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MWP Interested Parties meeting Report

26 September 2025

Role	Name
Chairs:	Kit Roes (MWP Chair) & Kristin Karlsson (MWP Vice Chair)
Participants:	**Industry:** Klavdija Kmetic (AESGP), Jürgen Hummel (EFSPI), Per Larsson (Organon), Rima Izem (Novartis), David Wright (EFSPI), Philip Hougaard (H. Lundbeck A/S), Silvia Paunova (Takeda), Milano Marcello (BioMarin), Paul Desert (Vaccines Europe), Nadege Le Roux (BMS), Susan Sandler (J&J), Fredrik Öhrn (EFSPI), Caroline Correas (BMS), Valeria Orlova (Novartis), Gracy Crane (Roche), Klaus Hellmann (Argenta), Stephen Matthews (Shionogi), Eadaoin O Mahony (Regeneron), Nina Heiss (Merck KGaA), Chris Price (PHUSE), Mina Grguri (Medicines for Europe), Cornelia Krueger (Shionogi), Christine Fletcher (GSK) **European medicines regulatory network:** Maria Grünewald, Wolfgang Jacquet, Elin Lindhagen, Jörg Zinserling, Marina Senek, Gabriel Westman, Florian Klinglmueller, Elina Asikanius, Markus Paulmichl, Michiel van den Heuvel, Jörg Engelbergs, Olaf Klungel, Sofia Kapanadze, Jacob Alsbæk Olsen, Flora Musuamba Tshinanu, Olga Kholmanskikh **EMA:** Amanda Langston, Demy van den Haak, Marie Orre, Theodor Framke, Diana Ferrer Prats, Ina-Christine Rondak, Frank Pétavy, Efthymios Manolis, Anouk Neven, Stefanie Prilla

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1. Summary

An Interested Parties meeting took place on 26 September to hear and reflect upon stakeholders' feedback on the priorities of 2026 as outlined in MWP's draft 2026-2028 workplan. Stakeholders were also given the opportunity to suggest areas where reordering the content might be beneficial. With regards to proposals for addition of new topics to the workplan, stakeholders were reminded that, if accepted, this may require deprioritisation of other topics.

Stakeholders were invited to present their comments and to engage with MWP members on these proposals.

MWP valued the exchange with stakeholders, and their feedback will be reflected in the revision of the workplan.

2. Introduction to MWP's revised 2026 priorities

The MWP Chairs introduced the main changes in the revised draft workplan (compared to the previous version 2025-2027), highlighting the priorities for 2026 as well as additional topics included in the workplan.

Notably, a seventh topic area was added to the workplan: Data management and analytical capability. This topic area seeks to ensure excellent data quality, data interoperability, and highly structured data for all data sources that inform regulatory assessment.

A list of guidelines, workshops, and training plans were presented. Activities that will be initiated in 2026 were explicitly highlighted.

3. Comments from Interested Parties and MWP responses

Interested Parties were invited to comment and submit questions regarding MWP's draft 2026-2028 workplan. Comments were received from Medicines for Europe, Vaccines for Europe, European Federation of Pharmaceutical Industries and Asssociations (EFPIA), and Association of Veterinary Consultants. Responses to comments are summarised below.

3.1. Comments from Vaccines Europe

Proposal to adding the following to section 2.4. "Multidisciplinary collaboration": "Notably, this will be done in collaboration with the 3Rs Working Party (3RsWP) on modelling and simulation approaches in the context of New Approach Methodologies (NAMs)."

Proposal to acknowledge the established collaboration with the 3Rs Working Party (3RsWP) on New Approach Methodologies (NAMs) in the guideline on predictive biomarker assays, and guideline on reporting of mechanistic models.

MWP supported these comments and will reflect thoroughly how to implement these proposals.

3.2. Comments from EFPIA

Clarify that different initiatives are organised under separate categories, but many will be connected to each other and will need to be consistent.

MWP welcomed this reflection on the structure of initiatives in the workplan. While in some instances, various initiatives are distinguished in the workplan, MWP views them as overlapping areas with opportunities for collaboration. The spirit of MWP is to engage in multidisciplinary work that seeks to connect and harmonise different disciplines. For example, the planned guidance on the assessment and reporting of mechanistic models in the context of model-informed drug development will be supported by experts from biostatistics, clinical pharmacology, and modelling and simulation disciplines.

Confirm if there is opportunity for overlap in the timing of guidance development across initiatives, particularly for related initiatives.

MWP confirmed that, indeed, activities are connected and overlapping. MWP intentionally limits parallel activities to ensure focused efforts on selected initiatives at a time. One way to keep oversight of overlapping activities beyond the scope of the MWP workplan is having MWP representation and involvement in other relevant scientific committees, working parties and groups. This helps to ensure that there are no duplicate efforts and that MWP remains aware of other relevant activities.

For the 'Biostatistics' guidance, more guidance on the evaluation of and appropriate use of novel approaches from different stakeholder perspective is recommended.

MWP emphasised that there is no intention to develop detailed guidance for every specific statistical method and context of use. Instead, regulatory guidance on methodological aspects will often outline general principles which will be applicable to multiple settings. Nevertheless, feedback is welcomed on specific approaches not covered by the currently available guidance and those already included in the workplan. The current draft workplan reflects a shift away from strict categorisation of guidance as either biostatistics, modelling and simulation, or otherwise. It now reflects that future guidance development requires a multidisciplinary approach.

Will the 'Data Science and AI' guidance be appropriately flexible so that it can be applicable to a broad range of AI models and tools? The ongoing activities do not mention the fact that the AI guidance is under development.

