"Uniting industry leaders to analyse advanced commercial developments & to identify successful strategies of Biosimilars"

23rd & 24th June 2021, Virtual Conference (Time Zone - BST)

AGENDA AT A GLANCE

Key Speakers Include



CLAUDIA LOUATI Policy Advisor FDA



FREDRIK SUNDBERG Global Director, Strategic Technology Partnership, Cytiva (Formerly GE Life Sciences)



RAJESH DESIKAN Vice President & Head, US Marketing, Oncology & Immunology Biosimilars Fresenius - Kabi



JULIE MARECHAL JAMIL Director Biosimilar Policy & Science Medicines for Europe



MATTHEW TURNER Senior Director Government Affairs and Policy Biosimilars Europe, Asia, Latam & Canada, Fresenius Kabi



CECIL NICK Vice President Parexel



ANNA AILLERIE Brand Management Lead, Europe Dr Reddy's Laboratories SA



MIGUEL NAVARRETE OLMEDO Hospital & Biosimilars Commercial Director STADA Arzneimittel



LOUIS BOON CSO Polpharma Biologics



HANMANT BARKATE Vice President & Head Medical Services (India, MEA), Glenmark



SWEETY MATHEW Regulatory Affairs Biocon

NIKLAS EKMAN





OMAR ALI Pharmacist Consultant QIPP Adviser Payer Network



RENE ANOUR Senior Clinical Expert/Head of National Scientific Advice, Austrian Medicines & Medical Devices Agency (AGES)

Head of the Biological Section, Finnish

Biosimilar Working Party (BMWP), EMA)

Medicines Agency (Vice-Chair of the



BER OOMEN Executive Director, ESNO (European Specialist Nurses Organisations)

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MICHEL MIKHAIL International Expert in Biosimilars Global Expert in Regulatory Affairs



LENNEKE DE WINTER Senior Scientist USP Polpharma Biologics



JAKOB LANGE Senior Director Delivery Systems Ypsomed



ANDREAU SOLDEVILA Founder & CEO Syna Therapeutics



INGRID SCHWARZENBERGER Senior Regulatory Consultant, Independent Consultant (Former Head Global Regulatory Policy, Sandoz)

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Senior VP, Business Development



SANDY EISEN **Chief Medical Officer** Frontline Pharma Consulting Ltd



ZIQUN HAN Director Zen Medical Science



MARIE MANLEY Partner, Head of the UK Life Sciences Sidley Austin



ALEXANDER ROUSSANOV Life Sciences Regulatory & Privacy Lawyer Arnold & Porter



ROBERT A. JOHNSTONE Board Member International Alliance of Patients Organisations

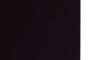












BERT THOMAS Bio -Thera Solutions



Key Speakers Include

JOHAN DE MUNTER Assistant Nurse Manager Cancer Center University Hospital Ghent, President, European Oncology Nursing Society

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Plus more COMING SOON

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AGENDA AT A GLANCE

Key Speakers Conference Info Day One Day Two **Booking Details**

CONFERENCE INTRODUCTION

Global biosimilars market size is expected to grow from USD 35.7 billion by 2025 from USD 11.8 billion in 2020, at a CAGR of 24.7%. This industry is experiencing significant growth due to the rising incidence of chronic diseases and the increasing demand for biosimilars due to their cost-effectiveness. The growth in the market may be attributed to the cost-effectiveness of the biosimilars when compared to reference biologics coupled with the patent expiration of the many blockbuster biologic drugs. Increasing investment by the companies for the development of biosimilars will also be the key factor driving the market. According to a recent report, as many as nine drugs in the biologics category have either gone off patent or will do so by 2025. Their total revenue was \$62 billionin 2018. This creates a major opportunity for their respective biosimilars. It is estimated that revenue of these biosimilars will grow by 24 per cent annually for seven years to \$13.3 billion in 2025 in the US and Europe. That offers a big opportunity

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Our 15thBiosimilars Congregation 2021 will provide insight into the current state of play in the EU and stimulate debate, in a multi-stakeholder setting, on the vital role of biosimilar medicines in the sustainability of healthcare systems. Beyond a comprehensive multi-stakeholder setting, on the vital role of biosimilar medicines in the sustainability of healthcare systems. Beyond a comprehensive outlook of key European market access policies, our speakers will outline the key recent developments in regulatory science and regulatory policy in the EU and other international jurisdictions. Special emphasis will be placed on strengthening the link between regulators and medical communities as an essential basis for greater understanding and acceptance of biosimilar medicines. This Biosimilars conference will focus on multiple aspects of Biosimilar product development to successfully deliver safe, Biosimilar products to the market place. By attending this conference, you will gain a comprehensive outlook on the key issues surrounding Biosimilars. This event will provide an important platform for Biosimilars stakeholders to discuss and share best practices in furthering Biosimilars development.

