EMA Methodology Working Party Update

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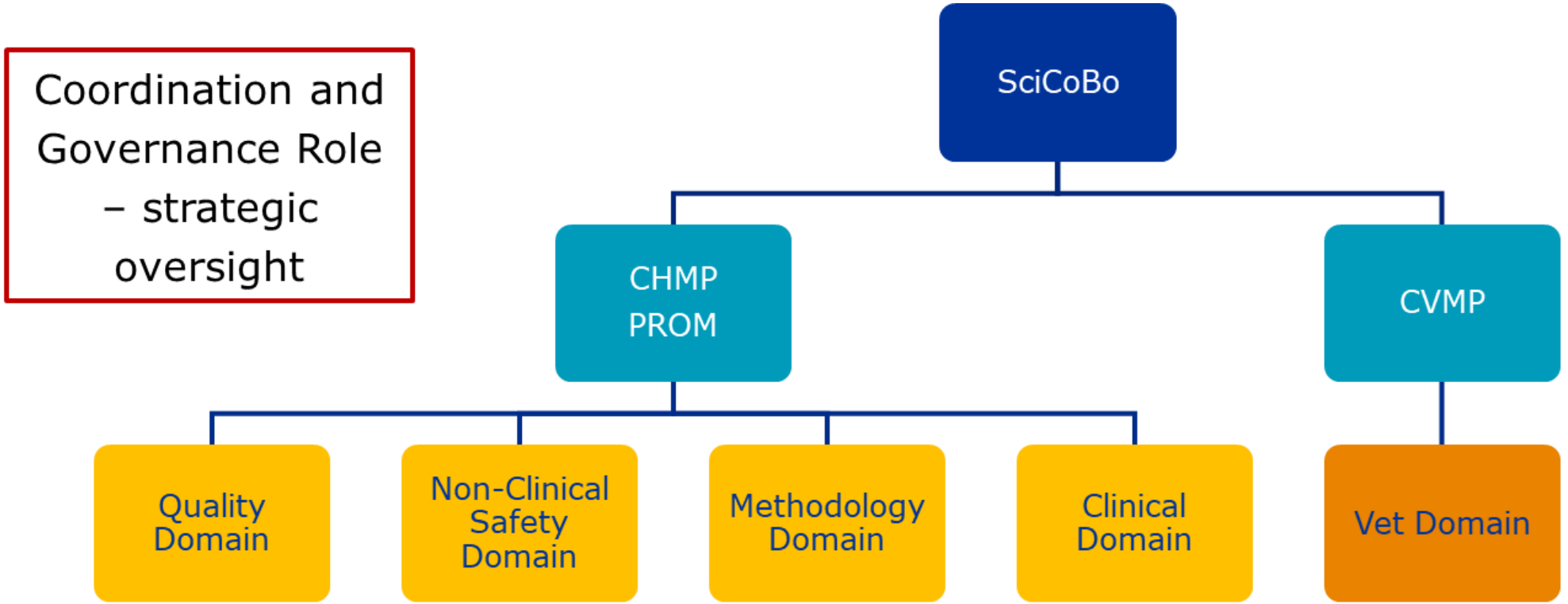
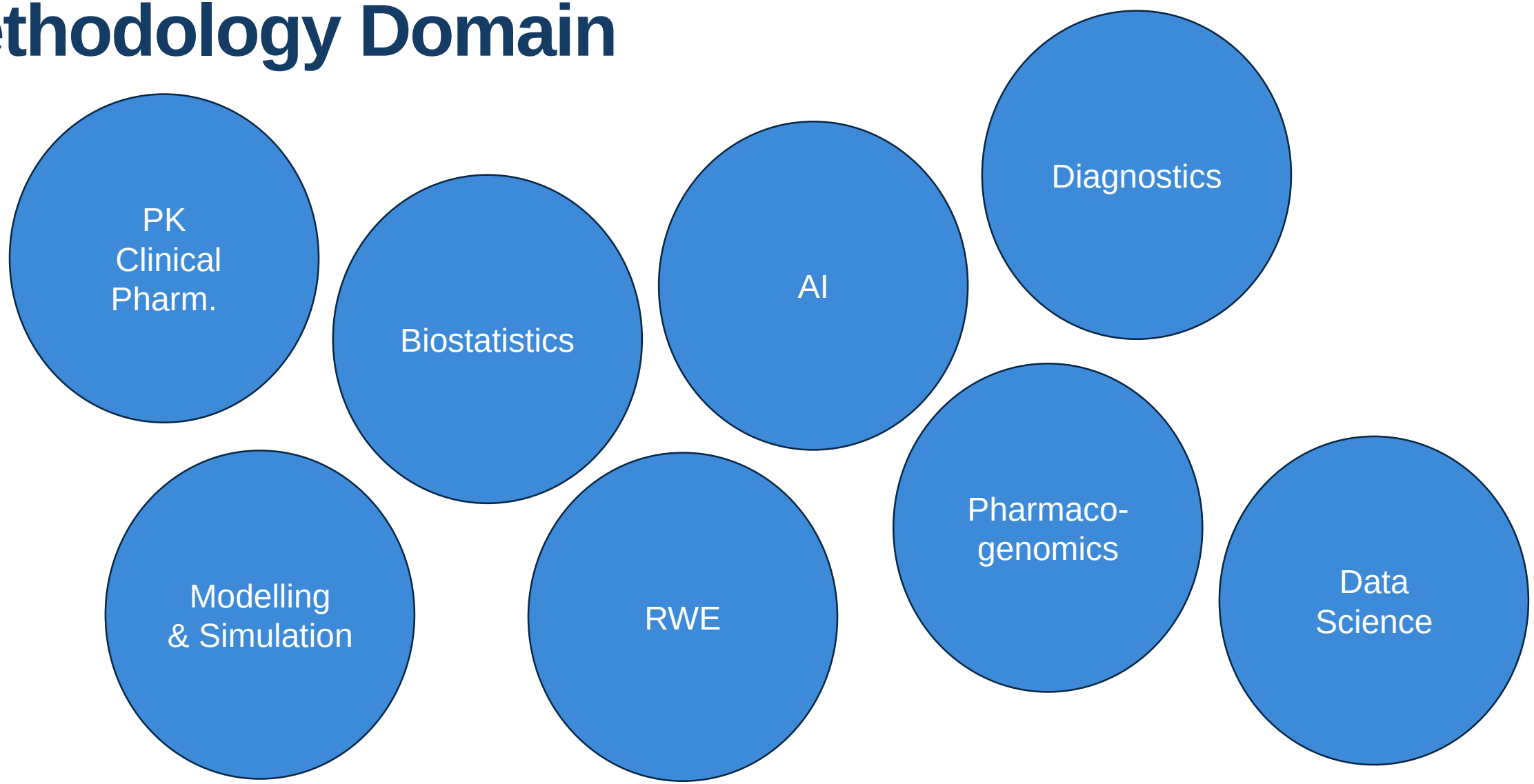
Disclaimer