MWP aims to make any guidance developed in this field as timeless as possible, discussing principles rather than specific examples. Guidance should provide enough flexibility to accommodate future development expected in this field. If necessary, existing guidance will be updated to reflect progress in technologies and science.

Is EMA open to drafting more formal guidance on the use of AI in pharmacovigilance and clinical development? In the meantime, is it sufficient to follow the collective guidance from 1) the Q&A paper stemming from the 2024 AI reflection paper; 2) the upcoming AI terminology and principles papers; and 3) domain specific Q&As to guide AI use in product development?

MWP confirmed that related discussions are important and ongoing. MWP also acknowledged potential gaps in guidance regarding the essential requirements for applying AI in evidence generation and medicinal product development. It's critical to continue the work to merge the understanding of all stakeholders involved in all parts of the medicine lifecycle. The AI principles document will likely be a good starting point, and future scientific guidance is expected to address more specific aspects, providing a path for meeting regulatory standards.

Can MWP clarify how the reflection paper on the use of external controls will align with the Q&A document on synthetic data? It would be useful if the guidance developed the inclusion of synthetic data versus real data to satisfy external control arm as covered. Could the scope of this guidance be broadened to include more general applications and use, including what is considered to be acceptable even just for publication purposes. A multi-stakeholder workshop to discuss conditions of use and methodology is recommended.

A multi-stakeholder workshop on the use of external controls will be organized on 3 November 2025 and the related concept paper is undergoing public consultation until 31 October 2025. At the moment, synthetic data (e.g. data generated algorithmically) is not in scope of the reflection paper because the use of synthetic data is seen as a fundamentally different use case. Also, not many requests for scientific advice on the use of synthetic data have been observed yet. Nonetheless, the general principles to be outlined in the future reflection paper aim to be generalisable to that setting as well.

With regard to external control guidance, why is the focus on whole external control arms rather than hybrid approaches?

Studies using fully external controls differ fundamentally from those using hybrid controls. These two settings also have different methodological concepts. Providing a focused reflection paper on the use of external controls is believed to be more helpful both for industry and regulators and it will be delivered faster.

Are there plans for writing future guidance on hybrid controls?

The Bayesian reflection paper is currently being developed and the methodological approach outlined there will be important for the frequentist setting with hybrid designs. Coupled with the Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence, there might not be many gaps left, and MWP will need to see what needs to be addressed in the future (e.g. with Q&As or appendices to existing guidance).

For '(C) Activities to be started later' regarding pragmatic trials, could this work be initiated in 2026 together with the work on RWE and registry-based trials as the two are closely related?

The review and revision of the guideline on registry-based studies is planned to be initiated in 2026. Although this guideline relates to pragmatic trials, the details will be outlined in the new guidance to be developed on pragmatic trials. The working party must prioritise their activities and therefore cannot commit to start the guidance on pragmatic trials in 2026.

For 'Ongoing MWP support to ICH guidelines' could there be an opportunity to hold a workshop in collaboration with the EFPIA/EFSPI sponsored Estimand Implementation Working Group (EIWG) to share key learnings in the last 6 years from implementing ICH E9(R1) and key aspects where further clarification is needed?

The current focus of the EMRN lies on the implementation of the estimand framework in disease-specific settings and related multi-disciplinary interactions. It is also recognised that methodological challenges remain and deserve further discussion (e.g. estimation aligned with the estimand of interest, or how to handle terminal events when not part of a composite primary endpoint). The MWP is open to contributing to discussions, including in a workshop format. Including the clinical perspective in any interaction will be an important factor for success.

Regarding training and workshops, will these be a result of ICH work or related to EMA training plans?

Planned workshops covered in the MWP workplan are currently related to EMA guidance development as are subsequent training plans.

Are there any specific initiatives planned that relate to veterinary medicine, recognising that quite a few initiatives would require different considerations for animal health?

MWP has engaged with the veterinary medicines regulatory field, although engagement has so far been limited to the early stages of veterinary medicine development. It was highlighted that the recently published AI reflection paper was developed in collaboration with veterinary medicine experts, and the link between areas of work for MWP and veterinary field is very evident in the paper. MWP is in the process of strengthening and adding systematic engagement with the veterinary community which shall be highlighted in future versions of the work plan.

3.3. Comments from Medicines for Europe (addressed in writing)

A dedicated meeting on the implementation of ICH M13A would be appreciated, specifically to address unanswered questions from the 3rd Bioequivalence Forum in February.

MWP plans to share more details on ongoing work related to ICH M13A and will liaise with stakeholders to assess the need for a dedicated meeting on this topic.

From November 2024, the Clinical Pharmacology Operational Expert Group has started the review of all existing 91 product-specific bioequivalence guidelines in line with the new ICH M13A guideline. Of these, 19 guidelines were out of scope (e.g., suspension for injection, prolonged release), while 72 were within the scope of M13A and have been reviewed accordingly. This has resulted in four guidelines undergoing a major change, meaning that, after revision, MWP now requires a more elaborate bioequivalence study design. These four guidelines are currently under public consultation until 7 October 2025. Thirty-five more guidelines have been updated concerning minor changes, which are textual changes that have no influence on the bioequivalence study design. A further batch of 25 oncology product-related guidelines is currently under additional review, and it is expected that these will be published in due course as well. MWP is furthermore currently reviewing all related clinical pharmacology Q&As (mainly section 4), whose final versions are anticipated to be published before the end of this year.

4. Next steps

Accounting for the comments received during the targeted consultation on the priorities for 2026, MWP will finalise its 2026-2028 workplan by the end of the year. The workplan will subsequently be published on the Agency's website.