

The Data Quality Framework and Its Practical Impact on Data Quality

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Definitions

Article 2(z) and 2(aa) EHDS



- 🔍 **'data quality'** means the degree to which the elements of electronic health data are suitable for their intended **primary use** and **secondary use**;
- 🔍 **'data quality and utility label'** means a graphic diagram, including a scale, describing the data quality and conditions of use of a dataset;



Recital 57 EHDS

- 🔍 *„Health data users who benefit from access to datasets provided for under this Regulation could enrich the data in those datasets with various corrections, annotations and other improvements, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of the data in the datasets.*
- 🔍 *Health data users should be encouraged to report critical errors in datasets to health data access bodies. To support the improvement of the initial database and further use of the enriched dataset, Member States should be able to establish rules for the processing and the use of electronic health data containing improvements related to the processing of those data. The improved dataset should be made available free of charge to the original health data holder together with a description of the improvements (...)*”

Data quality and utility label (Article 78 EHDS)



Article 78

Data quality and utility label

1. Datasets made available through health data access bodies may have a Union data quality and utility label applied by the health data holders.
2. Datasets with electronic health data collected and processed with the support of Union or national public funding shall have a data quality and utility label covering the elements set out in paragraph 3.
3. The data quality and utility label shall cover the following elements, where applicable:
 - (a) for data documentation: metadata, support documentation, the data dictionary, the format and standards used, the source of the data and, where applicable, the data model;
 - (b) for assessment of technical quality: the completeness, uniqueness, accuracy, validity, timeliness and consistency of the data;
 - (c) for data quality management processes: the level of maturity of the data quality management processes, including review and audit processes, and bias examination;
 - (d) for assessment of coverage: the period, population coverage and, where applicable, representativity of the population sampled, and the average timeframe in which a natural person appears in a dataset;
 - (e) for information on access and provision: the time between the collection of the electronic health data and their addition to the dataset and the time needed to provide electronic health data following the issuing of a data permit or a health data request approval;
 - (f) for information on data modifications: merging and adding data to an existing dataset, including links with other datasets.



Data Quality Framework (DQF)



- The Data Quality Framework (DQF) is the structured set of standards, tools, and processes that govern how health data is assessed, certified, and maintained across the EHDS ecosystem.
- DQF can transform data:
 - Trustworthy Research;
 - Policy Evidence Base;
 - Reduced Duplication;
 - Patient Safety;
 - Accountability.



DQF quality dimensions

uniqueness

accuracy

timeliness

consistency

validity

completeness



Recommendations

- Investing in interoperability infrastructure and shared tooling to reduce per-Member-State costs;
- Providing targeted capacity-building support for HDABs in new Member States and smaller systems;
- Phasing compliance timelines to allow progressive adoption without disrupting health services;
- Engaging data holders early through co-design of quality metrics.





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Thank you for your time!



Co-funded by
the European Union

This project is co-funded under the EU4Health Programme
2021–2027 under grant agreement no. 101101187

