General IGBA (International Generic and Biosimilar medicines Association)

- > Definitions of reference, comparator and global comparator product
- > Criteria to qualify as comparator product
- > Rationale for the global comparator product approach
- > Circumstances where bridging studies between local and foreign reference can be waived

15:20 TBA

By [Gillian Woollett](#) - Senior Vice President at Avalere Health

16:00 Coffee & Networking Break

17:00 **Clinical studies of mAb biosimilars: are there any regional differences in requirements?**By [Roman Ivanov](#) - Vice President, Research & Development at BIOCAD

- > EMA vs. FDA requirements
- > Clinical study design issues in China, Russia, India and Latin America
- > Requirements for local clinical studies

17:40 Chairman's Closing Remarks

19:00 Cocktail Reception

08:00 Registration and Welcome Coffee

08:20 Opening Address from the Chairperson

BIOSIMILAR CLINICAL DEVELOPMENT: SCIENTIFIC CONSIDERATIONS AND NEW METHODOLOGIES

08:30 Immunogenicity: anticipating and avoiding issues for biosimilar development

By **João Gonçalves** - Group Leader/Principal Investigator at Research Institute for Medicines / Instituto de Investigação do Medicamento (iMed.Ulisboa)

09:10 Clinical Evidence of Trastuzumab Biosimilar

By **Justin Stebbing** - Professor of Cancer Medicine and Oncology at Imperial College London

09:50 Switching to biosimilars: What have we learned?

Experience of Portuguese rheumatology centers in switching from biooriginators to biosimilars
By **José Marona** - Resident of Rheumatology at Centro Hospitalar de Lisboa Ocidental, EPE – Hospital de Egas Moniz

- > General principles of risk management
- > Risk management plan (RMP): GVP guidelines
- > EU and US approach: RMP vis-à-vis REMS

10:30 Morning Coffee & Networking Break

11:00 Biosimilars: patient perspectives, challenges and emerging solutions

By **Francois-Xavier Frapaise** - Principal at F.-X. Frapaise Consulting

BIOSIMILARS | ACCESS & REIMBURSEMENT

11:40 Biosimilar Transition – A Canadian Insurer’s Experience and Perspective

By **Ned Pojskic** - Leader, Pharmacy & Health Provider Relations at Green Shield Canada (GSC)

- > This session will explore the evidence supporting biosimilar transitioning and will present one Canadian insurer’s experience with a biosimilar transitioning program for patients on Remicade and Enbrel. The results of the program will be presented, with a particular focus on strategies to ensure optimum patient experience, uninterrupted access to safe and effective therapy while providing an important pathway for future sustainability of drug plans

12:20 Portugal, a case of success of pioneer measures that can inspire other countries

By **Fernanda Aleixo** - Director Policy & Market Access at Mylan

- > Reimbursement procedure
- > Access: tenders, prescription, selection of medicine, traceability
- > Access: more patients treated, at earlier stage of the disease

13:00 Business Lunch

BIOSIMILARS MANUFACTURING & COMMERCIALIZATION

14:00 The state of US biosimilar utilization and post-marketing surveillance initiatives to support treatment and coverage decisions

By **Cate Lockhart** - Program Director at Biologics and Biosimilars Collective Intelligence Consortium

- > Describe the background of generic drug uptake in the United States and how it relates to the current biosimilar market landscape
- > Discuss some of the barriers to market access and utilization of biosimilars in the US: Regulatory questions; Commercial tactics; Stakeholder uncertainty
- > Explain the limitations of clinical trial data in supporting clinical and formulary decisions
- > Describe one approach to addressing the lack of real-world data and how it could be used for treatment and coverage decision

14:40 Solve the technical challenges in developing biosimilar antibodies

By **Emile van Corven** - Chief Development Officer at Bioceros

- > High titer processes
- > Modulation of quality attributes
- > Decrease in COGs
- > High throughput analytical methods

15:20 Commercializing Biosimilars in Emerging Markets

By **Rahul Padhye** - Head of Business Development and Licensing at Cipla

- > Market size/opportunity
- > Regulatory considerations
- > Business models
- > Key success factors

16:00 Chairman’s Closing Remarks and End of Summit

SPEAKERS BIOGRAPHIES



SUZETTE KOX, BE
Secretary General
at IGBA (International
Generic and Biosimilar
medicines Association)



Suzette Kox was nominated Senior Director International in October 2015, following 14 years in the position of EGA's Senior Director Scientific Affairs and Coordinator of the European Biosimilars Group (EBG), now Biosimilar Medicines Group, a sector group of Medicines for Europe (formerly EGA). She was the first Chairperson of the Biosimilars Committee of the International Generic and Biosimilar Medicines Association (IGBA).



