



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Methodology Working Party

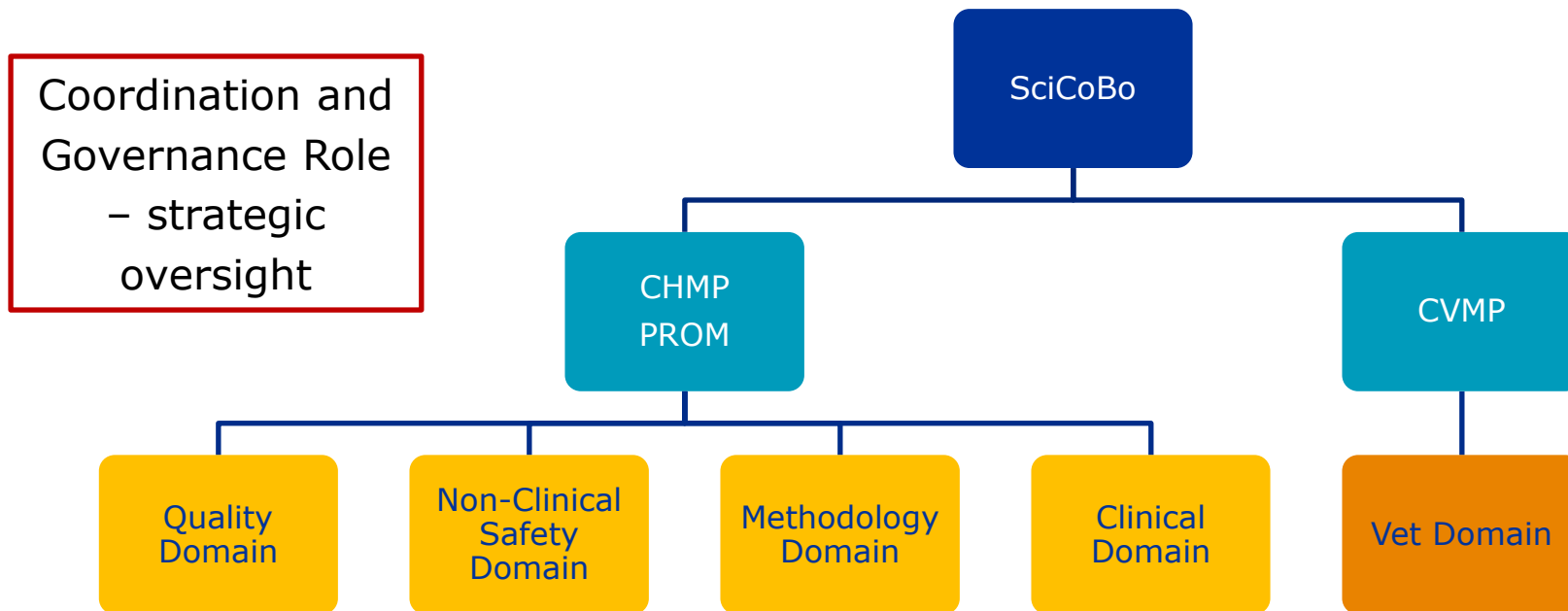
Overview and Work Plan Highlights

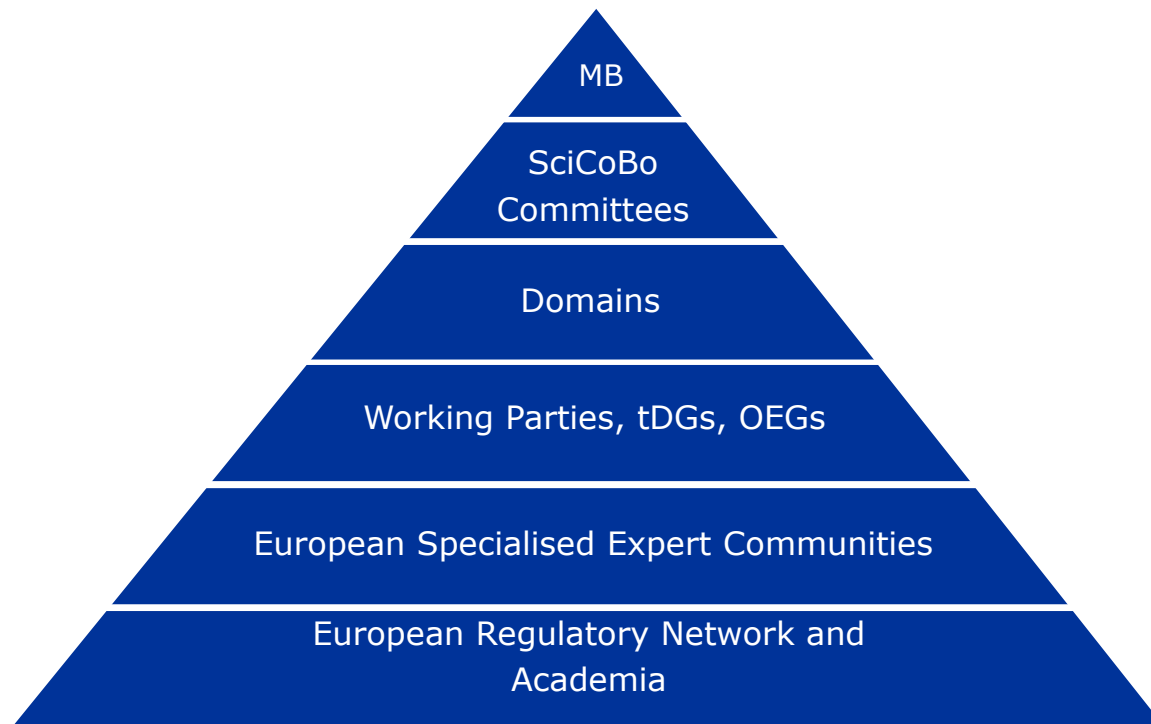
SAWP January 2023



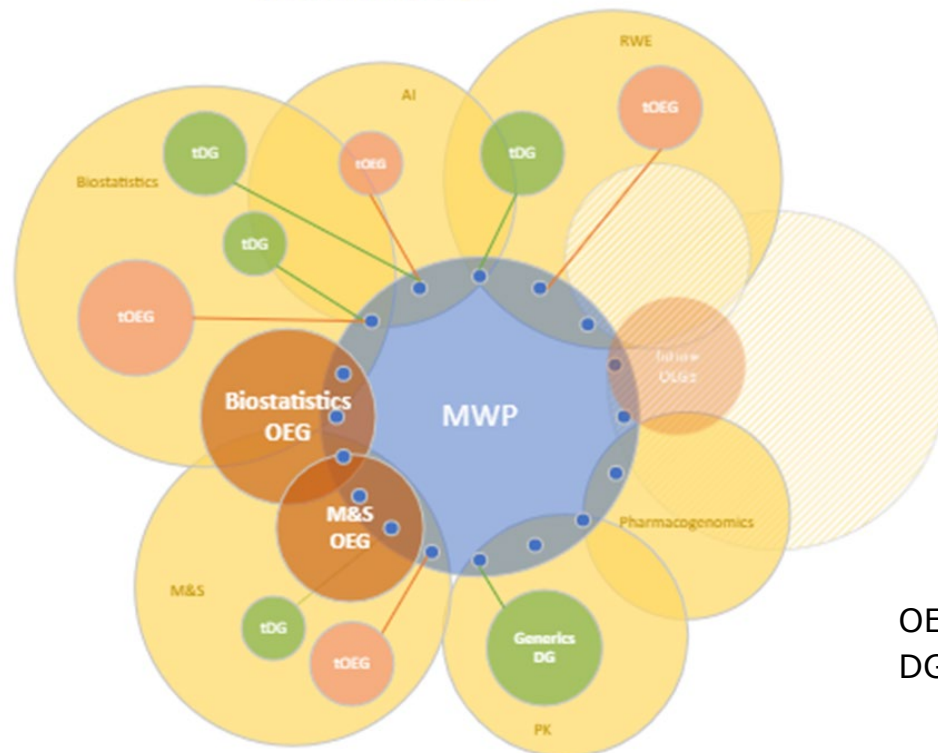


Reorganisation of Retained Working Parties and other Groups into ***Five Domains***





European Specialised
Expert Community
for Methodology
(ESEC)



- Everyone need not do everything
- Best structures to deliver work plan
- MWP a hub at the centre
- Each group has an MWP 'linking pin'
- Groups (OEGs & tDGs) lead by MWP can be multi-disciplinary, and from broad background (esp. tDG).

