



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the working party implementation project

Current status of the implementation plan

8th Industry stakeholder platform on the operation of the centralised
procedure for human medicines
27 June 2022

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Human Medicines Division

An agency of the European Union



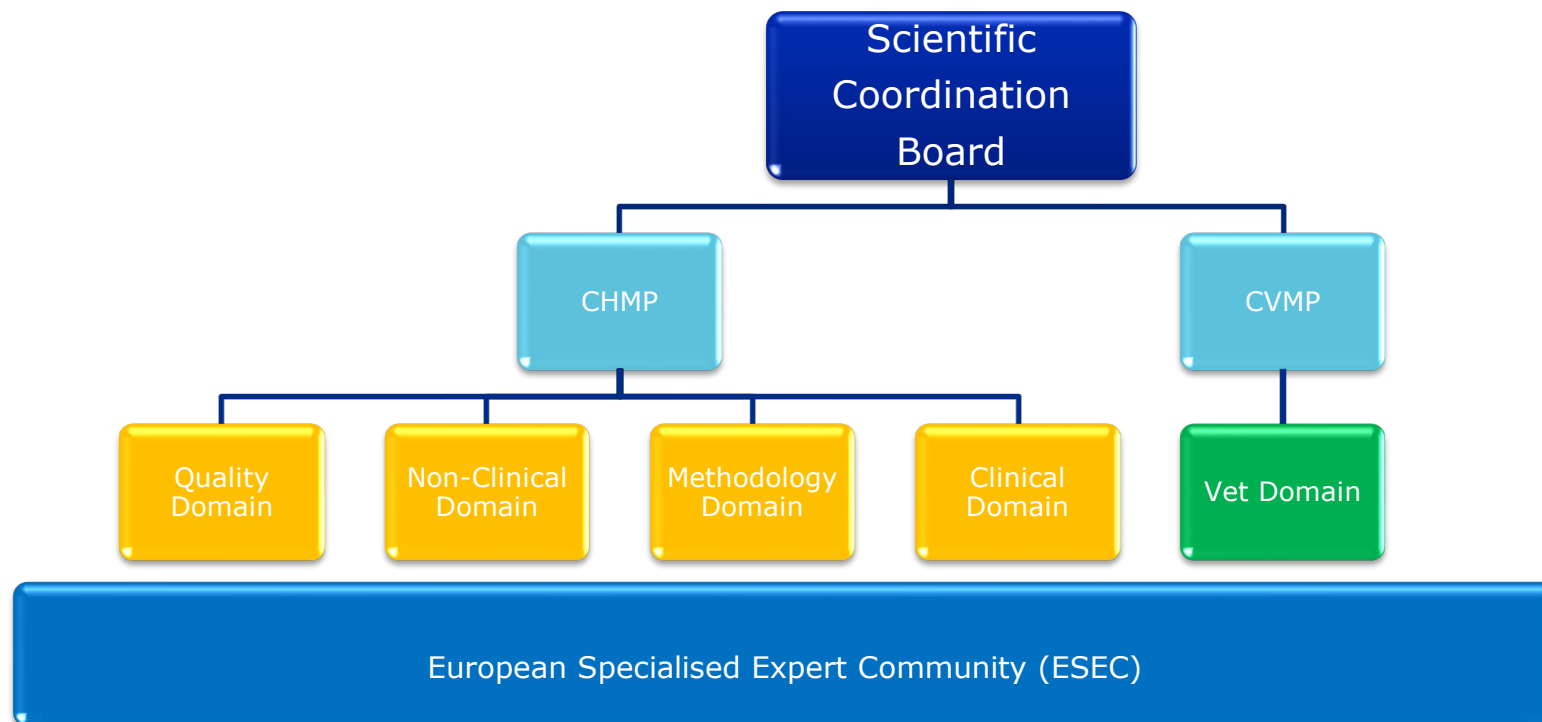


Introduction

- Background on the re-organisation of the Working Parties
- Progress report on the implementation plan of the new model
- Next Steps



Five Domains



Benefit of the new model

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





Roadmap overview



- 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
 - Operational activities are taking precedent, no disruption to ongoing core activities
- 2-phase approach:
 - Phase 1: includes Clinical, Non-clinical and Methodology domain
 - Phase 2: Quality domain (QWP, BWP, BMWP,...) following lessons learned exercise
- Projection that the majority of WPs will become active starting from 2Q 2022

