



Brussels, 18 April 2024

10TH MEETING

SUBGROUP FOR METHODOLOGICAL AND PROCEDURAL GUIDANCE

18 APRIL 2024

Location

Conference Centre Albert Borschette (CCAB) (Room 2C), Rue Froissart 36, 1040 Brussels

The meeting is taking place in hybrid format

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 9th meeting

9.15 – 10:15

2) Discussion of the guidance on outcomes for JCA

- Overview of the SG comments received
- Overview of comments solved in working group including discussion of questions from SG members
- Discussion of open comments
- **Decision point:** validation of the guidance on outcomes for JCA

Supporting documents: answered comments and revised guidance; supporting document with open questions for consideration before the meeting; compiled results from the survey (available in the MPG SG meeting section on the IT platform)

10.15 – 11:00

3) Discussion of the guidance on validity of clinical studies

- 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)

11.00 – 11:15

Break

- 11.15 – 11:45** **4) Overview of the guidance on specific medicinal products (renamed as: Criteria defining medicinal products subject to joint clinical assessments)**
- Overview of the SG comments received
 - Overview of comments solved in working group including discussion of questions from SG members
 - **Decision point:** validation of the guidance
- Supporting documents: answered comments and revised guidance (available in the MPG SG meeting section on the IT platform)
-
- 11.45 – 12:15** **5) Discussion of experiences from the PICO surveys**
- Consolidation of outcomes
-
- 12.15 – 12:45** **6) Update on the guidance concerning the JCA process and the corresponding templates**
- Working groups and timelines
 - Next steps
- Supporting documents: Implementing Act for public consultation and EUnetHTA 21 deliverables (available in the MPG SG meeting section on the IT platform)
-
- 12.45 – 12:55** **7) General information**
- Update on the IT Platform by DG Sante
 - Next steps
-
- 12.55 – 13.00** **8) Closing of the meeting**
- AOB and concluding remarks by Chair and co-Chair