Opening remarks

Data Quality Framework for medicines regulation workshop

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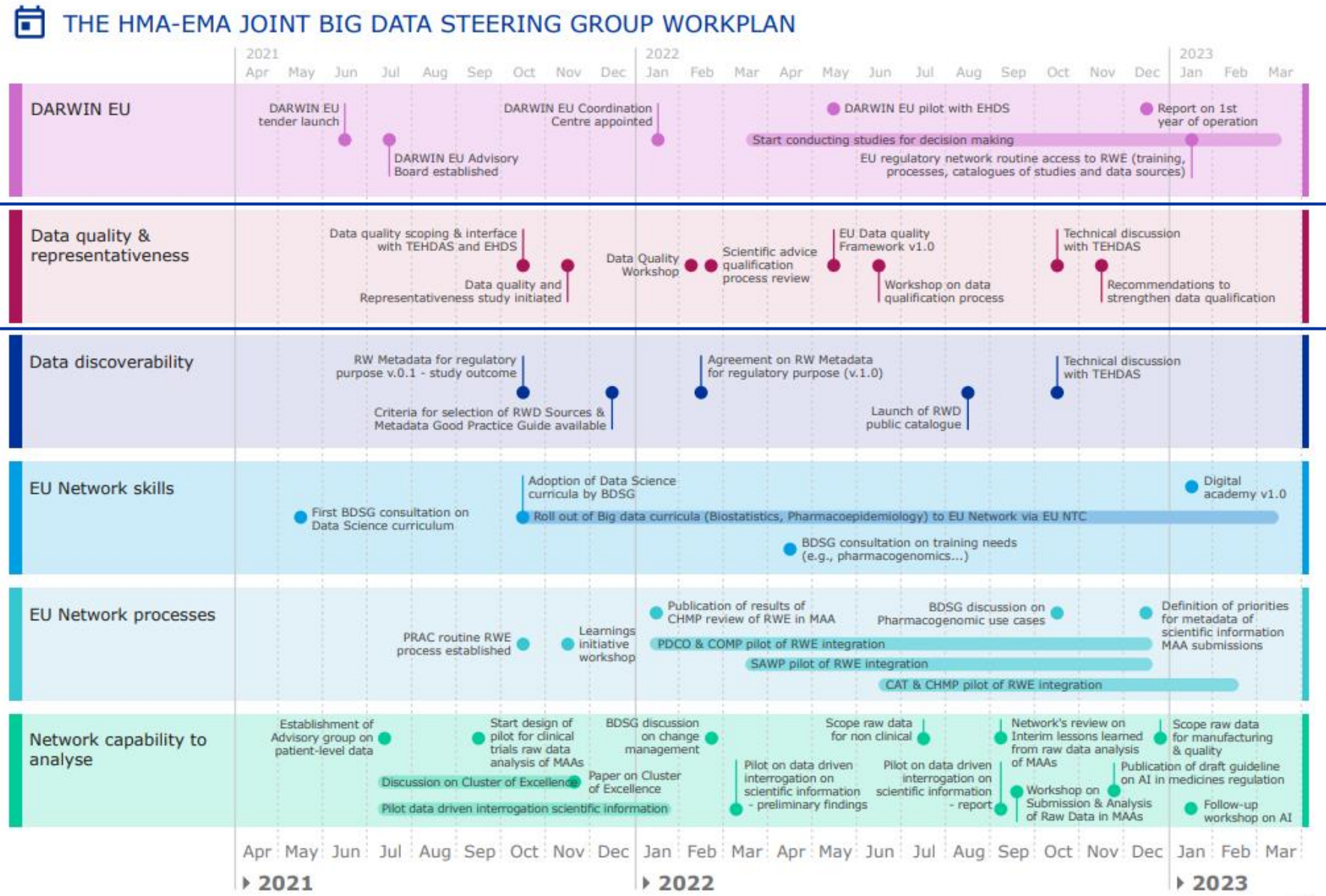

Scope - BDSG report and recommendations

5.2. Establish a framework which describes data quality

Establish a certification process for data sources '

'Data quality is not a static construct and is context, disease and question dependent and dependent on the healthcare system. Assessments need to be constant and documented every time the data is refreshed'

Public consultation comments

The Big Data vision requires the use of data not originally intended for regulatory decision-making and understanding quality is challenged by a lack of standardisation, sometimes limited precision and robustness of measurements (e.g. proteomics data), missing data, variability in content and measurement processes, unknown quality and constantly changing datasets. One possible exception to this is the well standardised adverse drug reporting datasets. As an example a recent analysis revealed that the number of European databases that meet minimum regulatory requirements for content across a broad range of regulatory use cases and which are readily accessible is disappointingly low [3]. See figure 1 for illustration of the data landscape for real-world data.