JOSÉ MARONA, PT
Resident of Rheumatology
Centro Hospitalar de
Lisboa Ocidental, EPE -
Egas Moniz Hospital



José Marona initiated Rheumatology residency in 2016 at Hospital Egas Moniz - CHLO (Lisbon, Portugal). Since 2017 he is also a volunteer lecturer of Rheumatology in NOVA Medical School (Lisbon, Portugal) and a collaborator at the Center of Chronic Diseases from NOVA Medical School (CEDOC-NMS). He has participated in several clinical trials and research projects with particular focus on the impact of Biosimilars in the Portuguese market.



RODEINA CHALLAND, UK
Director at Challand Biosimilar
Consulting



Rodeina Challand B.Sc., Director, Challand Biosimilar Consulting Ltd., Graduate from London University with over 25 years of experience in healthcare, cancer research and pharmaceutical industry across a wide range of roles including developing and implementing clinical development strategies for biosimilars at Hospira Inc. as Director of Clinical Projects and Head of Clinical Operations in the EU.



BRENDA GOMES VALENTE, BR
Health Surveillance and
Regulation Specialist
at ANVISA



Brenda Valente is a Pharmacist, Master in Microbiology by the Federal University of Minas Gerais and Specialist in Pharmaceutical Technology and Health Surveillance. Currently holds the position of Health Surveillance and Regulation Specialist of the Brazilian National Health Regulatory Agency (ANVISA). She works at the Biological's Office at Anvisa since 2005 and her activities includes collaboration in the elaboration of Brazilian regulatory norms and guides on biological products.



EMILE VAN CORVEN, NL
Chief Development Officer
at Bioceros



Dr. Emile van Corven is Chief Development Officer at Bioceros. He has a track record of more than 27 years in the biopharmaceutical industry: global head of process development and pilot plant GMP manufacturing of MAbs and vaccines (Crucell/J&J), and the development or recombinant proteins (Pharming). He was also head of the regulatory authority control lab for the release of blood products/vaccines, and head of the regulatory group for review of biotech CMC dossiers.



NED POJSKIC, CA
Leader, Pharmacy
& Health Provider Relations at
Green Shield Canada



Ned Pojskic is Green Shield Canada's Leader for Pharmacy and Health Provider Relations. In this role, he is responsible for setting GSC's strategic direction with respect to provider and drug benefits management. He takes the lead in managing stakeholder relations with all health care providers, including pharmacy, dental, and paramedical. Ned is also responsible for overall drug formulary management, including pricing and policy as well as pharmaceutical industry partnerships.



RAHUL PADHYE, IN
Vice President and Head,
Business Development &
Licensing at Cipla Limited



Rahul Padhye has been working with Cipla since 2016 as Head BD& Licensing and recently he was assumed responsibility as Global Corporate Development Head. Prior to this, he worked in Reliance Group for 20+ years in various business divisions such as petroleum marketing, infrastructure, alternative energy and life sciences. In life sciences business, he was part of the Executive Management team and was responsible for heading global pharmaceuticals and biosimilars business divisions.



GILLIAN WOOLLETT, US
Senior Vice President
at Avalere Health



Gillian Woollett, Senior Vice President, leads our FDA Practice. She provides the "prequel" of scientific and regulatory strategic policy expertise that supports medicinal products gaining approval at the FDA in a manner that allows them to be successful in the public and private reimbursement world. She is building a bridge for Avalere clients from the FDA space into the traditionally separate Centers for Medicare & Medicaid Services and healthcare policy/business world.



