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

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on behalf of HTA European Special Interest Group, sponsored by PSI and EFSPI

EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY
Representing Statistical Associations in Europe

Planning development program to cater to both regulatory and HTA needs

EMA submission triggers Joint Clinical Assessment (JCA) for HTA

Consolidated PICOs communicated (~120d before CHMP opinion)

JCA report published (≤30d post EC decision)

Manufacturer submits evidence dossier (≥45d before CHMP)

Population
Intervention
Comparators
Outcomes

x **27**

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

Insufficient training in advanced HTA statistical methodology and thinking

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

WHITE PAPER

- 3 white papers in development

- Participation at relevant conferences/events (ISPOR, DIA, PSI, EFSPI)

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

- 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!

[1]https://theeffectivestatistician.com/

CHMP = Committee for Medicinal Products for Human Use, EC = European Commission, ESIG = European Special Interest Group, HTA = Health Technology Assessment, JCA = Joint Clinical Assessment, PICO = Population, Intervention, Comparators, Outcome

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Join us