EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Working parties and new ways of working

11th Meeting of the Industry Stakeholder Platform on the operation of the centralised procedure for human medicines

Presented by Silvy da Rocha Dias on 24 November 2023
Head of Office Expert Panels and Groups

Outline of presentation

- Working Party implementation project – update
- Stakeholder engagement – Workplans
- New EU survey tool to capture comments on guidelines

Timelines for the WP implementation plan

2021

Phase 1 – WP model design

MARCH
- MB adoption of high level implementation plan on the review of the activities of the Working parties

SEPTEMBER
- Kick start the implementation plan for the reorganisation of the Working Parties

OCTOBER- NOVEMBER
- Review the 3 year rolling workplans for the Non-clinical, Clinical and Methodology domains

DECEMBER
- Discuss expertise and draft call for nominations

2022

Implement phase 1 and preparation for phase 2

JANUARY - APRIL
- Launch of the call for nominations for the Non-clinical, Clinical and Methodology working parties
- WPs constituted, Chair and Vice-Chairs elected

MAY - JUNE
- New Operational model active
- Pilot Oncology ESEC

JULY - AUGUST
- Collect experience with the new model for WPs and the ESEC
- Lessons learned and identify further improvements

SEPTEMBER - DECEMBER
- Embedding new WP and governance domain structure with new IT tools
- Discussions at MB
- Preparation to launch the re-organization of the Quality Domain

2023

Phase 2 – Quality domain

JANUARY - MARCH
- Discussions at the Quality Domain Governance level
- Agreement at MB on main principles for the new QWP and BWP

APRIL - MAY
- Discussion at the Quality Domain governance on the expertise required for the call of interest based on the workplans
- Launch of the call for nominations for QWP, BWP and BMWP
- Nomination and selection of experts

JUNE - JULY
- QWP, BWP and BMWP constituted, Chairs elected

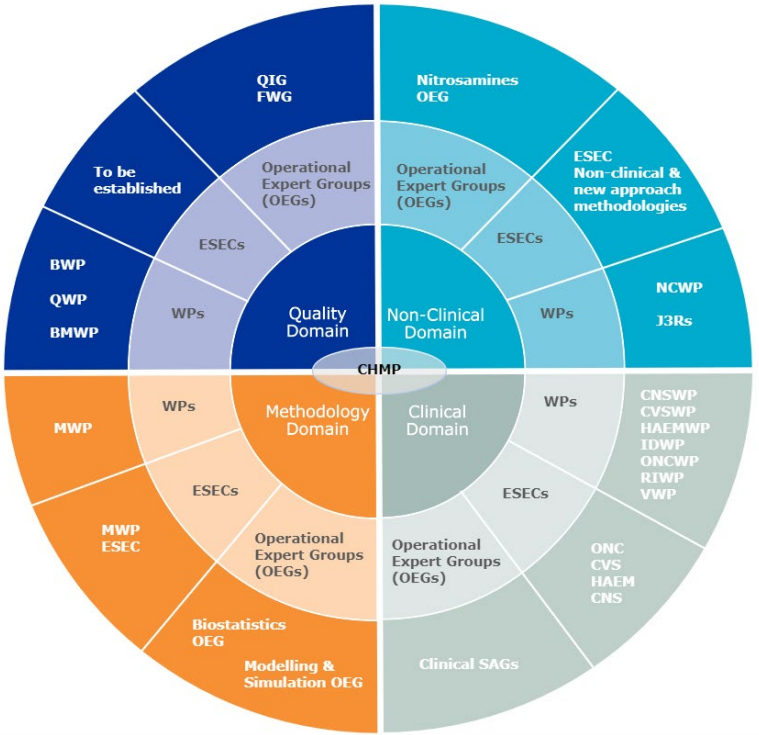
SEPTEMBER
- Vice-Chairs elected
- First meetings with new members of the QWP, BWP and BMWP

New model for the Working Parties

- **Domain** perform STORES (Strategic, Tactical, Operational, Reactive, Educational, Stakeholder) functions and produce three-year rolling strategic plans.
- Four organisational entities report to the domains governance:
  - **Working Parties** (WPs) have expertise in specific scientific fields and provide advice to the Committees
  - **Operational Expert Groups** (OEGs)=> provide advice on specific scientific topics and support operational activities of the domain
  - **Temporary Drafting Groups** (tDGs) => responsible for drafting guidance documents.

