19 March 2026
EMA/61118/2026

Final Minutes – HMA-EMA joint Network Data Steering Group meeting

9 March 2026, 14:00-16:00pm, MS Teams Meeting

Co-Chairs: Karl Broich (HMA), Peter Arlett (EMA)

Item	Preliminary draft agenda	Presenters / Sponsors	Action	Time
1.	Adoption of the draft agenda & minutes	Karl Broich, Peter Arlett	For adoption	5’
2.	Review of methods: Biostatistics	Katrien Oude Rengerink, Florian Klinglmueller, Frank Petavy Discussants: all	For discussion	45’
3.	Review of methods: Modelling & Simulation	Flora Musuamba Tshinanu, Katrien Oude Rengerink, Frank Petavy, Efthymios Manolis Discussants: all	For discussion	45’
4.	Scientific Explorer new release: searching for initial marketing authorisation procedures	Flora Musuamba Tshinanu, Jane Moseley Discussants: all	For information	15’
5.	A.O.B.			

Role	Name
Attendance	Peter Arlett (EMA), Karl Broich (BfArM, DE), Harald von Aschen (BfArM, DE), Claus Møldrup (DKMA, DK), Kristin Karlsson (MWP), Angelo Molinaro (AIFA, IT), Vincent Gazin (ANSM, FR), Gabriel Westman (MPA, SE), Eftychia-Eirini Psarelli (EMA), Marie Orre (EMA), Eleonora Agricola (EU-IN), Anne-Marie van Nederkassel (EMA), Anabela Marcal (EMA), Florian Klinglmueller (AGES, AT), Patricia McGettigan (PRAC), Francisco Penaranda (EMA), Joerg Zinserling (BfArM, DE), Katrien Oude Rengerink (CBG-MEB, NL), Ivelina Gushlekova (CTCG), Momir Radulovic (Jazmp, SI), Flora Musuamba Tshinanu (SAWP), Stefanie Prilla (EMA), Georg Neuwirther (AGES, AT), Pelle Persson (MPA, SE), Marta Slomka (Payers), Siobhán O’Sullivan (Ethics), Dag Jordbru (NOMA,

	NO), Anthony Oshea (EDQM), Michael Vogl (EMA), Christina Kyriakopoulou (EC), Ana López de la Rica Manjavacas (AEMPS, ES), Jacobus van Wyk (EMA), Laure Baduel (CVMP), Paul Lynn (EMA), Rico Slingerland (CMDv), Christopher Javris (EDQM), Frank Petavy (EMA), Steven Le Meur (EMA), Gianmario Candore (EMA), Jane Moseley (EMA), Efthymios Manolis (EMA).
Apologies:	Aina Staisiuniene (EMA), Sandra Bertulat (BVL, DE (vet)), Jerome De Barros (EC), Edurne Lazaro (AEMPS, ES), Javier Martínez Arribas (Payers), Vaia Apostolidou (EC), Kaisa Immonen (EMA), Aimad Torqui (MEB, NL), Markus Kalliola (SITRA, FI), Carla Torre (CHMP), Konstantina Boumaki (EPF), Hilmar Hamann (EMA), Niklas Hedberg (HTA), Pier Paolo Olimpieri (AIFA, IT), Paolo Alcini (EMA), Kimmo Porkka (EHA), Patrice Verpillat (EMA), Pero Ivanko (CIPH, HR), Alessandro Blasimme (Ethics representative), Bruno Delafont (CHMP), Anastasia Pagida (EC).
Administrative support and minutes	Jolanta Palepsaitiene (EMA) and Francois Domergue (EMA).

1. Adoption of the draft agenda & minutes

The draft agenda was adopted. The minutes of 11th February 2026 NDSG meeting were adopted as final.

Francois Domergue informed the group that the updated Network Data Steering Group workplan 'Data and AI in medicines regulation 2026 to 2028' will be published on the dedicated EMA webpage during the second week of March 2026.

2. Review of methods: Biostatistics

The biostatistics methods review was presented by Frank Pétavy (EMA), Katrien Oude Rengerink (MEB, NL) and Florian Klinglmüller (AGES, AT), with support from Joerg Zinserling (BfArM, DE). The objectives of this review were to map current progress, identify challenges and gaps, and discuss with NDSG considerations to enable further use of biostatistics methods for evidence generation for regulatory decision-making.

