



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reorganisation of EMA working parties

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Presented by Alberto Ganan Jimenez
Head of Committees and Quality Assurance Department

An agency of the European Union





Introduction

- Background on the re-organisation of the Working Parties
- New model for working parties
- ESEC and EU-NTC



MB adopted recommendations

- Introducing a **new strategic oversight for each of the domains** populated by chairs of the relevant working parties and chairs and/or vice-chairs of CHMP/SAWP/CVMP and SAG chairs, as appropriate
- The main principle is to reorganise in five main “Domains” i.e. Quality, Non-Clinical, Methodology, Clinical and Veterinary
- Working Parties should receive directions from their (decision making) oversight structures principally CVMP and CHMP/SAWP



MB adopted recommendations

- 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 Engagement¹ at domain level to underpin strategic priority planning and individual guideline generation/revision

Benefit of the new model

• **Domain governance:** designed to deliver the **strategic, tactical and operational** goals of the domain (e.g. quality, clinical...)



• **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 and inclusivity:** Integration of all groups into the ESECs for optimal information flow and knowledge management



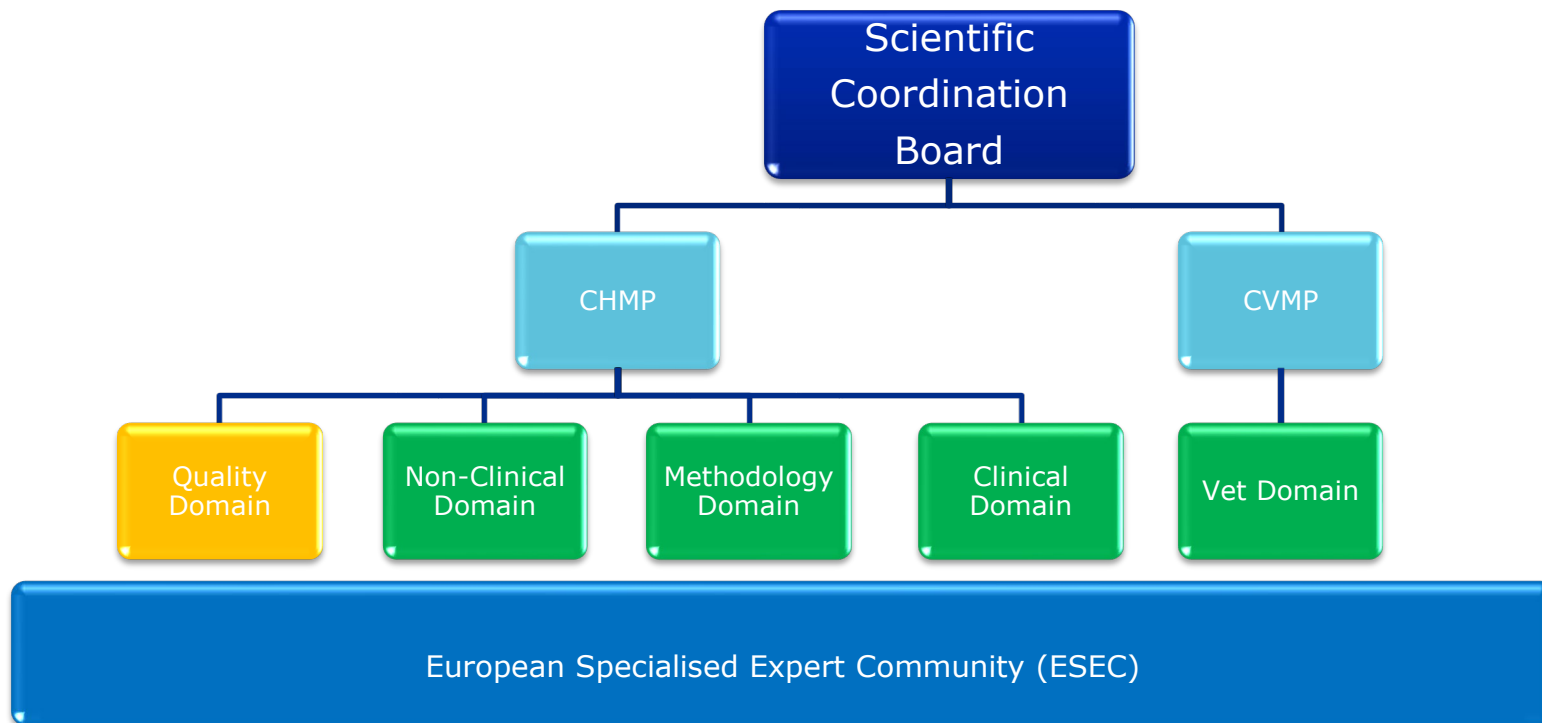


Working parties, Operational Expert Groups, Drafting Groups and European Specialised Expert Communities

