



Big Data Steering Group

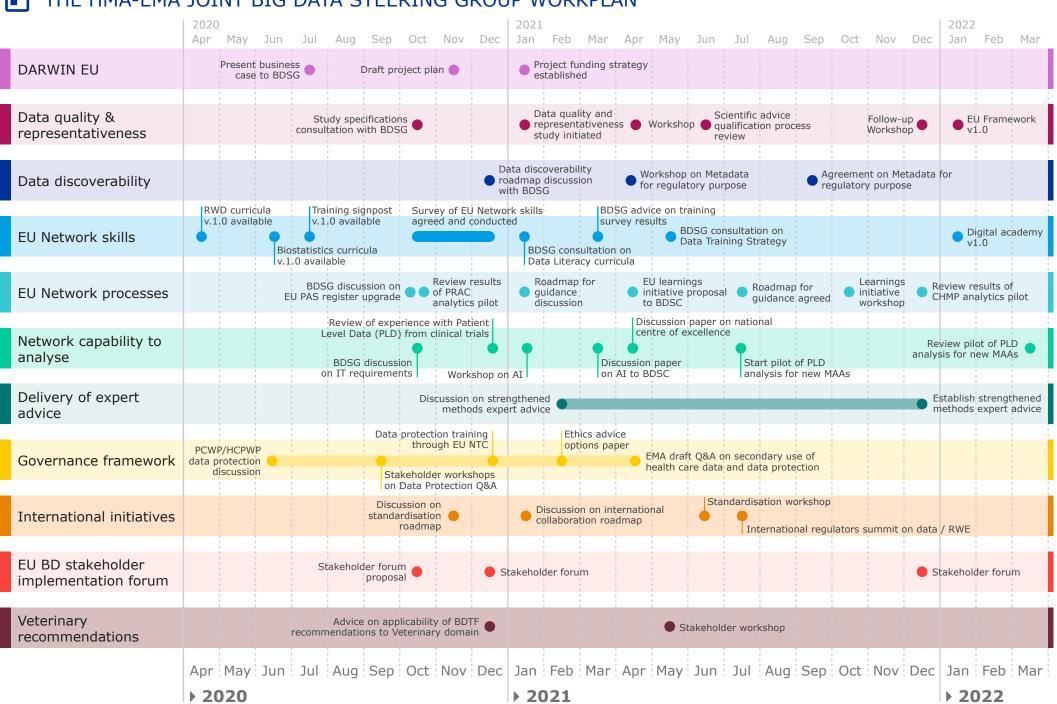
Workplan

The HMA-EMA joint Big Data Steering Group (BDSG) workplan was adopted on **27 July 2020**. The document includes a brief description of each topic and deliverables. The plan was prepared based on the BDSG mandate and is structured in line with the key recommendations of the Big Data Task Force (see Annex I). Implementation of the actions in the Big Data Steering Group workplan 2020-21 will need to be flexible given uncertainties on the resources that will need to be prioritised towards the regulatory response to the COVID-19 pandemic.

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THE HMA-EMA JOINT BIG DATA STEERING GROUP WORKPLAN



TOPIC DESCRIPTION

DARWIN EU

The Data Analytics and Real-World Interrogation Network (DARWIN-EU) is the first and most ambitious recommendation of the Big Data Task Force. Work is ongoing to finalise the detailed business case, to develop the project plan and to secure funding (both for the project phase and for long-term maintenance).

July 20 Present business case to BDSG

Nov 20 Draft project plan

Jan 21 Project funding strategy established

Data quality & representativeness

Engagement with stakeholders and leveraging the ongoing work of external parties will be critical to delivering a data quality framework for the EU Regulatory Network. It is therefore proposed to contract an external study to analyse existing data quality initiatives and to discuss data quality with a wide range of stakeholders. The aim is to deliver the first version of the framework in early 2022.

It is proposed to review the Scientific Advice qualification process and this review should start in mid-2021.

Oct 20 Study specifications consultation with BDSG

Jan 21 Data quality and representativeness study initiated

Apr 21 Workshop

Jun 21 Scientific advice qualification process review

Dec 21 Follow-up Workshop

Jan 22 EU Framework v1.0

Data discoverability

Closely linked to the work on data quality will be the agreement by the EU Regulatory Network on metadata to be used to describe and identify big data sets. In 2021, a workshop on metadata will be held and this may be combined with the workshop on data quality.