OEG = Operational Expert Group -> Product support
DG = Drafting Group -> Guidance documents

Operational Support

- To CHMP
- To other committees and SAWP
- Specific focus on products

Guidance Documents

- Structured plan for development
- Prioritised
- What we need now
- What we *will* need

Knowledge Building Capacity

- Share learnings from assessments
- Training and development of network

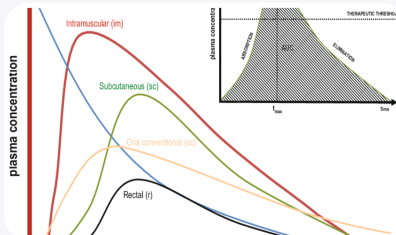
Expertise Network

- Build links:
 - Across NCAs
 - With academia

Global Leader

- Work with international regulatory partners
- Leading voice in global collaborations

Structured under four main areas:



Clinical Pharmacology

- Includes product – specific bioequivalence
- Modelling and simulation Q&A documents

Real World Evidence

- Reflection Paper on AI also foreseen

Clinical Trial Modernisation

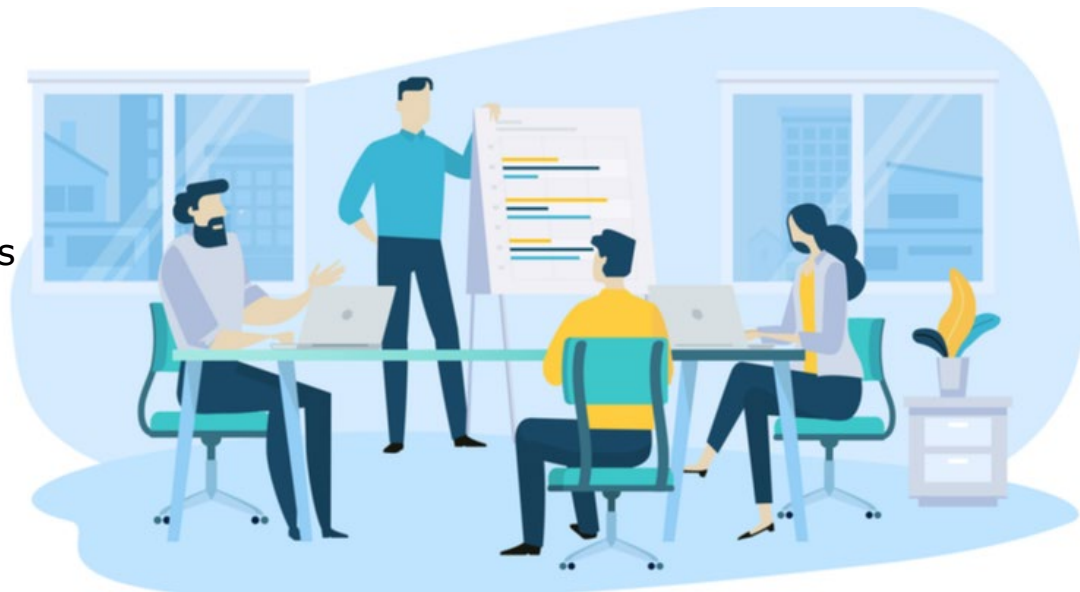
- Implementing ICH guidance
- Trials of the future

Pharmaco - genomics

- Be ready for IVD legislation and implementation
- Update guidance

ESEC is crucial for delivery

- Comprehensive curricula foreseen
- Build on experience in biostats
- Training of methodologists
 - Use of case studies from committees
- Training of wider network
 - Work closely with EU-NTC
 - Upcoming Joint Action



ESEC is crucial for delivery

Key Stakeholders



Industry – organised on
'traditional lines'



Global Regulators –
individually, and as a
group – along
'traditional lines'



EU projects – includes
ACT-EU, BDSG

Principles:

- MWP responsible for delivery.
- ESEC crucial network for knowledge, engagement and agile delivery.

Alignment of objectives with other initiatives, including e.g. BDSG, ACT-EU:

- “Establish the Network ability to assess applications supported by data science including AI models created through machine-learning algorithms.”
- P8 “Develop and publish key methodologies guidance e.g. on AI/ML impacted CTs, complex trials, decentralised CTs and IVDR/CTR interface”. Also linked to P7 (Coordination between scientific advice, approval and innovation in methodology).
- Training and development in general

Specifically act as a hub for capacity building across the network



Any questions?

Further information

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