




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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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	Real-world data curricula v.1.0 available
June 20	Biostatistics curricula v.1.0 available
Jul 20	Training signpost v.1.0 available
Oct-Dec 20	Survey of EU Network skills agreed and conducted
Jan 21	BDSG consultation on Data Literacy curricula
Mar 21	BDSG advice on training survey results
May 21	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	Data protection training through EU NTC
Sep 20	Stakeholder workshops on Data Protection Q&A
Feb 21	Ethics advice options paper
Apr 21	EMA draft Q&A on secondary use of health care data and 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** Discussion on standardisation roadmap
- Jan 21** Discussion on international collaboration roadmap
- Jun 21** Standardisation workshop
- Jul 21** International 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



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