It gives me great pleasure in welcoming all of you to the Virtue Insight's 15thBiosimilars Congregation 2021.

숚 CERTIFICATION 🙀

E-Certificate of attendance would be provided to attendees on request, upon completion of conference

KEY THEMES

- Strategies for market access and expansionby identifying key changes and future projections Understanding the biosimilars opportunity for pharma companies Consequences of Brexit & this pandemic situation on Biosimilars Current Challenges and Opportunities for future- Strategies in developing Biosimilars A Clinician's Guide to Biosimilars in Oncology: understanding the Science of Extrapolation and Interchangeability Biosimilars Pricing & Market access Bringing it faster into market

- GMP, GCP, QC & R&D Current challenges and opportunities strategies to develop Biosimilars Payer perspective on biologics and Biosimilars Biosimilar Interchangeability: The newest regulation

- Biosimilar Physicians and Patients perspective CMC, Preclinical and clinical considerations for Biosimilars and Follow-on Biologics
- Impact of Technology
- Commercial landscape & market access for Biosimilars: Predicts to prepare for a successful tomorrow Hear case studieson biosimilars drug development from pre-clinical to clinical and the various testing required such as immunogenicity and bio-similarity tests
- Research-based industry Biosimilar strategies
- Considerations for the analytical similarity assessments when designing a Biosimilar development program
- Determining the right investments & potential returns from Biosimilars
- Latest developments in regulation to increase speed of entry and compliance
- Future of next generation biosimilars
- Be part of a major networking opportunity

WHO SHOULD ATTEND

CSOs, CMOs, Vice Presidents, Presidents, Heads, Directors, Team Leaders, and Senior Scientists from the following roles:

Biopharmaceuticals/ Biotherapeutics, Follow on Biologics/Follow on Proteins/Biosimilars, Biologics/Biotechnology/ Biogenerics, Legal Affairs, Intellectual Property, Health Economics, Pricing and Reimbursement, Clinical Immunology, Principal Scientist, Chief Scientific Officer, Process Control and Analytical Technologies, Analytical Characterisation, Regulatory Compliance, Pharmacovigilance, Drug Safety & Risk Management, Quality Affairs/ Quality Control, New Product Development, Process Science, Portfolio Management, Research & Development, Business Development, Business Operations, Scientific Affairs, Commercial Affairs, Marketing

WHY SHOULD YOU ATTEND

Get more from the event, enjoy and make the best out of our dedicated networking drinks time, meet the leading international vendors showcasing the products of tomorrow in the co-located exhibition. **Expand your knowledge** of the latest business models and strategies in the high-level conference. Whether you are on the branded or generic side, you cannot afford to miss this opportunity to benchmark your tactics and strategies against the industry leaders who will be the first to traverse the pathway. Devise an immediate action plan for your biosimilar prosecution and litigation strategies in light of the barriers to entry, research and development costs, and regulatory hurdles, which are balanced against an enormous potential for increased profit margins.

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AGENDA AT A GLANCE

DAY ONE - 23rd June 2021

09:30 - Welcome Address & Virtual Conference Platform Instructions

MARKET OVERVIEW & ANALYSIS

Innovation and Technology for Biosimilar Development

PAYER'S PERSPECTIVE

10:20 - Biosimilars - Bringing it into the market quickly

Strategies in overcoming obstacles in Biosimilar

Requirements for product development program

Bridging the 'uncertainty gap' between payers &

..........

CHALLENGES & OPPORTUNITIES

Effective strategies for product design

Global impact of biosimilars over generics

How Payers are aligning biosimilars?

pharma - the shifting paradigm

What to expect in the next 2 years?

