



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Working Party Implementation Project

Silvy da Rocha Dias – Project Manager for the Implementation of the Working Parties

7th Meeting of the Industry Stakeholder Platform on the Centralised procedure 01/12/2021





Introduction

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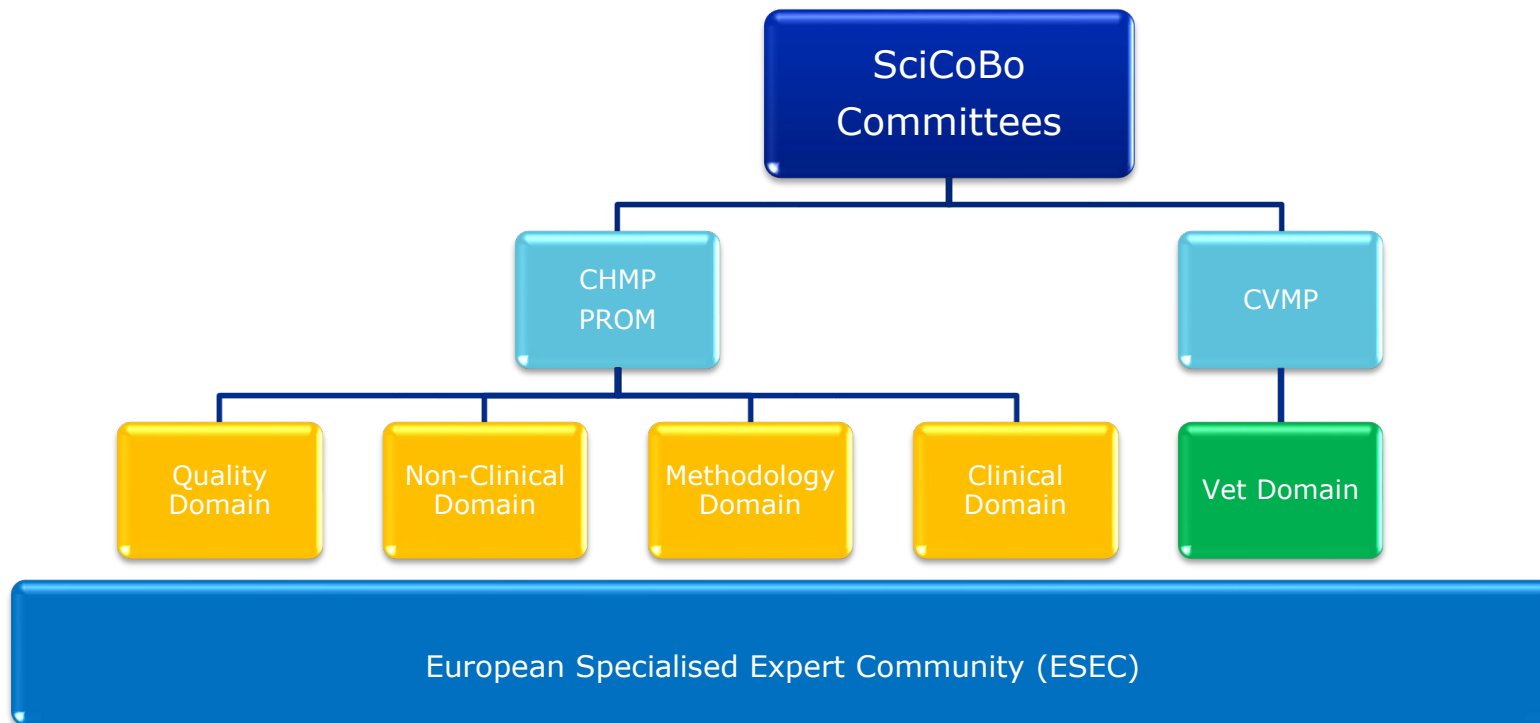
- Fosters the exchange across the network - true multinational assessment teams/working structures
- Experts may choose the level of activity from listening to topics to becoming major contributors in agreement with their nominating Head of Agency
- Activity level ranging from ESEC, temporary Drafting Groups (tDG), Operational Expert Groups (OEGs), standing Working Parties (WPs) to Committee membership
- The European Specialised Expert Communities (ESECs) will enhance the involvement of network experts
- Takes advantage of the post-pandemic acceptance of remote meetings and cooperation.