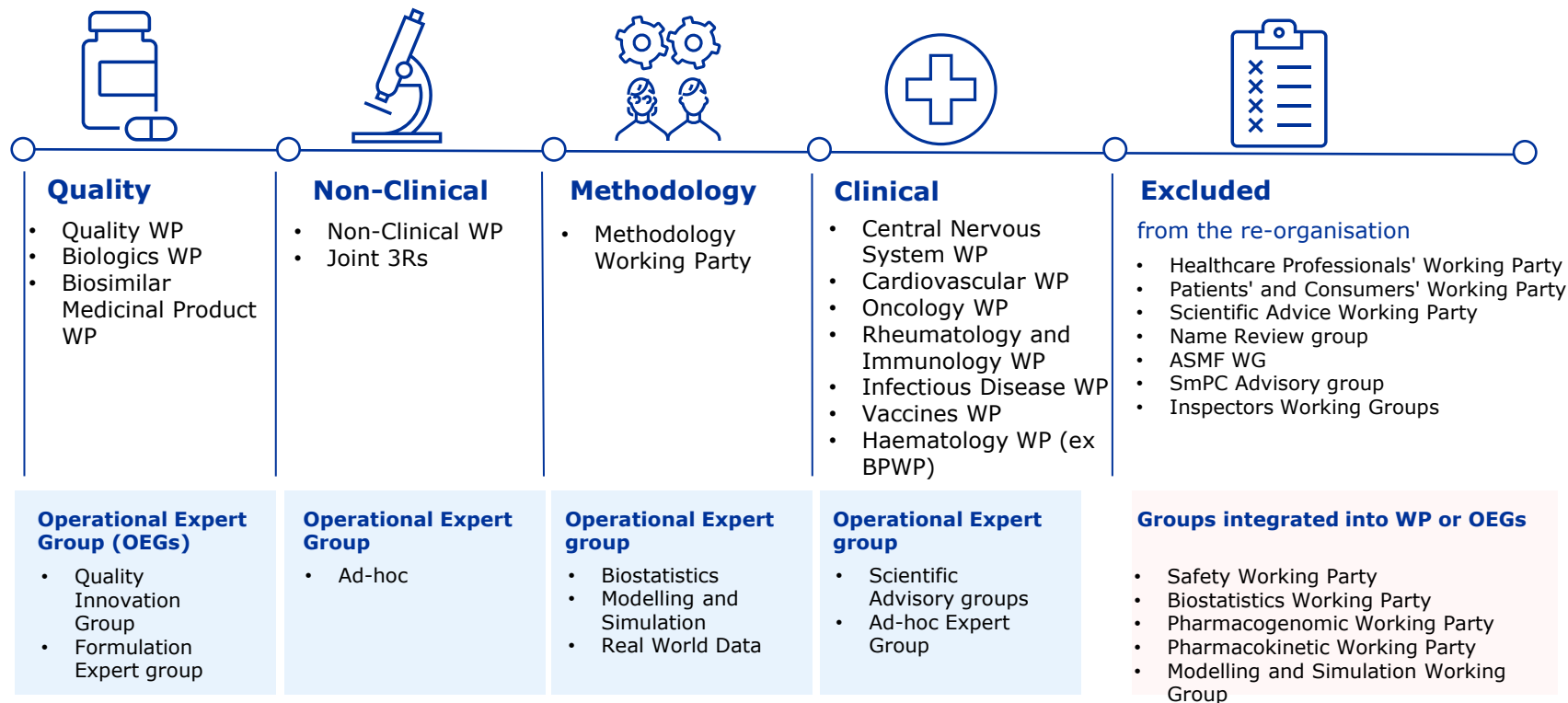


Phase 1 implementation: Achievements



- The working parties (WPs) have been re-organised, based on expertise of members, to deliver on the workplans.
- Membership of WPs were adopted at the CHMP March 2022, with Chair and Vice-Chair elected in April-June 2022 CHMP plenary meeting.
- Draft 3-year rolling workplans have been introduced at domain level, with a yearly operational workplan on guideline development, trainings and stakeholder engagement plans will be published.
- Launch of European Specialised Expert Community (ESEC) pilot in May 2022 with Oncology ESEC pilot.