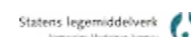
LORRAINE FINCHAM, UK
Commercial Research
Initiative Manager at NIHR
National Institute for Health
Research



Lorraine Fincham is the Commercial Research Initiative Manager for the NIHR Clinical Research Network (CRN). Lorraine has worked actively as an academic researcher for several London Universities, working on prostate and bowel cancer studies after finishing her degree in Psychology and MSc in Health Psychology. She moved to the NIHR Clinical Research Network in 2007, firstly working locally in the North West London Diabetes Research Network as a Primary Care specialist before moving to the NIHR CRN Coordinating Centre in 2010.



STEINAR MADSEN, NO
Medical Director at
Norwegian Medicines Agency



Dr. Steinar Madsen is medical director at the Norwegian Medicines Agency. He has been working with generic substitution since it was introduced in Norway in 2001 and with biosimilars since 2006. He is member and previously chairman of the committee for generic substitution at the Agency. Dr. Madsen is also engaged in the drug information service, with a special interest in the safe and cost-effective use of drugs. He is a specialist in internal medicine and cardiology and works part time as a consultant in cardiology.



ROMAN IVANOV, RU
Vice President, Research
& Development at BIOCAD



Dr. Ivanov was in charge of clinical development and registration of the first biosimilar monoclonal antibody approved in Russia - Acellbia (rituximab). He was also in charge of developing the first Russian biosimilar granulocyte colony stimulating factor, the first biosimilar trastuzumab and bevacizumab approved in Russia. Two next-in-class pegylated biologics developed under his supervision have been launched in Russia. Currently he supervises clinical development of several other biosimilars and next-in-class biologics as well as non-clinical studies of multiple innovative products developed by BIOCAD.



NIKOLAI BRUN, DK
Chief Medical Officer.
Director of Division at
Danish Medicines Agency



Dr. Nikolai Brun practiced as a physician in the clinical field (Pediatrics) for a couple of years before continuing research and development work in the pharmaceutical industry especially working with biopharmaceuticals. Dr. Brun has authored a long list of publications in high-impact journals. Recently he joined the Danish Medicines Agency and has now worked 2 years as Chief Medical Officer and Director of the Division for Medical Evaluation and Biostatistics. Dr. Brun is the Chair of the European Medicines Agency (EMA)/Heads of Medicines Agencies (HMA) Big Data Task Force as of April 2018.



CATE LOCKHART, US
Program Director
at Biologics and Biosimilars
Collective Intelligence
Consortium



Cate Lockhart, MS, PharmD, PhD is the Program Director for the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC.org) where she is responsible for both the business and research programs of this large, multi-stakeholder research collaboration. She has done extensive research, medical writing and consulting in multiple disease states and therapeutic areas, producing clinical and economic reviews, pharmacoeconomic models and AMCP dossiers to support formulary decisions and value assessments of pharmaceutical products across a variety of therapeutic areas.



JOÃO GONÇALVES, PT
Group Leader/Principal
Investigator at iMed-The
Research Institute for
Medicines



João Gonçalves is Head of the Biopharmaceutical Biotechnology Unit at the Institute of Innovative Medicines and Professor of Immunology and Biotechnology both part of the Faculty of Pharmacy, University of Lisbon, Portugal. He is also Head of Antibody Engineering Laboratory at iMed - Faculdade Farmacia Universidade Lisboa. Professor João Gonçalves has a pharmaceutical degree and PhD in Immunology at the University of Lisbon, and has obtained Pharmaceutical Medicine management post-graduation from the University of California at San Diego and Post-doctoral training at Scripps Research Institute at La Jolla.



ANNA ROSE WELCH, US
Chief editor
at Biosimilar Development



Anna Rose Welch is the chief editor of Biosimilar Development, an online publication featuring executive interviews and thought leadership columns about biosimilar industry trends and regulatory/commercialization challenges. In addition to being a speaker at several U.S. biosimilar conferences, she was also invited to Brazil in 2018 to address members of the Brazilian Ministry of Health, ANVISA, and local biologics and biosimilars manufacturers about how to establish a national biosimilar policy. Her writing will be featured in a book on biosimilars forthcoming from Springer.



