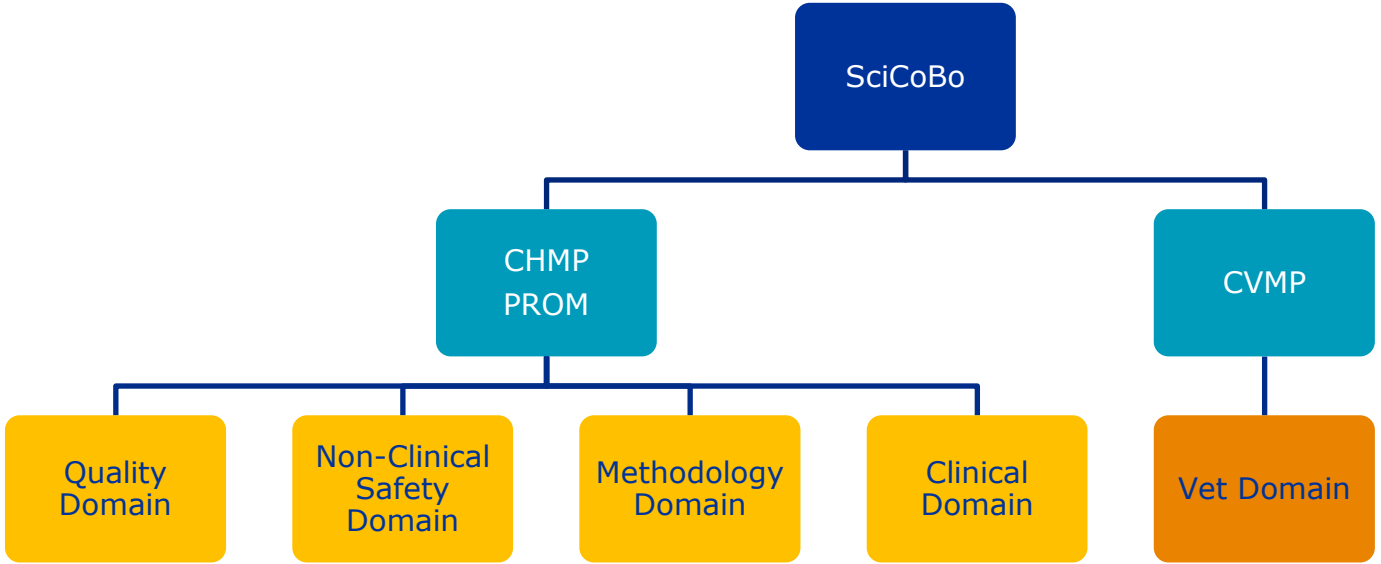
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to the Methodology Working Party