Supported by:

  - **European Specialised Expert Communities** (ESECs) => complement the knowledge within the domain by contributing to specific topics and are a source of expertise for the network.



Roadmap overview for the Quality Domain

- Initial 2-phase approach:
  - Phase 1: included Clinical, Non-clinical and Methodology domain;
  - Phase 2: Quality domain (QWP, BWP, BMWP, Paediatric Formulation-OEG, Herbal DG) following lessons learned exercise
- Balance for the memberships of the Biologics Working Party (BWP) and Quality Working Party (QWP), needed to consider:
  - The value of member state representation in an expertise-based model for BWP and QWP;
  - The need for alignment of approach across all working parties, with an "as needed" expertise composition which relies on active contribution of all expert members
- In March 2023, agreement at MB on an expertise-based model that provided flexibility on expertise and composition of WP

Phase 2 implementation of Quality domain: Main principles

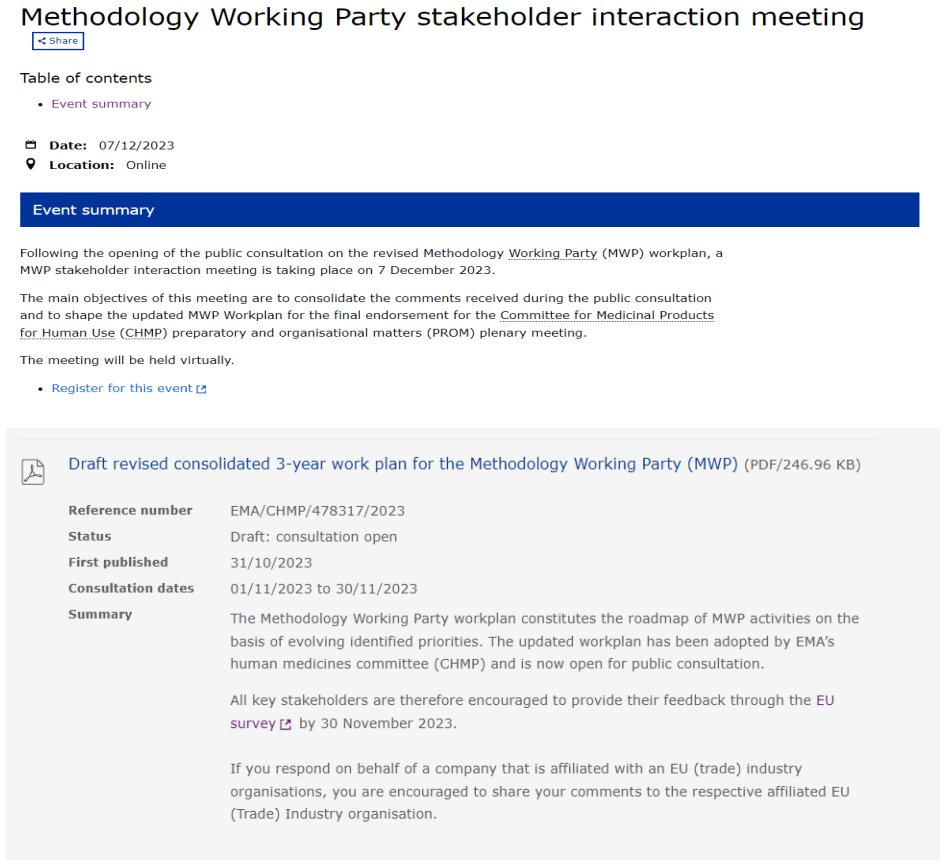
- Established WPs in the Quality Domain function under main principles:
  - QWP and BWP WPs are established for a period of 3 years, BMWP membership follows a revision on annual basis
  - Quality domain prioritised expertise, taking into account the geographical spread of the nominations. Therefore, MS representation no longer key factor for membership
  - Continuously inactive members are to be replaced
  - EDQM maintains an observer status in BWP and QWP
  - ESEC establishment by nomination of Committee members, open call without set deadline, and may have the possibility to listen in BWP and QWP meetings

Stakeholder engagement

- Due to BCP and Covid-19, stakeholder engagement for WPs was paused temporarily
- Stakeholder Engagement at Domain level
  - Structured Stakeholder Engagement for priority planning and generation/revision of new/revised individual guidelines
  - Public/targeted consultation of workplans
- Stakeholder Engagement at WP level
  - Interested parties meetings:
    - general matters or specific scientific issues as foreseen in the 3-year rolling strategic plan
    - Webinars on new/revised guidelines with high public health impact
  - Workshops
  - Training

Workplans

- Pilot stakeholder consultation on 3-year rolling workplan for Methodology Domain
- Open consultation for 1 month
- Stakeholder interaction meeting to address comments on the workplan



Methodology Working Party stakeholder interaction meeting

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- Event summary

Date: 07/12/2023
Location: Online

Event summary

Following the opening of the public consultation on the revised Methodology Working Party (MWP) workplan, a MWP stakeholder interaction meeting is taking place on 7 December 2023.