New Operational Model for Working Parties





Working Parties for the Non-Clinical, Methodology and Clinical domains



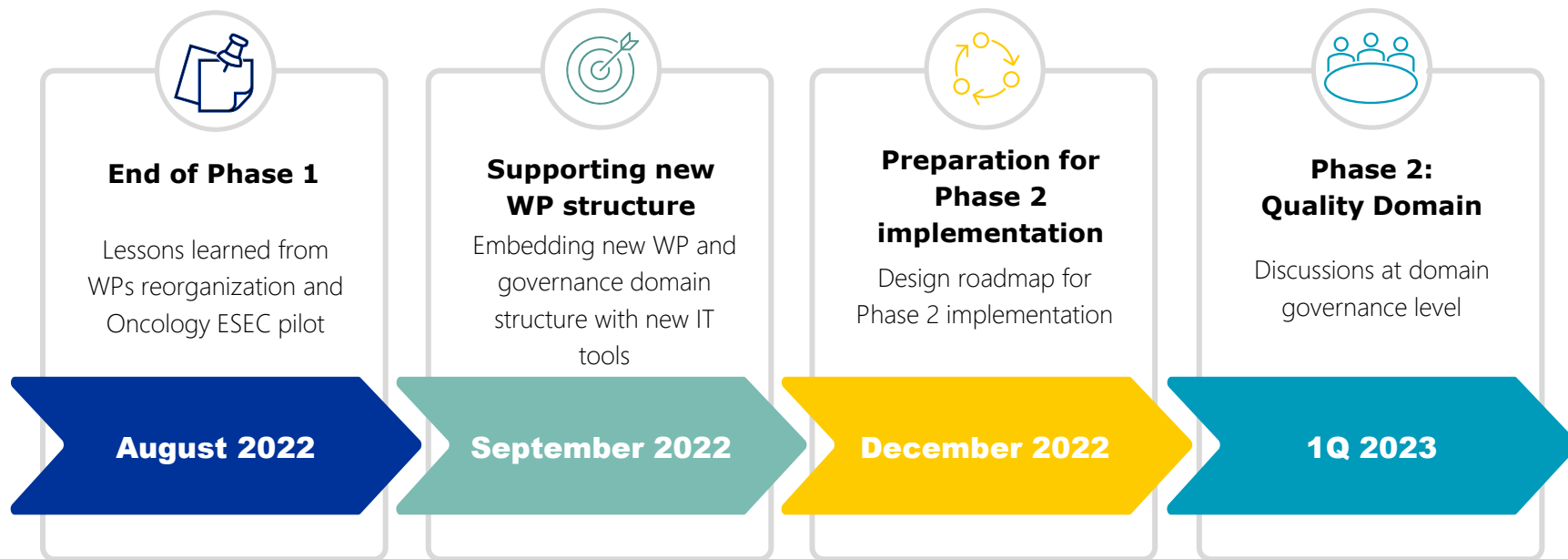
- The call for nominations generated high number of experts across the EU, both from NCA and non-NCA, for Non-Clinical, Methodology and Clinical domains
- The number of selected experts:
 - 57 members Clinical Domain (+ additional call for expertise)
 - 31 members Non-Clinical Domain
 - 18 members Methodology Domain (+ additional call for expertise)
 - Majority of members were previously in WPs/Committees, however new members from the Network have been also nominated

Launch of ESECs



- 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 included in the expert database
- Training: awareness sessions and knowledge sharing
- Stakeholder engagement: organisation of events
 - Webinars for ESEC members or public on special topics, external stakeholder meetings, workshops and symposiums
- Oncology ESEC pilot was initiated with oversight from the Clinical domain and Oncology WP

Next Steps and timelines for implementation plan of the Working Parties





Summary



- Successful start of implementation of Phase 1 of the project, with the re-organisation of the working parties from the Non-clinical, Methodology and Clinical domains.
- Expertise in the WPs was diversified across the MS and experience was retained, with majority of experts selected having been members of previous WPs/Committees.
- Oncology ESEC pilot is an important new step in creating inclusion and knowledge sharing across the Network.
- Lessons learned exercise at the end of phase 1 will help embed and plan for the Phase 2 (Quality Domain) of the implementation of the new model of working parties.



Thank you for your attention

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