The data discoverability roadmap will focus on the delivery of a publicly available tool to enable big data to be catalogued using the agreed metadata. This will support the identification of relevant datasets for studies and the interpretation of those studies.

| Dec 20 | Data discoverability roadmap discussion with BDSG |
|---------|---|
| Apr 21 | Workshop on metadata for regulatory purposes |
| Sept 21 | Agreement on metadata for regulatory purposes |

EU Network skills

Significant progress has already been made, through the EU Network Training Center, on the delivery of training curricula to upgrade the skills available to the EU Regulatory Network. Curricula development and training content delivery will continue throughout this workplan. In Q4 2020 a survey of EU Network skills relevant to big data will be launched. The results will inform the further development of training.

| Apr 20 June 20 Jul 20 | Real-world data curricula v.1.0 available Biostatistics curricula v.1.0 available Training signpost v.1.0 available |
|---|---|
| Oct-Dec 20 Survey of EU Network skills agreed and conducted BDSG consultation on Data Literacy curricula | |
| Mar 21 May 21 | BDSG advice on training survey results BDSG consultation on Data Training Strategy |

EU Network processes

Four streams are identified:

- 1. The BDSG will discuss options to further increase the transparency of observational research through enhanced public registration of studies (including a possible enhancement of the EU Post-Authorisation Studies Register).
- 2. Linked to the modernisation of expert advice to the Network, work is

initiated to deliver a roadmap for the development of guidance on data characterisation, data analysis, study methods and presentation of protocols and results.

- 3. In 2020 PRAC is piloting rapid analytics of real-world data to support its decision-making and a similar pilot by CHMP will be conducted in 2021. Results will inform the improvement of core regulatory processes to incorporate real-world data.
- 4. In order to develop processes, guidance for industry and deliver data-driven decisions, it will be critical to systematically learn from applications to the network that include big data. A 'learnings initiative' will be the subject of a workshop in 2021.

| Oct 20 | BDSG discussion on EU PAS register upgrade |
|--------|--|
| Oct 20 | Review results of PRAC analytics pilot |
| Jan 21 | Roadmap for guidance discussion |
| Apr 21 | EU learnings initiative proposal to BDSG |
| Jul 21 | Roadmap for guidance agreed |
| Oct 21 | Learnings initiative workshop |
| Dec 21 | Review results of CHMP analytics pilot |
| | |

Network capability to analyse

To enable analytics of data by the EU Network, technology will need to be delivered and the BDSG will be consulted, together with the established EU Network Telematics Governance.

Pilots of the analysis of patient level data (PLD) from clinical trials will be initiated so that policy, process and technology choices are informed by evidence.

The Big Data Task Force made a number of observations and recommendations on artificial intelligence (AI) and the BDSG will discuss the implications for the Network.

The BDSG will discuss national centres of excellence in data analysis drawing on existing experience.

| Nov 20 | BDSG discussion on IT requirements |
|--------|--|
| Dec 20 | Review of experience with PLD from clinical trials |
| Mar 21 | Discussion paper on AI to BDSG |

| Apr 21 | Discussion paper on national centre of excellence |
|--------|---|
| Jul 21 | Start pilot of PLD analysis for new MAAs |
| Mar 22 | Review pilot of PLD analysis for new MAAs |

Delivery of expert advice

The recommendation of the Big Data Task Force to strengthen expert advice relevance to big data will be taken forward as part of the EMA Management Board mandated review of the Agency's experts working parties and groups. It is anticipated that by late 2021 the gaps in big data expert advice will have been resolved and the delivery of advice will have been modernised.

| Feb 21 | Discussion on strengthened methods expert advice |
|--------|---|
| Dec 21 | Establishment of strengthened methods expert advice |

Governance framework

The work on data governance is being informed by dialogue with EMA's Patients and Consumers Working Party and Healthcare Professionals Working Party and a series of discussions and virtual workshops are taking place in 2020. To guide stakeholders, to support compliance and to enable public health research that supports medicines regulation, a key deliverable will be a Question and Answer document on data protection in the context of secondary use of healthcare data. This should be finalised and made public in the second quarter of 2021. The Big Data Task Force recommended strengthening the availability of ethics advice on Big Data. The BDSG will discuss an options paper on ethics advice in 2021.

| Jun 20 | PCWP/HCPWP data protection discussion | | |
|---|--|--|--|
| Aug 20 | Aug 20 Data protection training through EU NTC | | |
| Sep 20 Stakeholder workshops on Data Protection Q&A | | | |
| Feb 21 | 21 Ethics advice options paper | | |
| Apr 21 EMA draft Q&A on secondary use of health care date | | | |
| | data protection | | |

