What's the HTA ESIG doing to prepare for EU HTA?



Emma Crawford (MSD), Anders Gorst-Rasmussen (Novo Nordisk), Sandro Gsteiger (Roche), Kirsten H. Herrmann (Pharming Group), Katrin Kupas (BMS), Martin Scott (Numerus), Fred Sorenson (Xcenda) - on behalf of HTA European Special Interest Group, sponsored by PSI and EFSPI

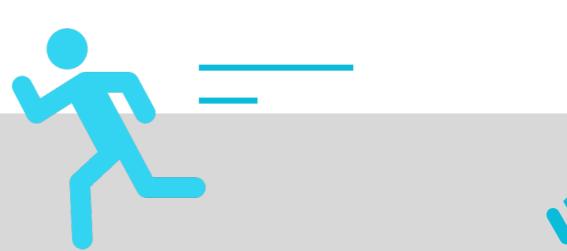


Planning development program to cater to both regulatory and HTA needs

Manufacturer
submits evidence
dossier
(≥45d before CHMP)



EMA submission triggers
Joint Clinical Assessment (JCA) for HTA



Consolidated PICOs communicated (~120d before CHMP opinion)



Population
Intervention
Comparators
Outcomes

x 27



JCA report published (≤30d post EC decision)



What are high-level EU HTA pain points that the ESIG identifies – and how are we addressing them?

An urgent need for collaboration and bridging – within and across disciplines



3 white papers in development



 Participation at relevant conferences/events (ISPOR, DIA, PSI, EFSPI) Insufficient training in advanced HTA statistical methodology and thinking



- Podcasts with The Effective Statistician¹
- 1 webinar in 2022, 2 webinars in development
- HTA handbook update in progress
- HTA training for PSI (& beyond!)

Practical and scientific challenges that pharma statisticians are uniquely positioned to advise on



- Cross-ESIG collaborations
- Representing EFSPI at the European Commission HTA Stakeholders Network



 Communicating about methodological aspects (eg, EUnetHTA21 public consultations)



Communications is overarching!

- Leading active discussions on LinkedIn
- Collaborating with relevant professional societies
- Promoting our activities via PSI and EFSPI communication channels
 See our HTA ESIG webpage for latest updates!





What are YOUR EU HTA pain points – and how can the ESIG help YOU address them?

Share your answers on a Post-it here!



