



Brussels, 19 February 2023

**8<sup>TH</sup> MEETING**

**SUBGROUP FOR METHODOLOGICAL AND PROCEDURAL GUIDANCE**

**19 FEBRUARY 2024**

*The meeting is taking place online*

**10.00 – 10.15**

**1) Opening of the meeting**

- Welcome by Chair and Co-Chair
- Information on COI and request for updates to DOI forms
- Approval of the agenda
- Approval of minutes from 7<sup>th</sup> meeting

**10.15 – 11:00**

**2) Discussion and validation of the Guidance on direct and indirect comparisons**

- Overview of the SG comments received and the revisions resulting from the comments
- Discussion of open questions
- **Decision point:** Validation of the guidance on direct and indirect comparisons by the SG

supporting documents: answered comments and revised guidances (available in the MPG SG meeting section on the IT platform)

**11.00 – 11.30**

**3) Overview of the guidance on validity of clinical studies**

- Working group and timelines for guidance on validity of clinical studies
- Overview of the EUnetHTA21 guidance on validity of clinical studies

supporting document: EUnetHTA21 guidance on validity of clinical studies (available on: <https://www.eunetha.eu/d4-6/>)

*11.30 – 11:45*

*Break*

**11.45 – 12:45**

**4) Discussion of the Guidance on endpoints**

- Overview of the SG comments received
- Overview of comments solved in working group including discussion of questions from SG members
- Discussion of open comments

Supporting documents: answered comments and revised guidance (available in the MPG SG meeting section on the IT platform)

**12.45 – 12:55**

**5) General information**

- Update on the IT Platform by DG Sante
- Next steps

**12.55 – 13.00**

**6) Closing of the meeting**

- AOB and concluding remarks by Chair and co-Chair