- Introducing a **new strategic oversight for each of the domains** populated mainly by chairs¹ of the relevant working parties and chairs and/or vice-chairs of CHMP/SAWP/CVMP
- The main principle is to reorganise in five main “Domains” i.e. Quality, Non-Clinical, Methodology, Clinical and Veterinary
 - For joint Working Parties which require veterinary specific views and action, a veterinary representative may be involved in the relevant Domains
- Working Parties should receive directions from their (decision making) oversight structures principally CVMP and CHMP/SAWP

¹ Or delegated to vice-chairs, as needed

- Generate a **3-year rolling strategic plan at domain level** and linked to EMRN Strategy to 2025 / EMA RSS to 2025
 - Work plans should address training delivery to the wider network as part of structured offering via the EU-NTC platform
- Introduce systematic and structured Stakeholder Engagement² at domain level to underpin strategic priority planning and individual guideline generation/revision

² Industry, academia, healthcare professionals, patients and international regulators





Working parties, Operational Expert Groups, Drafting Groups and European Specialised Expert Communities

New structures of the operational model

- The principle of “best and available” expertise to be applied and commitment to diversify selection across the network as far as possible
- Nomination to WPs is based on predefined expertise needs; nominated and appointed by CxMP members, review of membership on a routine basis (3 years)
- Virtual, F2F, hybrid meetings, customized to specific needs
- Chairs of WPs are essential component of Domain governance:
 - Drive strategical component of the WPs
 - Engages with stakeholders/ industry

- EMA Committees and SAWP request, on an as-needed basis, **scientific support to operational core business**
- These requests that can be integrated into various regulatory procedures and delivered over all phases of the lifecycle
- Experts appointed on a temporary basis for specific tasks defined by project scope; product support
- Expertise can be drawn from ESEC and include academic input as needed, may also include rapporteur and peer reviewers

- tDGs are designed as lean structures primarily constituted for the purposes of drafting guidelines with each member has a designated role in primary drafting of part of the document
 - Volunteers from relevant ESEC can be supplemented by academic expertise /multidisciplinary expertise as needed.
 - Lead by Coordinator/Alternate (usually a WP or Committee member)
 - Composition directed by domains, approved by relevant WP
- Virtual meetings as needed (flexible frequency, timing, duration)
- Formed after a proposal for a GL/RP/Q&A is approved by the Domain and via CHMP/CVMP as relevant

		Quality	Non-Clinical	Methodology	Clinical
Working Parties	Operational expert groups	• BWP* • QWP* • BMWP*	• NCWP* • J3Rs	• MWP	• CNSWP • ONCWP • CVSWP • IDWP • RIWP • VWP • HAEMWP
		• Paediatric Formulation Group • Quality Innovation Group • Ad-hoc expert groups	• Ad-hoc expert groups	• Modelling & Simulation • Biostatistics • RWE • Ad-hoc expert groups	• Clinical SAGs • Ad-hoc expert groups

*Standing working parties can also discharge operational functions in addition

- ESECs are a community of experts with special knowledge and interest in a given topic area who contribute to the European Regulatory Network
 - best available expertise and resources made available from network and academia to cope with a fast-evolving environment of innovative medicinal product developments
 - the size of ESECs is likely to be very variable, depending on the specific area of expertise
 - to address learnings as well as training of assessors
- ESECs foster leadership across the whole network with much wider reach than current working parties
 - facilitate dissemination of information/knowledge through the network
 - to allow a more efficient and dynamic process and outreach to the whole network

- Designed to deliver the **strategic, tactical and operational** goals of the domain
- **Future proof & agility**: Expertise-based model → continuous adaptation in parallel with evolution of science and product development
- **Outreach**: strong and managed interaction with relevant stakeholders (i.e. Industry & Learned society and Universities)
- **Consistency**: Integration of all groups into the ESECs for optimal information flow and knowledge management



- Working parties implementation project initiated in September 2021
- The new WP model is being implemented in a step-wise approach
 - different domains being activated based on workload
 - prioritisations of the workplans and activities for each domain is under way
 - operational activities are taking precedent, no disruption to ongoing core activities
- A 3-year rolling plan at the domain level is being introduced, with a 1-year operational plan for 2022 to be published next year (timing TBC)
- QIG survey will be launch mid-December 2021 to re-confirm findings from RSS2025, identify new developments and feed into the expertise requirement for the new QIG membership in 2Q 2022
- It is expected that most WPs will become active starting from 2Q 2022



Any questions?

Further information

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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