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# Joint HMA-EMA Big Data Steering Group

Mandate

The HMA-EMA joint Big Data Steering Group (BDSG) is a strategic group established to steer better analysis and use of big data in medicines regulation for the benefit of public and animal health in the European Union (EU).

Big data are generally large, accumulating rapidly, incorporate multiple data types and forms, and are of varying value and quality. In the context of medicines regulation, Big Data includes clinical trial raw data, real world data such as electronic health records, registry data and claims data, pooled clinical trials data, datasets from spontaneously reported suspected adverse drug reaction reports, and genomics, proteomics and metabolomics datasets[1]. This may also include non-clinical data, chemistry, manufacturing and controls (CMC) data, and supply data.

The BDSG's work progresses the European Medicines Agencies Network (EMAN) strategy to 2025 and focuses on data that are received, analysed, or advised upon by EMRN.

This document provides the first BDSG mandate revision. The purpose of this mandate revision is to ensure that proportionate network data governance is in place to propose and manage EMAN data analysis strategy, guidance and related pilots and EMRN experimentation to maximise the analysis and use of big data and strengthen the EU decision-making.

The revision follows a joint review of the BDSG mandate (EMA/95333/2020, dated 24 February 2020) and the EUNDB Terms of Reference (EMA/231985/2016, dated 10 January 2018) and replaces the BDSG mandate of 2020.

## 1. Role of the BDSG

Within the EMAN, the BDSG serves as a strategic steering group on analysis and use of data that are received, analysed, or advised upon by the network. The initial scope of the activities of the BDSG was provided by the 2020 recommendations of the Big Data Task Force (10-priority recommendations) with one additional priority recommendation covering the veterinary domain.

Tasks of the BDSG:

1. Makes proposals to HMA and EMA MB for the prioritisation, planning and monitoring of actions to implement the recommendations from the Task Force report and Pillar 2 of the EMAN strategy to 2025.
    - Oversee those actions that the Network decides to run as Big Data initiatives.
    - Monitor other relevant actions that are not run at Network level.

[1] HMA-EMA Joint Big Data Taskforce Phase II report: Evolving Data-Driven Regulation (europa.eu)

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    - Monitor ongoing EU Regulatory Network projects relevant to Big Data.
2. Provides advice for planning including the EMANs and EMA multi-annual workplan.
3. Promotes and agrees common network recommendations and positions on data analysis strategy and guidance to maximise the analysis and use of big data.
4. Supports pilots and EMAN experimentation for the analysis of data, including advanced analytics (AI/ML).
5. Supports communication and engagement on Big Data with the Network and its stakeholders.
6. Ensures international collaboration and alignment/harmonization on analysis, methods and use of big data in medicines regulation.
7. Monitors advances in data science, technology, legislation, and regulation of Big Data to identify opportunities and threats and make recommendations to HMA and EMA MB.
8. Identifies product applications relevant to Big Data, not fully regulated by the current EU framework.
9. Contributes to impact assessments and implementation of EU legislative initiatives; Ensures coordination and alignment towards goals with the European Commission services (including the European Health Data Space and the Pharmaceutical Strategy for Europe), HMA and EMA on any ongoing or new initiatives.
10. Identifies need for funding opportunities relevant to the priority recommendations on Big Data.
11. In the Network IM portfolio governance, BDSG is represented by the Network Data Board (NDB). BDSG is informed about calls for experts.
12. Ensures liaison with the EMA Data Board and the NDB.
13. Ensures that the perspectives of patients, pet and livestock owners and healthcare professionals are considered when making recommendations.

## 2. Composition and appointments

Members of the BDSG represent business expertise in data analysis, use and decision-making from Member States' NCAs, EMA, EC as well as representing key stakeholders.

- Member State's NCA representatives (5-8) following a call for interest from the HMA. Ideally, one to two representatives should come from a joint or veterinary agency.
- Representatives of the European Commission (3).
- A representative of the EHDS community on secondary uses of health data (1) and a representative of the Health Data Access Bodies (1)
- A representative of the EU Innovation Network (1)
- A representative of the NDB (1).
- A representative each from the CHMP, CVMP, PRAC, SAWP and MWP.
- A representative of CTCG (1)
- Representatives of EU Patient associations (1) and of EU healthcare professional associations (1).

- Representative of ethic bodies or networks (2)
- A representative of HTA bodies (1) and Payers (1)
- Representatives from EMA (5)

## 3. Appointment, terms and renewal

**NCA BDSG members:** When nominating the NCA representative, the competences that the nominee brings to the group should be described. If more than eight persons are nominated, the co-chairs should select the nominees in a way that ensures the best combination of competences. Competencies covered should include EU healthcare data, observational methods, biostatistics, advanced analytics, and 'omics.

**European Commission:** Commission representation will be coordinated by DG SANTE and DG RTD and may include other DGs depending on the agenda topics being discussed. Commission representation will focus on ensuring coordination and alignment with Commission goals.

**EHDS community on secondary uses of health data and Health Data Access Bodies:** Nomination is coordinated by the Commission services. Participation to facilitate coordination with activities related to EHDS and its implementation, as well as facilitating communication with Health Data Access Bodies once established.

**EU Patient associations and of EU healthcare professional associations**: Nomination of representatives will be through the EMA Patients and Consumers Working Party and Healthcare Professionals Working Party. Ideally the representative of healthcare professionals should be able to represent the views for human and veterinary medicines.

**Co-Chairs:** Two co-chairs are nominated for BDSG for the duration of the mandate, representing EMA and an NCA, respectively.

**Terms and renewal:** This mandate will be reviewed before the end of 2025. The appointment of the Steering Group and its members will be for the duration of this mandate.

## 4. Performance and reporting

Every year, the BDSG agrees a multi-annual workplan and measures its performance against that plan.

The BDSG reports quarterly to both HMA and EMA Management Board. The multi-annual workplan and an annual report are presented to both HMA and EMA Management Board.

## 5. Meetings

BDSG meets approximately on a monthly basis.

## 6. Interactions

BDSG is responsible for the interaction with:

- Experts: subject matter experts can be invited on ad-hoc basis to BDSG meetings on specific topics.
- Other stakeholders such as industry, international regulators/partners, standardisation organisations, data holders and data access bodies, may be engaged when required.

- Meetings are organised to exchange on topical issues with the wider group of stakeholders. At least one multi-stakeholder meeting is organised annually.
- Meetings may be organised up to twice a year to exchange on specific needs and issues with industry association representatives.
- BDSG liaises with NDB to exchange and align on data matters of common interest.
- BDSG acts in liaison with EMA Data Board

## 7. Secretariat

The secretariat is provided by EMA. This includes meeting organisation, agendas, minutes, monitoring of progress and outcomes, and communication with the various BDSG stakeholders. Agendas and minutes of the BDSG meeting will be published on EMA website.

**Endorsed by HMA at the 112th HMA meeting in Sweden in May 2023.**

**Endorsed by EMA Management Board at the 120th Management Board meeting in Amsterdam in June 2023.**