11:00 - Morning Coffee/Tea & Discussion

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09:40 - The biosimilar business case - A Growth formula

for generics biosimilars

Globalization of Biosimilars GMP, GCP, QC & R&D

Licensing of biosimilars

development

OMAR ALI

Pharmacist Consultant

QIPP Adviser Payer Network

Generics and Biosimilars: Industrial Strategy

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Moderator:

LOUIS BOON CSO **Polpharma Biologics**

Panellists:

CLAUDIA LOUATI Policy Advisor FDA

JULIE MARECHAL JAMIL **Director Biosimilar Policy & Science Medicines for Europe**

MATTHEW TURNER Senior Director Government Affairs and Policy Biosimilars Europe, Asia, Latam & Canada, Fresenius Kabi

RENE ANOUR Senior Clinical Expert/Head of National Scientific Advice Austrian Medicines & Medical Devices Agency (AGES)

JOHAN DE MUNTER Assistant Nurse Manager Cancer Center University Hospital Ghent, President, European Oncology Nursing Society

SANDY EISEN **Chief Medical Officer** Frontline Pharma Consulting Ltd

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12:00 - Topic TBC

BER OOMEN Executive Director ESNO (European Specialist Nurses Organisations)

......

12:40 - Networking luncheon

PATIENT'S PERSPECTIVE

13:50 - Analysing Physicians and Patients perspective

- National and International developments in biosimilar medicines
- Physicians education Challenges
- Importance of Physician and Patients inputs to shape the international standards for biosimilars
- Encouraging physicians Policies

- Looking at sustaining growth through pandemic Current Challenges and Research trends in Biosimilars & Biologics
- Issues to overcome to increase uptake of biosimilars

11:20 - Keynote Panel Discussion: Understanding the biosimilars opportunity for pharma companies

Latest developments, Trends and Future of Biosimilars

- Generate enough interest and enthusiasm for biosimilars
- Lack of stakeholder confidence what does this lead to?

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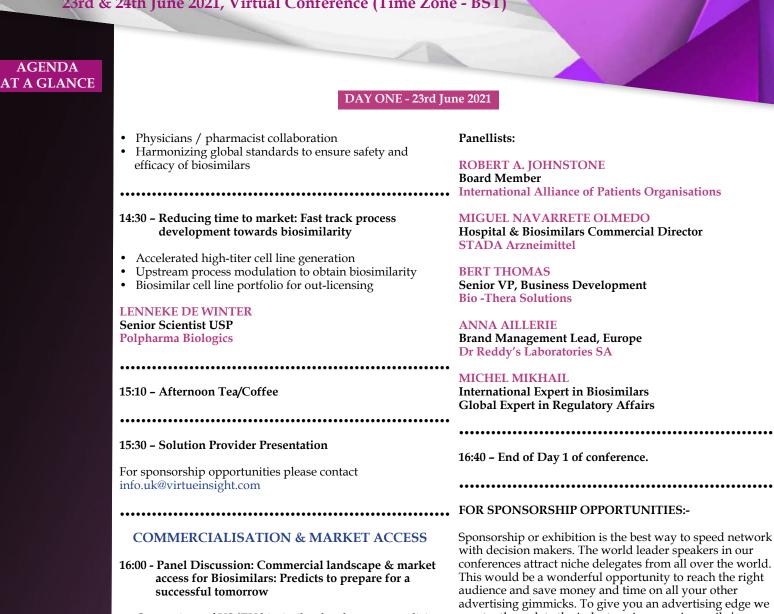


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- Comparison of US/EU biosimilar developments, policies and guidelines
- The impact of Biosimilars on the competitive landscape of biological products
- Challenges and obstacles faced by manufacturers in developing biosimilars
- Bringing the next generation of Biosimilars to the market
- Ensuring market access and reimbursement
- Evidence generation will be the key to future success
- Stakeholders approach in successfully bringing Biosimilars to the market

Moderator:

RAIESH DESIKAN

Vice President & Head, US Marketing, Oncology & Immunology Biosimilars, Fresenius - Kabi

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conferences attract niche delegates from all over the world. advertising gimmicks. To give you an advertising edge we constantly update the industry pioneers via emails/news letter about the event and advertise the event via different forms of media.

