



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6th Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

30th June 2021

Presented by: Tony Humphreys

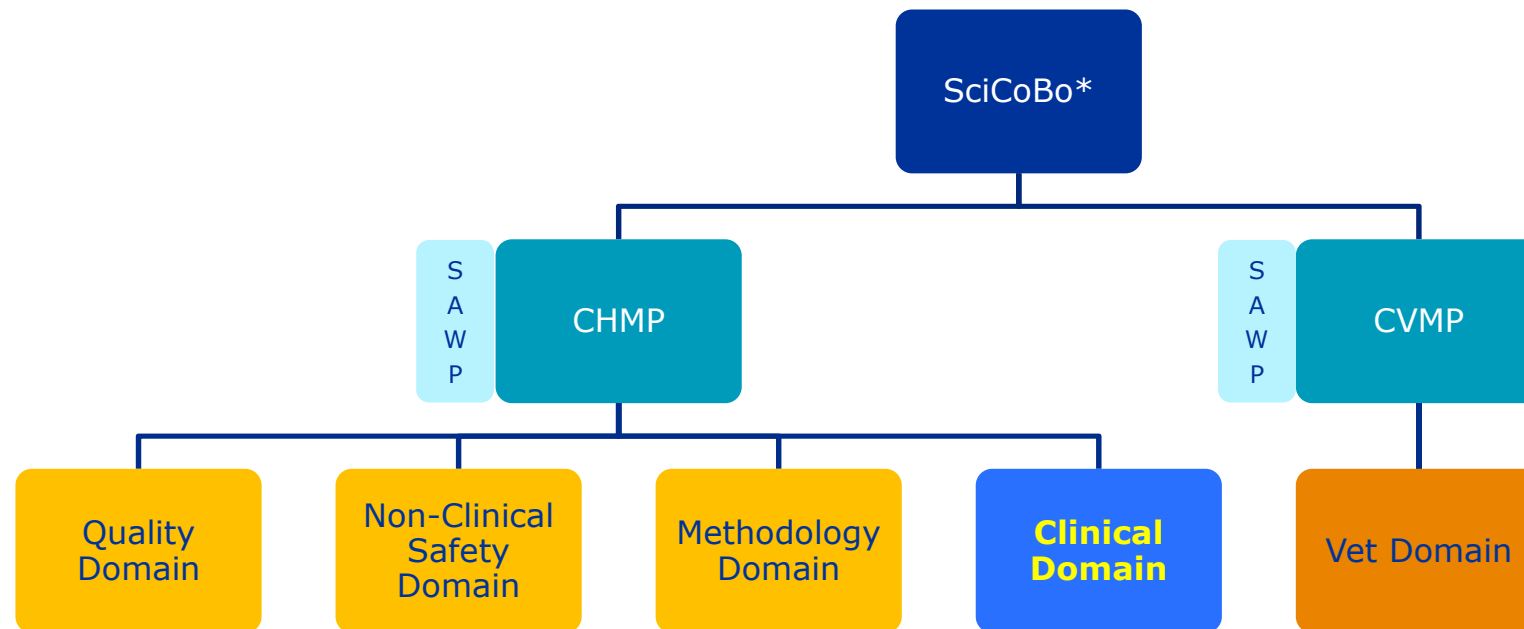
An agency of the European Union



Five domains serving the expertise needs of the committees



EUROPEAN MEDICINES AGENCY



*CAT, CHMP, COMP, CMDh, CVMP, HMPC, PDCO, PRAC, SAWPh, SAWPv



The new model in a nutshell

Domains provide strategic direction for 3-year workplans (e.g. guidelines) of the expert groups.

There are 4 types of expert groups under each domain:

Working Parties (WP) focusing on non-product work (e.g. guidelines).

Operational Expert Groups (OEGs) focusing on product work (an OEG can also be a WP, e.g. BWP). SAGs are part of the OEGs.

Temporary Drafting Groups (tDGs) created and disbanded based on the guidelines to be developed from the 3-year workplan.