International initiatives

Standardisation will be critical to realising the full potential of big data to drive regulatory decision-making and stakeholders will be engaged in a standardisation roadmap at a workshop planned for mid-2021. More broadly, the BDSG will be consulted on a roadmap for international collaboration on big data and a summit with international regulators is foreseen for 2021.

| Nov 20 D | Discussion on standardisation roadmap | | |
|-----------------|--|--|--|
| Jan 21 D | iscussion on international collaboration roadmap | | |
| Jun 21 S | Standardisation workshop | | |
| Jul 21 Ir | nternational regulators summit on data / RWE | | |

EU BD stakeholder implementation forum

A first big data stakeholder forum will be held virtually before the end of 2020 and fora are anticipated to take place at least annually thereafter.

| Sep 20 | Stakeholder forum proposal discussed at BDSG |
|--------|--|
| Dec 20 | Stakeholder forum |
| Dec 21 | Stakeholder forum |

Veterinary recommendations

The Big Data Task Force recommendations did not cover veterinary medicines. However, the EMA management board and the Heads of Medicines Agencies (HMA) recommended that veterinary medicines be included in the scope of work of the big data steering group. The steering group will consider the applicability of the recommendations to the veterinary domain and a vet stakeholder workshop is anticipated for 2021.

| Dec 20 | Advice on applicability of BDTF recommendations to |
|--------|--|
| | Veterinary domain |
| May 21 | Stakeholder workshop |



ANNEX I: PRIORITY RECOMMENDATIONS OF THE HMA-EMA JOINT BIG DATA TASK FORCE

| I — | Deliver a sustainable platform to access and analyse healthcare data from across the EU | Data Analysis and Real World Interrogation Network - DARWIN. Build the business case with stakeholders and secure funding to establish and maintain a secure EU data platform that supports better decision-making on medicines by informing those decisions with robust evidence from healthcare. |
|----------|---|---|
| II | Establish an EU framework for data quality and representativeness | Establish an EU framework for data quality and representativeness. Develop guidelines, a strengthened process for data qualification through scientific advice, and promote across Member States the uptake of electronic health records, registries, genomics data, and secure data availability. |
| III | Enable data discoverability | Identify key metadata for regulatory decision-making on the choice of data source, strengthen the current ENCePP resources database to signpost to the most appropriate data, and promote the use of the FAIR principles (Findable, Accessible, Interoperable and Reusable). |
| IV — | Develop EU network skills in big data | Develop a big data training curriculum and strategy based on a skills analysis across the network, collaborate with external experts including academia, and target recruitment of data scientists, omics specialists, biostatisticians, epidemiologists, and experts in advanced analytics and AI. |
| v _ | Strengthen EU network processes for big data submissions | Launch a 'big data learnings initiative' where submissions that include big data are tracked and outcomes reviewed, with learnings fed into reflection papers and guidelines. Enhance the existing EU PAS register to increase transparency on study methods. |
| VI | Build EU Network capability to analyse big data | Build computing capacity to receive, store, manage and analyse large data sets including patient level data (PLD), establish a network of analytics centres linked to regulatory agencies, and strengthen the network's ability to validate AI algorithms. |
| VII)— | Modernise the delivery of expert advice | Build on the existing working party structure to establish a Methodologies Working Party that encompasses biostatistics, modelling and simulation, extrapolation, pharmacokinetics, real world data, epidemiology and advanced analytics, and establish an Omics Working Party that builds on and reinforces the existing pharmacogenomics group. |
| VIII | Ensure data are managed and analysed within a secure and ethical governance framework | Engage with initiatives on the implementation of EU data protection regulations to deliver data protection by design, engage with patients and healthcare professionals on data governance, and establish an Ethics Advisory Committee. |
| IX — | Collaborate with international initiatives on big data. | Support the development of guidelines at international multilateral fora, a data standardisation strategy delivered through standards bodies, and bilateral collaboration and sharing of best practice with international partners. |
| <u>x</u> | Create an EU big data 'stakeholder implementation forum' | Dialogue actively with key EU stakeholders, including patients, healthcare professionals, industry, HTA bodies, payers, device regulators and technology companies. Establish key communication points in each agency and build a resource of key messages and communication materials on regulation and big data. |