



Brussels, 18 March 2024

9TH MEETING

SUBGROUP FOR METHODOLOGICAL AND PROCEDURAL GUIDANCE

18 MARCH 2024

The meeting is taking place online

AGENDA

10.00 – 10.15

1) Opening of the meeting

- Welcome by Chair and Co-Chair
- Information on Conflicts of interest and request for updates to Declarations of interest forms
- Approval of the agenda
- Approval of minutes from 8th meeting

10.15 – 11:15

2) Discussion of the guidance on applicability of evidence for JCA

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

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

11.15 – 11:30

Break

11.30 – 12:00

3) Discussion of first experiences from the PICO surveys

- Request of specific analyses in the PICO survey
- Requests for safety outcomes in the PICO survey

12.00 – 12:30

4) Information on next steps concerning the JCA process and the corresponding templates

- Co-operation with the JCA subgroup
- Working groups on the JCA process and the dossier and report templates

Supporting documents: Implementing Act for public consultation (to be published in beginning of March on this website:

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13708-Health-technology-assessment-joint-clinical-assessments-of-medicinal-products_en)

12.30 – 12:45

5) Overview of the current gap repository

Supporting documents: the current gap repository (available in the MPG subgroup meeting section on the IT platform)

12.45 – 12:55

6) General information

- Update on the IT Platform by DG SANTE
- Information from other meetings
- Next steps

12.55 – 13.00

7) Closing of the meeting

- Any other business and concluding remarks by Chair and co-Chair