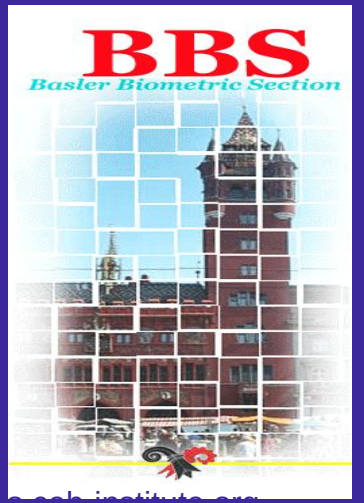
AmerisourceBergen
Xcenda

Precision & Innovative Medicine and Health Technology Assessment

BBS and EFSPI Virtual Seminar

Monday, June 28, 2021 **15:00 to 17:30 (CET)**



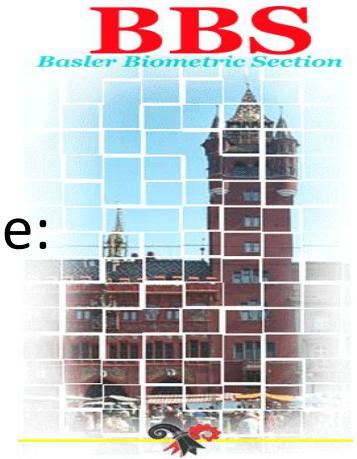
EFSPI

Welcome to the HTA Webinar

On behalf of the BBS, EFSPI & Organizing Committee:

- Pierre VERWEIJ (Idorsia, Switzerland) - BBS & EFSPI
- Egbert BIESHEUVEL (Danone, Netherlands) – EFSPI
- Fred SORENSON (Xcenda, Switzerland) - BBS
- Laurence GUILLIER (Roche, Switzerland)
- Bibiana BLATNA (Novartis, Switzerland)
- EFSPI administration (Kingston Smith, UK)

- Meeting housekeeping rules
- Agenda



bbs.ceb-institute.org

Webinar Housekeeping

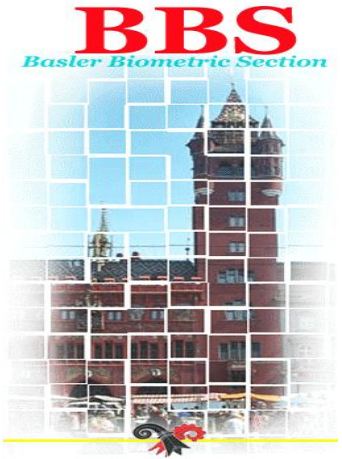
We will all aim to keep On-time

Switch-off micros and cameras / preserve network bandwith

Only the speaker is on

The webinar is being recorded and the presentations (as PDF) will be made available on the BBS and EFSPI websites shortly if granted approval by the presenters

Questions to be asked via the chat room & will be pushed to the panel discussion after each block of presentations



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EFSPI

Agenda – 1st Block of Presentations

15:05: The UK's Innovative Licensing and Access Pathway (ILAP) for medicines: A joint MHRA, NICE & SMC initiative

Dan O'CONNOR, Medical Assessor, MHRA, UK

15:20: IMPACT HTA - Recommendations for Developing Rare Disease Treatments

Karen FACEY, Evidence Based Health Policy Consultant & Visiting Senior Research Fellow, University of Edinburgh, UK

15:35: Adjusting Global Survival to Make Results More Relevant and Generalizable to Local Markets

Paul CISLO, Director of Biostatistics; Jinma REN, Director, Statistics (HEOR); Joseph C. CAPPELLERI, Executive Director of Biostatistics and Head of the HEOR Statistics Unit, Pfizer Inc., USA

15:50: Net benefit and correlation between benefit and harms

Marc BUYSE, Chief Scientific Officer at IDDI and Associate Professor of Biostatistics at Hasselt University, BELGIUM

16:05: Panel discussion with questions for all previous speakers

16:15: 5-minute break

Agenda – 2nd Block of Presentations

16:20: Closing the efficacy to effectiveness gap: Generalizing from RCTs to real world populations

Mark BELGER, Principal Research Scientist, Lilly, UK; Marie-Ange PAGET, Research Scientist, Lilly, FRANCE

16:35: Assessments and reimbursement of gene expression signature tests in Europe Treatments

Kirsten HERRMANN, Associate Director Market Access & Reimbursement DACH/ NL, Exact Sciences, GERMANY

16:50: Bridging the gap between Regulatory & HTA approval for Precision Medicine therapies: a case study from the Netherlands

Janneke BOERSMA, Chapter Lead Patient Access, Roche, NETHERLANDS

17:05: Acceptance and Uptake of Cell and Gene Therapies: Lessons Learned and Future Focus

Tay SALIMULLAH, Vice President, Global Head Patient Access, Novartis Gene Therapies, SWITZERLAND & USA

17:20: Panel discussion with questions for all previous speakers & end of webinar at 17:30

"Everything about cell and gene therapies is so unique… Every trial we learn something new, every patient we learn something new, every institution is different. So I don't want anyone to come and tell me they have all the answers. Instead, [we need to] grow together."

CGT Commercialization Lead

thank you