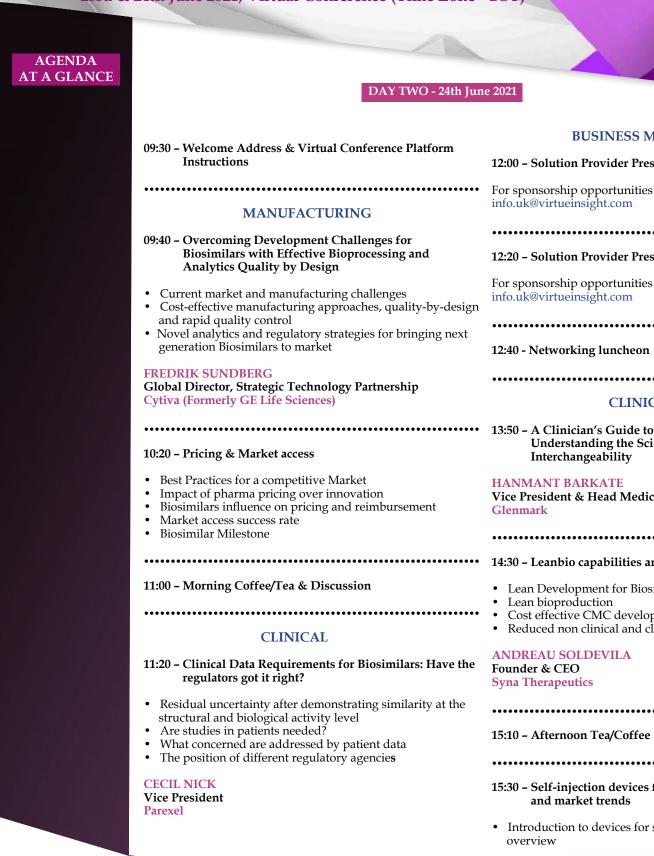
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BUSINESS MODELS

12:00 - Solution Provider Presentation

For sponsorship opportunities please contact

12:20 - Solution Provider Presentation

For sponsorship opportunities please contact

CLINICAL

13:50 - A Clinician's Guide to Biosimilars in Oncology: Understanding the Science of Extrapolation and

Vice President & Head Medical Services (India, MEA)

14:30 - Leanbio capabilities and pipeline

- Lean Development for Biosimilars
- Cost effective CMC development
- Reduced non clinical and clinical program

15:30 - Self-injection devices for biosimilars - overview

Introduction to devices for self injection with market

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AGENDA AT A GLANCE

DAY TWO - 24th June 2021

- Particular needs for the biosimilar area including IP aspects
- Recent trends from the market place 1 larger volumes
 Recent trends from the market place 2 carbon neutrality and renewable materials

JAKOB LANGE

Senior Director Delivery Systems Ypsomed

REGULATION OVERVIEW & UPDATE

16:10 - Panel Discussion: The developing regulatory framework in advanced and developing markets

- Market and regulatory developments in the Europe and globally
- Predicting the post Brexit changes in biosimilars regulation in UK
- EMA's act on switching & interchangeability?
- How regulators, payers and policy makers take initiatives to make healthcare more sustainable
- Collaboration with HTA's for patients benefit
- CMC regulatory considerations for Biosimilar products development
- Regulatory changes necessary to maximize biosimilars potential
- The way forward

Moderator:

LOUIS BOON CSO Polpharma Biologics

Panellists:

INGRID SCHWARZENBERGER Senior Regulatory Consultant, Independent Consultant (Former Head Global Regulatory Policy, Sandoz)

NIKLAS EKMAN

Head of the Biological Section, Finnish Medicines Agency (Vice-Chair of the Biosimilar Working Party (BMWP), EMA)

SWEETY MATHEW Regulatory Affairs Biocon ZIQUN HAN Director Zen Medical Science

MARIE MANLEY Partner, Head of the UK Life Sciences Sidley Austin

ALEXANDER ROUSSANOV Life Sciences Regulatory & Privacy Lawyer Arnold & Porter

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16:50 - End of conference

FOR DELEGATE REGISTRATIONS:-

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - info.uk@virtueinsight.com

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Delegate Detail	ls:	
Title	Mr Mrs Ms Dr	E-Certificate of
First Name		request, upon co
Surname		FOR BANK T
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		Payment terms:

How to Pav (Choose one of the following payment options)

RESERVATION PRICING:

EARLY BIRD PRICE

1 Delegate @ £300 +VAT (Valid Till 17th May 2021)

3 Delegates @ £700 +VAT (Valid Till 17th May 2021)

STANDARD RATE

1 Delegate @ £500 +VAT (Valid From 18th May 2021) 3 Delegates @ £1200 +VAT (Valid From 18th May 2021)

PAYMENT:

ress
nts Ltd

Card type: Visa Mastercard Maestro Amex

CERTIFICATION

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attendance would be provided to attendees on ompletion of conference

ANSFER:

- Virtue Insight Events Ltd

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ank Name - Barclays Bank PLC	Sort Code - 20-84-20
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de: 026002574

CONDITIONS:

Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.

Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of £200

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Video : If you cannot attend the conference, you can still purchase the Video of the virtual conferences for £300.

Indemnity: Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will reschedule the event.

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