The views expressed in this presentation are those of the speaker and are not necessarily those of MPA or EMA.

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

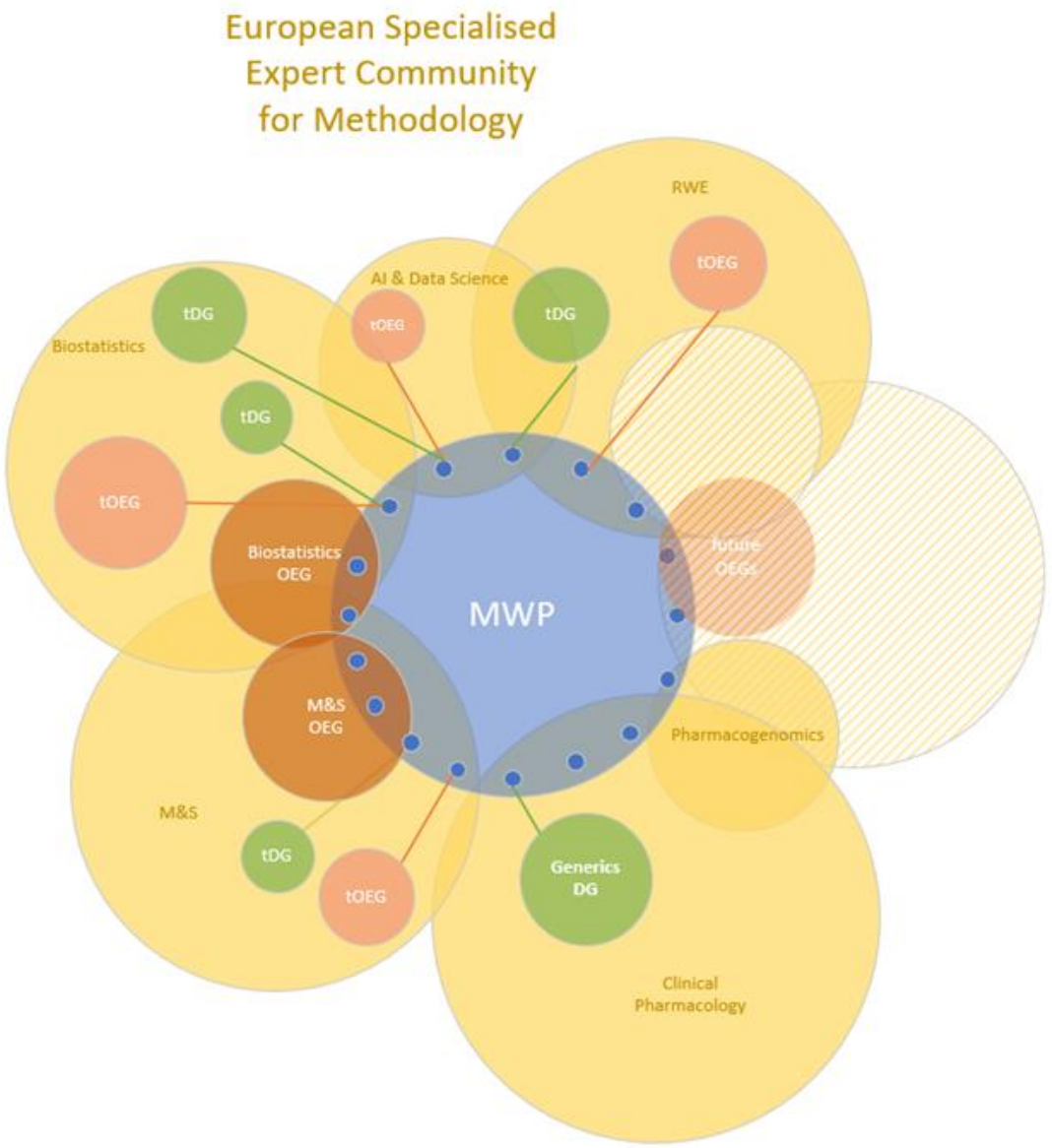


Methodology Domain



Methodology WP and friends

- MWP a hub at the centre
- Groups lead by MWP can be multi-disciplinary, and from broad background



OEG = Operational Expert Group -> Procedure support

DG = Drafting Group –> Guidance documents

Work Plan – Strategic Goals

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

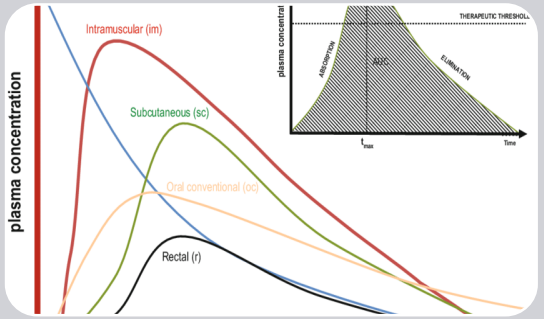
- Build links:
  - Across NCAs
  - With academia

Global Leader

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

Work Plan – Guidelines

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

Work Plan – Guideline activities

- Reflection paper regarding establishing efficacy based on single-arm trials. Establishing efficacy based on single-arm trials submitted as pivotal evidence in a marketing authorisation | European Medicines Agency (europa.eu) Consultation open until 30 September 2023.
- Reflection paper on the use of artificial intelligence in the lifecycle of medicines. Reflection paper on the use of artificial intelligence in the lifecycle of medicines | European Medicines Agency (europa.eu) Consultation open until 31 December 2023.

Work Plan – Guideline activities

Non exhaustive list

Real World Evidence

- Concept Paper on the use of Real World Evidence for regulatory decision making.
- Roadmap for development or RWE guidance.

Clinical Trial Modernisation

- Revision of Guideline on Multiplicity issues in Clinical Trials.
- Revision of Guideline on the Non-Inferiority Margin, and possibly the Guideline on Switching between Superiority and Non-Inferiority.
- Reflection Paper on Bayesian Methods in Clinical Development.
- Reflection paper on platform trials.

Work Plan – Trainings

- Core grounding in methodology, advances and state of the art methodology, reflection of hot topics
- Training on all new guidelines
- Work closely with EU-NTC
- Comprehensive curricula in data science, biostatistics, modelling and simulation and epidemiology, with close liaison with Big Data Steering Group and EMA

Work Plan – Stakeholder engagement

Key Stakeholders

Industry – individually, and as a group

Global Regulators – individually, and as a group

EU projects – includes ACT-EU, Big Data Steering Group

Upcoming activities of interest

- Revision of the Methodology WP Work Plan
- AI Workshop 20-21 November 2023 (Joint HMA/EMA AI workshop)
- Stakeholder Interaction Meeting

Any questions?