Precision & Innovative Medicine and Health Technology Assessment

BBS and EFSPPI Virtual Seminar

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

- We will all aim to keep On-time

- Switch-off micros and cameras / preserve network bandwidth
  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
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