New structures of the operational model



Five Domains



Architecture of new model



The new model combines groups with expertise-based and 'inclusive' membership (i.e. ESECs) for knowledge sharing.

| Roles | Quality | Non-Clinical | Methodology | Clinical | Veterinary |
|-----------------------------------|--|--|--|--|--|
| Work plan | Domain governance | Domain governance | Domain governance | Domain governance | Domain governance |
| Work on Products | Operational Expert Groups | OEGs | OEGs | SAGs | OEGs |
| Guide-lines | Working parties | Working parties | Working parties | Working parties | Working parties |
| | Drafting groups | Drafting groups | Drafting groups | Drafting groups | Drafting groups |
| Expertise-based membership | | | | | |
| Training & Knowledge | ESECs (European Specialised Expert communities) | ESECs (European Specialised Expert communities) | ESECs (European Specialised Expert communities) | ESECs (European Specialised Expert communities) | ESECs (European Specialised Expert communities) |
| | "Open & inclusive" membership | | | | |



Working Parties (WPs)



- The principle of “best and available” expertise to be applied and commitment to **diversify selection across the network** as far as possible
- Working party members are typically expected to be both **high profile** (proven expertise and experience outside purely regulatory work) and **high input** (members given the time to work for WP)
- Nomination to WPs is based on predefined expertise needs, nominated and appointed by CxMP members (review of membership on a routine basis)
- Chairs of WPs are essential component of Domain governance:
 - Drive strategical component of the WPs
 - Engages with stakeholders/ industry



Operational Expert Groups (OEGs)



- **Provide the scientific support to operational core business** on an as-needed basis to EMA Committees and *SAWP upon request*. These requests that can be integrated into various regulatory procedures and delivered over **all phases of the lifecycle of a product**:
 - Pre-Submission: Scientific advice/Protocol assistance, Qualification advice, PIP, ODD, ITF and pre-submission queries; Initial MAAs; Post-Authorisation: Safety signals, referrals and crisis situations; Decentralised procedures requested through CMDh, or HMPC
- Experts appointed on a **temporary basis for specific tasks** defined by the scope of the request; product support (e.g. Nitrosamines)
- Expertise drawn from ESEC, can include academic input as needed
- Appointment by CHMP members and/or Working Party

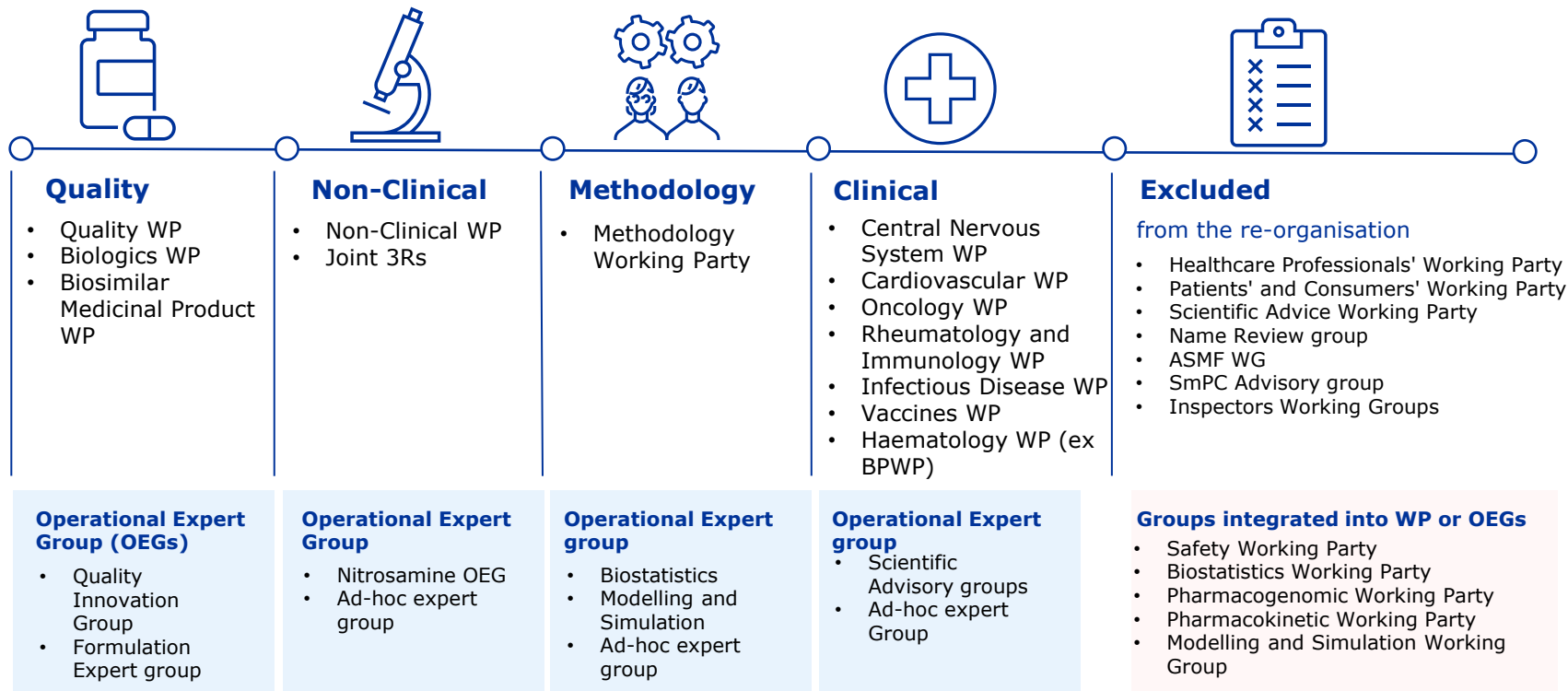
Temporary drafting groups (tDGs)



