RWD87

# From data to decisions: enhancing real-world data quality – a survey of health-data producers in France

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## INTRODUCTION

- High-quality real-world data (RWD) is essential for ensuring the reliability of research outcomes, supporting effective healthcare decision-making, and gaining recognition from health authorities.
- The fragmentation and scarcity of RWD, coupled with limited public access to datasets, and challenges in conducting feasibility studies, present significant barriers to robust research.
- Several RWD resources exist in France (Portail Epidémiologie – France,[1] Health Data Hub,[2] Commission Nationale de l'Informatique et des Libertés [CNIL][3]), but the accessibility of information on RWD quality remains insufficient.[4]
- The European Health Data Space Regulation, which came into force in March 2025,[5] imposes a quality label for publicly funded data, reinforcing the urgent need to standardize and improve the accessibility of RWD quality indicators.

## OBJECTIVES

- To identify best practices for ensuring RWD quality and to facilitate the effective conduct of feasibility studies.

## METHODS

- The Comité Stratégique de Filière des Industries et Technologies de Santé (CSF-ITS) in France conducted a survey among health-data producers in France in May and June 2025.
- The survey was disseminated through the CSF, LEEM, and the Alliance pour la Recherche et l'Innovation des Industries de Santé (ARIIS) networks.
- The survey was both quantitative and qualitative (10-item questionnaire with multiple-choice and open-ended responses) and non-anonymized.
- The survey explored the following topics: availability and accessibility of information, governance and access procedures, confidentiality and data-sharing practices, adaptations based on partner type (academic vs industry), frequency and modality of data extraction and reporting, tools and methods for data quality control, feasibility-study practices and project evaluation, representativity assessments, and compliance with data privacy regulations (e.g. the European Union's General Data Protection Regulation [GDPR], CNIL).

## RESULTS

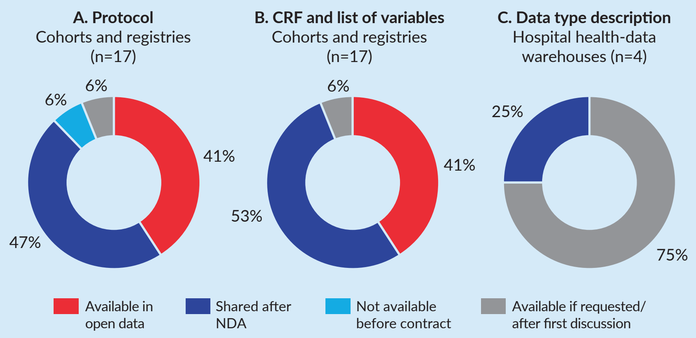
### Participants

- A total of 21 health-data producers participated in the survey: 17 cohorts or registries (structured databases), and four hospital health-data warehouses.

### Accessibility of data and documentation

- Most cohorts and registries do not share publicly any protocols or case report forms/lists of variables; most provide this information only in the context of a non-disclosure agreement (NDA) or contractual agreement (**Figures 1A** and **1B**).
- None of the hospital health-data warehouses share data type descriptions publicly; most (3/4; 75%) provide this information after the first discussion/if requested (**Figure 1C**).
- Approximately half of the cohorts and registries (9/17; 53%) provide data-quality-related information only after a contractual agreement, and 7/17 (41%) only after an NDA.
- Concerns regarding confidentiality were cited as the main reason for not sharing information during the initial discussions by 9/17 (53%) of cohorts and registries.
- For some cohorts and registries (3/17; 18%), academic partners have easier access to data than industry partners (e.g. simpler agreements); some restrictions apply to industry (e.g. no raw data, intellectual property clauses).

**Figure 1. Accessibility of data and documentation**

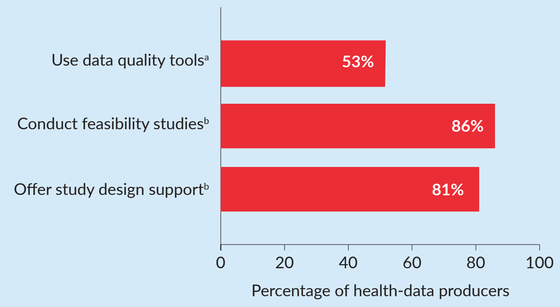



CRF, case report form; NDA, non-disclosure agreement.

### Data-quality evaluation and tools

- Approximately half of the cohorts and registries (9/17; 53%) use standardized data-quality tools (e.g. the Registry Evaluation and Quality Standards Tool [REQueST][6]) or internal tools/software (**Figure 2**).
- Data-quality evaluation is limited for hospital health-data warehouses outside specific projects because the data are not structured.
- Feasibility studies are conducted by most (18/21; 86%) health-data producers (**Figure 2**); most studies assess sample size, missing data, variable availability, and biases.
- Study design support (e.g. endpoints, follow-up duration) is offered by most health-data producers (17/21; 81%) (**Figure 2**).