Overview and Work Plan Highlights

HMA/EMA BDSG Workshop on RWE methods

Working Parties organised into ***Five Domains***



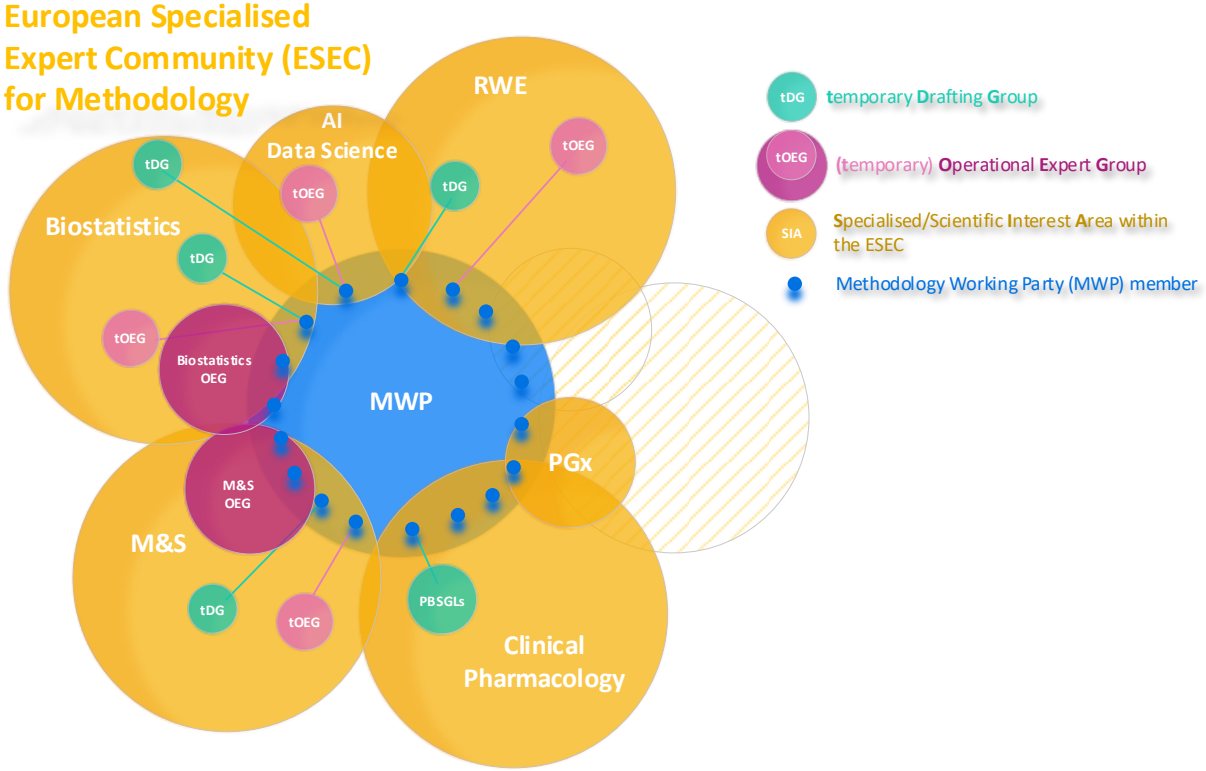
MWP: A working party of the CHMP, serving the EMRN more broadly.
Established 2022 following (a.o.) a recommendation of the Big Data Steering Group.

Key tasks of the MWP

- Providing **product-related support** when requested by EMA Committees and the Scientific Advice Working Party.
- **Preparing, reviewing and updating** guidelines and concept papers.
- **Engaging with stakeholders.**
- **Develop the EMRN methodology competence** and provide training and workshops to assessors.

23 members based on experience in Biostatistics, M&S, Clinical Pharmacology, RWE, Pharmacogenomics, AI & Data Science **meeting every 2 weeks**

European Specialised Expert Community core to MWP success



ESEC members by SIA	N
RWE	91
Biostatistics	83
Clinical Pharmacology	73
AI & Data Science	61
M&S	54
PGx	26
Total	202

A few outcomes relevant to todays workshop

Draft Reflection Papers……

- On establishing efficacy based on single arm trials submitted as pivotal evidence in a marketing authorization.
- On the use of Artificial Intelligence (AI) in the medicinal product lifecycle.
- Data Quality Framework.

- On use of real-world data in non-interventional studies to generate real-world evidence.

And on the draft MWP 3 year rolling workplan (selected)

To take into account Interested Parties input of June 7th and beyond….

- (Designs with) External controls
- Bayesian statistics
- Platform trials

- GL on predictive biomarker co-development
- AI in clinical development & AI in pharmacovigilance
- ……

Of note: Nature of guidance and supporting innovation

- Topics of substantial importance are multidisciplinary (MWP and beyond).
- In light of innovation: Scientific guidance on what is essential to consider for evidence solid enough for decision making – not on what is considered acceptable…..
- High standards of evidence in the interest of patients and society a joint effort.

Crossing borders

Evidence generation throughout the lifecycle

- Initiated coordination in Methodology across EMA MWP, CTCG and HTA CG Methodology.

MWP Chairs and Members directly engaged in Horizon Europe projects to innovate.

The interplay with medical devices important to address (e.g., AI RP, diagnostics, predictive biomarker co-development).

Any questions?

Further information

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