



Brussels, 25 June 2024

**12<sup>TH</sup> MEETING**

**SUBGROUP FOR METHODOLOGICAL AND PROCEDURAL GUIDANCE**

**25 JUNE 2024**

*Location*

*The meeting is taking place online*

**AGENDA**

**9.00 – 9.15**

**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 10<sup>th</sup> meeting

**9.15 – 10:00**

**2) Discussion and validation of the final Guidance on validity of clinical studies**

- Overview of the SG comments received and the revisions resulting from the comments
- Discussion of open questions
- **Decision point:** validation of the final guidance by the SG

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

**10.00 – 11:00**

**3) Discussion on the guidance on filling in the dossier template**

- Overview of the SG comments received
- Discussion of open questions
- Next steps

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

*11.00 – 11:15*

*Break*

**11.15 – 11:45**

**4) Update on the development of the procedural guidance for JCA (medicinal products)**

- Overview of main comments and open questions
- Next steps

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

**11.45 – 12:30**

**5) Discussion of the update of the scoping guidance**

- Open questions based on experience from PICO exercises
- Timelines of the update

**12.30 – 12:55**

**6) General information**

- Update on the IT Platform by DG Sante
- Report on guidance discussion with Stakeholder Network
- Update on JSC document review by MPG SG
- Next steps

**12.55 – 13.00**

**7) Closing of the meeting**

- AOB and concluding remarks by Chair and co-Chair