FRANCOIS-XAVIER FRAPISE, FR
Principal at F.-X. Frapaise Consulting

Dr. Francois-Xavier Frapaise, M.D has over 35 years of international drug development, strategic planning and marketing experience at major pharmaceutical companies including Sanofi, Bayer, Boehringer, Merck and Abbott; he has held multiple C-level positions (CSO,CMO,CEO) in different Pharmacos in the US and Europe. Until recently, he was heading Clinical Development, Medical Affairs and Pharmacovigilance at Merck KGaA Biosimilars Division; he has extensive experience of biosimilars development acquired at Boehringer-Ingelheim and Pfenex; he now runs a consulting business, based in Paris.



FERNANDA ALEIXO, PT
Director Policy & Market
Access at Mylan



Fernanda Aleixo is specialist in Regulatory Affairs and member of the council of specialists of the National Association of Pharmacists. Involved in the launch of first biosimilars medicines in Portugal; Epoetin (2008), Filgrastim (2010) and Infliximab (2013). Leader of the Technical Commission of Apogen (the trade association for generic and biosimilars medicines) from 2012-2015, and from 2016 until now. Developed several activities with different stakeholders aiming to increase the education of the science behind the biosimilars medicines with the goal to share their value for the society, to increase the confidence on these health technologies, and to contribute for more rational and conscientious decisions.



MARIA DO CÉU MACHADO, PT
President at the National
Authority of Medicines and
Health Products (INFARMED)



Maria do Céu Machado is a medical doctor (MD, PhD), President of the Executive Board of INFARMED (Portuguese Medicines Agency), Full Professor of Pediatrics at the Faculty of Medicine - Lisbon University, Vice-President of the Federation of European Academies of Medicine and Member of the National Council of Ethics for the Life Sciences. She is an Expert Consultant of the Portuguese Health Plan 2016 - 2020. Prof Machado was High Commissioner for Health (2006-2011) in Portugal, Director of the Department of Pediatrics and Clinical Director of the University Hospital Santa Maria in Lisbon, President of the Nacional Committee for the Children and Adolescents Health and President of the Pediatrics Medical Association.



BARBARA VALENTA-SINGER, CH
Chief Medical Officer
at Fresenius-Kabi SwissBioSim



Barbara, a MD and pharmacologist by training, has over 25year industry experience gained at Pharmacia, Pfizer, Whyet, Baxter and Baxalta in different medical, clinical, safety and regulatory roles working in local, regional and global organizations. She holds the position of the Chief Medical Officer of the Fresenius Kabi Biosimilar unit. Before joining industry, she had the opportunity to experience the perspective of a Regulatory Agency, Academia and direct patient interactions. Her deep understanding of drug development results from filling operational and strategic assignments with exposure to small molecules and biologics, innovative compounds and Biosimilar. The increasing demand for affordable treatments has attracted her to focus on the challenges of Biosimilar development.



JUSTIN STEBBING, UK
Professor of Cancer Medicine
and Oncology at Imperial
College London



Prof Stebbing undertook training and a residency programme at The Johns Hopkins Hospital in the US, returning to London to continue his career in oncology. Prof Stebbing's original PhD research investigated the interplay between the immune system and cancer; he was appointed a senior lecturer in 2007, and a Prof in 2009. Prof Stebbing has published over 600 peer-reviewed papers. The National Institute for Health Research (NIHR) awarded Stebbing its first translational research professorship in oncology, aiming to bridge the gap between the laboratory and the patient to ensure therapy is personalised. In 2016 Justin was internationally recognised with his appointment as Editor-in-Chief of Oncogene (Springer Nature's foremost cancer journal) and election to the American Society for Clinical Investigation.

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	<i>Super Early Bird Until December 14</i>	<i>Early Bird Until February 15</i>	<i>Discounted Ticket Until March 8</i>	<i>Normal Ticket After March 8</i>
Academic/ Med./ NPO Package	500€	600€	650€	850€
Industry Package	1,495€	1,695€	1,795€	1,995€
Premium Package	2,800€	3,000€	3,250€	3,550€

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Team Discounts	Until December 14	Until February 15	Until March 8	After March 8
2 Delegates	10%	5%	-	-
3 Delegates	15%	10%	5%	-
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