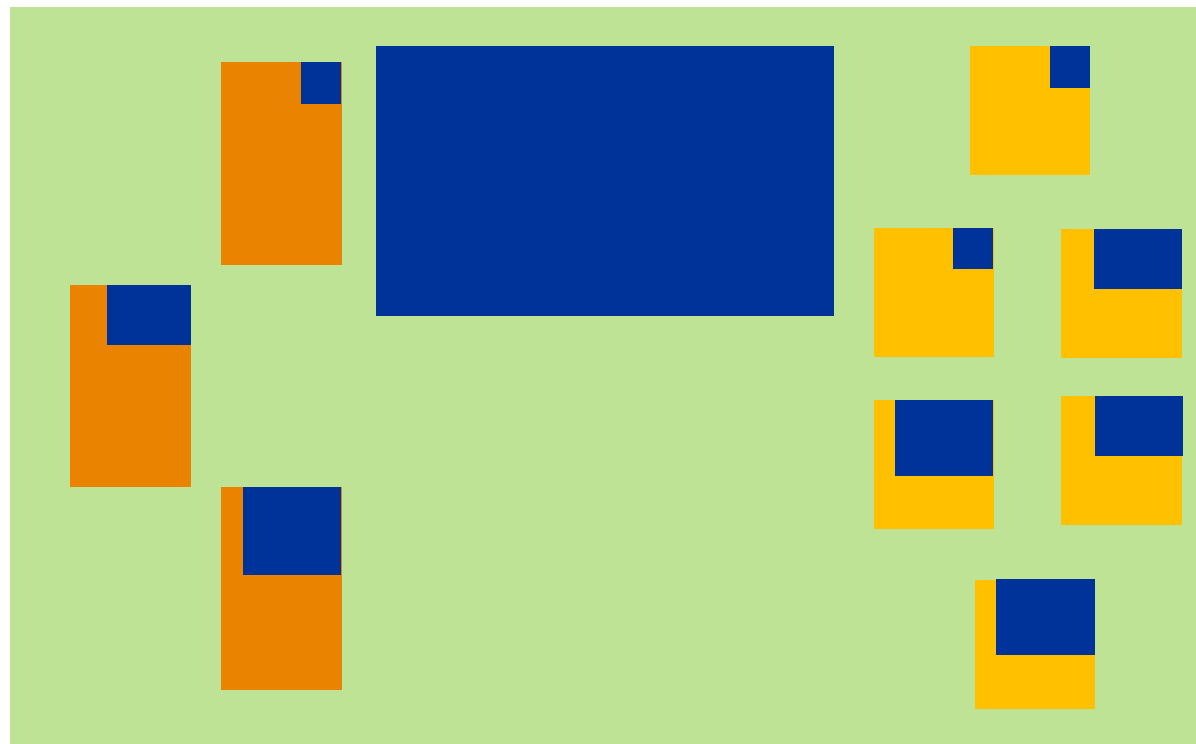
European Specialised Expert Communities (ESEC) promoting information flow and training of the Network. This pool of expertise, organised in expert communities by theme, will be available when required. The exact structure and number of communities still needs to be defined (e.g. Neurology, Biostats, Chemicals...).

Supported by an expert group secretariat (scientific and administrative) **operating model**.

ESECs, a source of expertise for all working structures



EUROPEAN MEDICINES AGENCY



European Specialised Expert Communities (ESECs)

Standing Working Parties

Operational Expert Groups

Temporary Drafting Groups

Benefits of the new model



EUROPEAN MEDICINES AGENCY

- Designed to deliver the **strategic, tactical and operational goals** of the domain
- **Future-proof and agility**
Expertise-based model which can be supplemented when required, adapting expertise to reflect evolution of science and product development
- **Outreach**
Strong and managed interaction with relevant stakeholders (i.e. Patients, Learned Societies, Industry and Academia)
- **Strategic leadership**
Domains exercise oversight of the work programme and prioritisation of the activities undertaken by the Working Parties and linked to delivering the support needs of the committees and wider network
- **Simplification of the domain**
Redistribution of expertise organised in more agile structures such as Operational Expert Groups (OEGs), Temporary Drafting Groups (tDG) and European Special Interest Communities (ESECs) and consequent reduction in number and membership of standing working parties

Translating innovative technologies



EUROPEAN MEDICINES AGENCY

- **Quality innovation group** ➡ mixed expertise from QWP, BWP, IWG and academia

Translating innovative technologies: novel / continuous manufacture technology including automation, artificial intelligence/big data approaches 'Pharma 4.0'; digital devices, data analytics & digital transformation; novel delivery systems & nano technology

- **J3Rs WP** ➡ mixed expertise from NC WP, V-SWP, BWP, IWP

From discovery toxicology towards animal-free innovations or new approach methodologies (NAMs); access and knowledge to in silico/QSAR applications

- **Methodology WP** ➡ mixed expertise including Biostats, kinetics, genomics, M&S, RWD, AI etc.

Focus on new and emerging clinical study designs and changing clinical development landscape. Excellence in all areas of methodology and leading voice in international collaboration.

Next steps



EUROPEAN MEDICINES AGENCY

High level implementation plan adopted by EMA Management Board in March 2021



2021 project implementation planning (Covid dependent)



Establishment of the transitional domain governance and timetabling of activities



Develop the prioritised portfolio of activities and expert group / secretariat operating model



Constitution of the expert groups and activation of the new model



EUROPEAN MEDICINES AGENCY

Thank you for your attention

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

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Follow us on  **@EMA_News**

Classified as public by the European Medicines Agency