**Figure 2. Data-quality evaluation and tools**

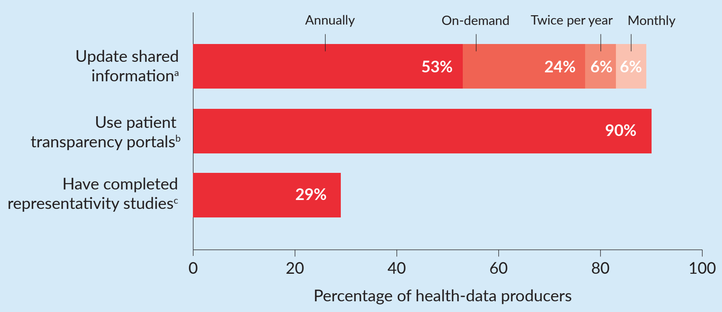



[a]Data are for cohorts and registries only (n=17). [b]Data are for all health-data producers (n=21).

### Data updates, privacy, and representativity

- Most of the cohorts and registries update shared information annually (9/17; 53%) or on-demand (4/17; 24%) (e.g. dashboards, newsletters, cohort reports) (**Figure 3**).
- Strong compliance with data privacy regulations (GDPR, CNIL, the US Health Insurance Portability and Accountability Act of 1996 [HIPAA]) was reported; pseudonymization and secure servers are common.
- Patient transparency portals are widely implemented (19/21; 90%) (**Figure 3**).
- Less than one-third of cohorts and registries have completed representativity studies (5/17; 29%) (**Figure 3**), but some studies are ongoing or planned; some use Système National des Données de Santé (SNDS) or Institut National de la Statistique et des Études Économiques (INSEE) sampling, or national registries for comparison.

**Figure 3. Data updates, transparency, and representativity**




[a]Data are for cohorts and registries only (n=17); 2/17 (12%) not applicable (data not shown).
[b]Data are for all health-data producers (n=21).
[c]Data are for cohorts and registries only (n=17).

### Willingness to collaborate and suggestions for improvement

- The majority of health-data producers (17/21; 81%) are open to completing the Haute Autorité de Santé REQueST tool.
- Survey respondents provided suggestions to improve data quality, such as more resources for data management and monitoring, early identification of key variables, enhanced interoperability and digitalization, and standardization of data collection tools and quality benchmarks (**Table 1**).

**Table 1. Suggestions to improve data quality**

| | |
|---|---|
| **Resource allocation** | • More staff dedicated to data management and monitoring |
| **Standardization and methodology** | • Harmonization of practices<br>• Definition of shared standards |
| **Data transformation** | • Development of digitalization at the source<br>• Improvement of interoperability |
| **Continuous qualification** | • Implementation of deadlines for completion and monitoring<br>• Regular quality audits |
| **On-site monitoring** | • Visits to collection centres<br>• Training of investigators |
| **Better scoping of projects** | • Early identification of variables of interest<br>• Strengthened collaboration with investigators |
| **Motivation of the centres** | • Sufficient compensation<br>• Academic promotion to encourage involvement |

## CONCLUSIONS

- This survey highlights existing best practices in France for ensuring high-quality RWD.
- Wide variability exists in health-data practices, including data-sharing, quality evaluation, feasibility-study methodology, and frequency of data updates.
- Importantly, the findings indicate a gap in health-data quality assessment, as the information related to health-data quality does not appear to align with international key performance indicators (KPIs; see box below).[7,8]

**International KPIs**

- **Reliability**: completeness, consistency, and credibility of data.
- **Relevance**: availability of key data elements (e.g. exposure, outcomes, covariates) for the research question.
- **Traceability**: ability to audit and verify data sources and transformations.

- Disseminating best practice is crucial for enhancing the quality of RWD, a prerequisite for gaining fair recognition by health authorities. The CSF is actively working to create and disseminate materials on best practice in health-data quality.
- In addition, there is a clear need to define simple, reproducible health-data quality KPIs and structured frameworks for transparency.

## LIMITATIONS

- This survey-based study was conducted in France, and the findings may not be representative of other countries in Europe.
- The two types of health-data producers participating in the survey – cohorts/registries and hospital health-data warehouses – are very different in their primary purpose, meaning that data-quality challenges differ substantially:
  - cohorts/registries are designed to meet specific research needs, whereas hospital health-data warehouses collect data primarily for care and management purposes.

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