What this means for stakeholders:

A data quality framework will support the trust of patients and healthcare professionals in the decisions reached by regulators when Big Data underpins those decisions. It will aid the choice of data source selected for a study (including those by industry) and it will inform the assessment of the study results and the benefit-risk dossier by regulators.

BDSG report

Recommendations

Establish a data quality framework (DQF) for regulatory use of big data sources with associated data quality metrics

Expansion of qualification advice process to establish renewable certification of datasets as well as Big Data methods and strategies

Establish criteria for reliability of device based diagnostic and other in vitro diagnostics

Proactive external communication to promote adoption of Data Quality Framework

Promote use of ISO-IDMP standard

Fiche #1 & 2

Scope – applicability and intended use

- The creation of a clear Data Quality Framework tailored for the intended regulatory purpose. The data quality framework will need to be applicable to various types of databases used in the medicinal products for human and veterinary use regulatory framework.

- Real world data (electronic health records etc.)
- Clinical trial data
- Spontaneous reporting
- Quality
- Manufacturing
- Genomic data
- Imaging data
- Veterinary
- …….

'Big data' is a widely-used term without a commonly-accepted definition. The HMA/EMA Big Data Task Force defined big data as '**extremely large datasets** which may be complex, multi-dimensional, unstructured and heterogeneous, which are accumulating rapidly and which may be analysed computationally to reveal patterns, trends, and associations. In general, big data sets require advanced or specialised methods to provide an answer within reliable constraints'.

A single dataset may not strictly meet the definition of big data but, when **pooled or linked with other datasets**, they become sufficiently large or complex to analyse to assume the characteristics of big data. Sources include real-world data (such as electronic health records, insurance claims data and data from patient registries), genomics, clinical trials, spontaneous adverse drug reaction reports, social media and wearable devices.

Medicines regulators will increasingly use insights derived from big data to **assess the benefit-risk of medicines** across their lifecycle.

EU Data Quality framework in the Network Strategy 2025

Data analytics, digital tools and digital transformation

(for discussion of the goals, see section 3.2)

Goal	Objectives
Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data	▸ Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU)
	▸ Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll out of such analysis.
	▸ Establish collaborations with external stakeholders (including patients, academia, NGOs and industry) and with international regulatory authorities on Big Data initiatives
	▸ Establish EU framework for data quality, discoverability and representativeness, through agreement on meta-data for regulatory purposes, a standardisation roadmap and registers of real-world data sources and of observational studies

Steps in drafting Data Quality Framework

Phase 1 (general scope) Feb 22 – Sep 22

- Starting point – the review of existing data quality frameworks (completed in preparatory phase)
- A skeleton of the proposed documents will be drafted (e.g.: chapters, big blocks proposed)
- Organise a data quality workshop to collect requirements and feedback on the structure proposed (April 22)
  - Collect in the consultation phase/during the workshop the *priority use cases* to be used for phase 2 (regulatory use cases)
- Draft the general scope of the data quality framework using the input received (finalised in June 22)
- Open written public consultation on the document drafted (July-Aug)
- Redrafting content based on feedback and further consultation within the network (finalised Sep 22)

Phase 2 (applied use cases) Mar 22 – Nov 22

- Drafting of applied use cases of the data quality framework ongoing throughout the drafting period (in parallel with the drafting of the general scope)
- Collection of requirements and prioritisation for specific use cases in the preparation phase and during the DQ workshop (fluid, agile process and content)
- Consult on the content of the use cases targeting specific experts and stakeholders (e.g.: manufacturing data with experts in the field)

Thank you!

For any question on this presentation, please contact: DataQualityFramework@ema.europa.eu
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