Katrien Oude Rengerink (MEB, NL) presented the scope of this review. The data from regulatory submissions, including from Scientific Explorer showed that 61% of scientific advice procedures contain statistical questions, demonstrating the importance of biostatistics in drug development. Four methodological 'cluster' topics were prioritised:

- High priority: Bayesian methods; Evidentiary standards.
- Medium priority: Biomarkers; Estimands and estimation.

The rationale for prioritisation included prevalence in regulatory work, knowledge gaps, and potential for scientific innovation.

Florian Klinglmüller (AGES, AT) then presented the key challenges, opportunities and gaps for each priority area, structured across seven categories: human resources, training, data, tools, collaboration, research, and guidance/international collaboration. Key considerations for each priority area were clustered under short-term, medium-term and long-term.

The main considerations included:

- Need for deeper expertise: While some expertise in Bayesian methods exists, hands-on experience across the Network remains limited. Further development of specialist expertise will be necessary through training efforts and targeted recruitment. This should be highlighted to all NCAs, as sustained investment in Bayesian methods and evidentiary-standards expertise will be required. A structured mentoring system could help build hands-on experience across the EMRN, while topic-focused foresight or "clusters of excellence" groups would support reflection on system-wide implications and ensure alignment with evolving methodologies. These needs closely link to EMANS to 2028 Theme 6 on strengthening the network's long-term sustainability.
- Training and upskilling: Both methodological assessors and clinical assessors could benefit from targeted training on Bayesian methods, evidentiary standards, Biomarkers in clinical trials and estimands. Training should be practical, developed around assessors' needs and case-driven rather than high-level overview.
- Data and tools: Access to historical datasets, clinical study data (via the clinical study data pilot), and shared code repositories was identified as enablers. The need for recommendation on open-source Bayesian tools and the need for high-performance computing capacity were highlighted. The NDSG Data Analytic framework should include requirements to receive, store, access and analyse such data.
- Cross-ESEC collaboration: Now that ESECs/SIAs are established, multidisciplinary interaction should be launched. The complexity of emerging methods requires stronger collaboration, particularly between biostatistics and modelling and simulation, and biostatics and quality assessors. The ESEC SIA on PGx (as subset of Biomarkers in clinical trials) should be also strengthened with methodological support, interdisciplinary collaboration and throughout-reach.
- Future guidance: Members acknowledged the importance of contributing to international regulatory discussions, including future ICH work on Bayesian methods and evidentiary standards. However, Network alignment was stressed as important and a prerequisite to international discussion.
- Research: Several regulatory science research needs were identified.

The group welcomed the structured overview and clarity of considerations and provided the following feedback:

- The use of Bayesian methodologies is becoming more prominent, especially for clinical trials involving small populations, and complex designs. They are seen as promising avenue for advancing research in niche areas. Several ongoing EU programmes (e.g. Horizon Europe) contain relevant projects.
- Advice on use of specific data analysis software/tools across the Network would be beneficial and could also support more targeted training needs.
- The need to train clinical assessors to collaborate effectively with methodological and statistical assessors was highlighted, with a proposal to integrate biostatistics and methodological topics into the next 'Assessor Day' training.
- An EU network position is needed on evidentiary standards, drawing on lessons from the ICH M15 guideline, before initiating any further engagement at ICH level.
- Each working party could organise at least one mandatory training sessions per year, with support from ESEC, to improve current practices and prepare for upcoming pharmaceutical legislation changes.

- Support to establish clusters of excellence was expressed, with a need to set clear objectives and to prioritise future direction for the Network.

The co-chairs thanked all contributors for the excellent first discussion and agreed that the key NDSG experts should debrief and prepare a consolidated summary of the key considerations for a follow up discussion at the April Network Data Steering Group meeting (**Action**: NDSG secretariat).

Next steps will include consulting the relevant working parties and expert groups (e.g. MWP, ESEC and SIAs) to validate the key considerations.