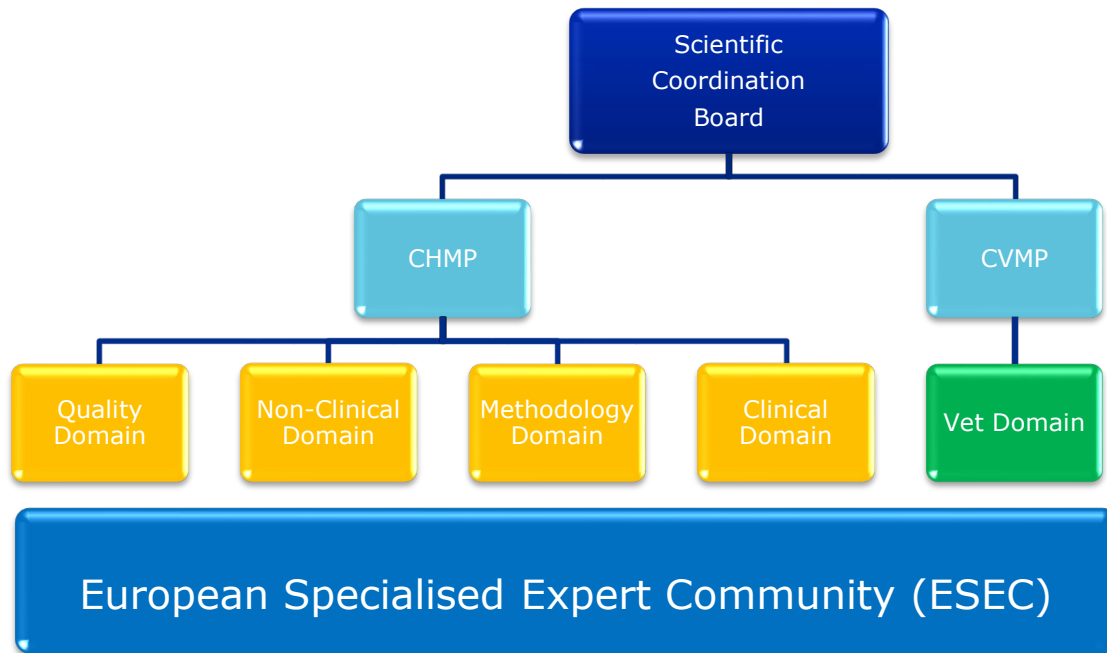
- tDGs are designed as lean structures, primarily constituted for the purposes of **drafting guidelines**:
 - Volunteers, supplemented by academic expertise /multidisciplinary expertise from ESEC as needed and lead by Coordinator/Alternate (usually a WP or Committee member)
 - Approved by relevant WP and Domain
- Report to WP on scientific progress and at milestones to Domains (eg draft release for consultation, restart after comment period, adoption of final document)
- Virtual meetings as needed (flexible frequency, timing, duration)
- Appointment by the Working Party from ESEC membership



New Operational Model for Working Parties



- **Community of experts** with special knowledge in a given area;
- **Accessible** to experts from the NCAs, SAGs, CHMP members, academic organisations that are/will be contributing to the regulatory system
- **To be a member:** be nominated by a Committee member (NCA), sign a confidentiality agreement and needs to be included in the expert database.





ESEC and EU-NCT



- New agile model strengthens the Network by connecting experts across the Network together
- The strategic oversight for guideline development at the level of the working party and the domain:
 - Joining forces of the ESEC and the EU-NTC delivering training plans for the Network
 - Expectation that every new guideline will have it's own training plan
 - ESEC to communicate and raise awareness through the EU-NTC
 - Important published guidelines may be chosen for editorials targeted at specific audience in journals
- Oncology ESEC pilot is an important new step in creating inclusion and knowledge sharing across the Network.



Any questions?

Further information

Silvy.darochadias@ema.europa.eu (EPG office)

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

Telephone +31 (0)88 781 6000

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