The main objectives of this meeting are to consolidate the comments received during the public consultation and to shape the updated MWP Workplan for the final endorsement for the Committee for Medicinal Products for Human Use (CHMP) preparatory and organisational matters (PROM) plenary meeting.

The meeting will be held virtually.

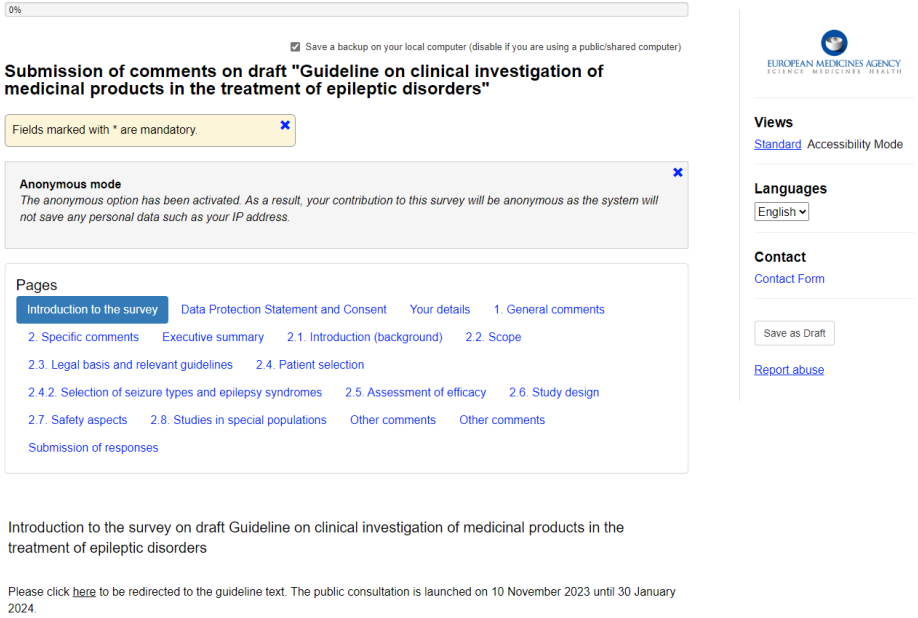
- Register for this event

Draft revised consolidated 3-year work plan for the Methodology Working Party (MWP) (PDF/246.96 KB)

Reference number	EMA/CHMP/478317/2023
Status	Draft: consultation open
First published	31/10/2023
Consultation dates	01/11/2023 to 30/11/2023
Summary	The Methodology Working Party workplan constitutes the roadmap of MWP activities on the basis of evolving identified priorities. The updated workplan has been adopted by EMA's human medicines committee (CHMP) and is now open for public consultation. All key stakeholders are therefore encouraged to provide their feedback through the EU survey by 30 November 2023. If you respond on behalf of a company that is affiliated with an EU (trade) industry organisations, you are encouraged to share your comments to the respective affiliated EU (Trade) Industry organisation.

New EU survey tool to capture comments on guidelines

- Login is not required to fill in the survey
- Once submitted, comments can still be edited until the end of the consultation
- Can save the survey as draft
- Submitted comments sent to email as PDF copy
- Facilitates the collection of comments



Summary

- Successful implementation of the re-organisation of the working parties from the Quality, Non-clinical, Methodology and Clinical domains
  - Quality domain prioritised expertise instead of MS representation, taking into account the geographical spread of the nominations
  - Review of the membership of WPs on an annual basis, BWP and QWP are established for a period of 3 years
- Stakeholder engagement with specific aims at the Domain and WP level
- Pilot on public consultation of 3-year rolling workplan for MWP
- New EU survey digital tool used for collection of comments rolled out for all public consultations of guidelines

Any questions?

Further information

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