3. Review of methods: Modelling & Simulation

Efthymios Manolis (EMA) and Flora Musuamba Tshinanu (SAWP) presented a review of modelling and simulation methods. The review followed the same structure as for the biostatistics review (see agenda item 2). Data from Scientific Explorer showed that around 26% of scientific advice procedures and nearly half of marketing authorisation applications reference modelling and simulation methods, demonstrating the high importance of such methods in medicines development. Paediatric extrapolation was identified as a priority area. Its conceptual framework is well-developed, but methodological maturity within the EMRN has not yet reached the same level. In the context of cross-product analyses, this will be a key enabler for strengthening benefit–risk assessment and labelling. It can also serve as a unifying area that drives methodological innovation and enhances system capacity, additionally benefiting related domains such as special populations (e.g. rare diseases, pregnancy, lactation), clinical trial design optimisation, and dose selection.

Flora Musuamba Tshinanu (SAWP) then presented the key challenges, opportunities, gaps. The outlined key considerations were clustered under short-term, medium-term and long-term. The main considerations included:

- Resourcing: Modelling and simulation require specialist expertise. There is a need to build additional capacity, including through collaboration and centres of excellence, to maintain high-quality assessment. This should be highlighted to all NCAs, that investment in M&S methods will be required. A mentoring system should be implemented to build hands-on experience within EMRN. This links with the work of the EMANS to 2028 Theme 6 on sustainability of the Network.
- Training: The field is evolving rapidly, and no single training programme covers all relevant methodologies, therefore this requires ongoing professional development and knowledge sharing. A multistakeholder workshop should be organised to take stock on current progress and regulatory landscape, listen from stakeholders and key regulatory science projects (e.g. ERAMET, INVENTS projects), and agree multi-stakeholder roadmap for implementation of ICH 11A and ICH M15.
- Data and tools: Members stressed challenges in obtaining modelling software across agencies. A model to facilitate access/sharing of M&S tools, a shared virtual environment for modelling tools and future access to individual patient-level trial data were identified as key enablers. The NDSG Data Analytic framework should include a requirement to receive, store, access and analyse such data.
- Cross-product learning and cross-ESEC collaboration: Systematic reuse and comparison of modelling strategies across products could greatly enhance consistency. Multidisciplinary interaction should be established, e.g. between M&S and biostatistics, within the ESECs and at committee levels. The recently launched MWP Extrapolation OEG (operational expert group, co-lead between EMA paediatrics and methodology teams) should be strengthened with more

'biostatistician' resources to foster and enable more collaboration between biostatisticians, modellers and clinicians.

- Research: Several regulatory science research needs were identified.

The group welcomed the structured overview and clarity of considerations and provided the following feedback:

- Consider facilitating inter-agency collaboration for knowledge sharing, by hosting exchange visits and mentoring programmes for assessors.
- The role of clusters of excellence was clarified during the meeting. They currently intend to facilitate procedural collaboration rather than scientific collaboration. The clusters of excellence on scientific collaboration should be considered in the future.
- It was highlighted that large number of modelling and simulation activities occur within type II variation procedures, which have shorter assessment timelines and requires rapid, in-house expertise to support such cases.
- In future, enabling access to data and the ability to analyse it could be highly beneficial.

The co-chairs thanked all contributors for the excellent first discussion and agreed that the key NDSG experts should debrief and prepare a consolidated summary of the key considerations for a follow up discussion at the April Network Data Steering Group meeting (**Action**: NDSG secretariat).

Next steps will include consulting the relevant working parties and expert groups (e.g. MWP, ESEC and SIAs) to validate the key considerations.

4. Scientific Explorer new release: searching for initial marketing authorisation procedures

Jane Moseley (EMA) presented the latest update on Scientific Explorer and gave a short demo on the AI-enabled knowledge-mining tool. Scientific Explorer was developed to address the challenge of retrieving relevant information from unstructured regulatory documents.

Following the successful implementation of scientific advice letters in the tool, the new release incorporates initial marketing authorisation procedures, allowing users to search assessment reports and procedural data. User surveys from the key stakeholders confirmed a strong demand for this expansion, which supports efficiency, consistency, and quality of assessments.

The new release was launched on 3 March 2026 and saw high engagement from the Network, with over 800 training registrations and significant increase in daily operations. The training materials were prepared to support the launch of the new release, which included a quick starter guide, comprehensive e-training module and two live/demo webinars.

The group congratulated the team and noted the very positive feedback received from NCAs on the tool, highlighting its contribution to more efficient use of resources and to improved quality of outputs. The group highlighted the need to continue training and change-management activities, and highlighted the importance of extending Scientific Explorer to additional procedure types to ensure comprehensive regulatory coverage