KEY FACTORS FOR THE QUALITY OF REAL-WORLD DATA AND REAL-WORLD EVIDENCE IN OBSERVATIONAL STUDIES

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BACKGROUND

- The interest shown by regulatory bodies such as EMA, FDA, AIFA in supporting the use of Real-World Evidence (RWE) in decision-making processes emphasizes the importance of the quality of Real-World Data (RWD) collected in real clinical practice and generated by the observation of patients during their therapeutic journey as a source of information complementary to the data collected during clinical trials (figure 1).
- RWE, as the clinical evidence derived from the analysis of RWD, provides valuable information on the potential benefits and risks associated with the use of drugs and medical devices after marketing authorization in support of pharmacovigilance and post-marketing surveillance, on therapeutic adherence and compliance with the indications for use, on the safety and efficacy of long-term therapy in the observed population, on the impact of the disease from an epidemiological and economic point of view.

METHODOLOGY

- The experience gained in the management of more than 164 observational studies with RWD analysis from more than 377943 patients collected in collaboration with 4377 investigational sites distributed in 26 countries around the world has led to the identification of the key factors to ensure the quality of the RWD and RWE produced on behalf of the promoters of each study.
- For quality of RWD it is intended to:
  - ✓ avoid bias of results using an appropriate study design and an adequate data analysis;
  - ✓ assure authenticity, completeness and validity of the data;
  - ✓ assure the compliance to the applicable regulations and rules (figure 2).

RESULTS

- Each observational study in a real-world setting requires a systematic approach to answer a question of scientific value.
- Each study design is unique and shaped considering the scientific questions to be replied, the study objectives, the data sources, the data variables and the consistency of RWD collected in the database with the study design elements.
- The database quality is reached combining validated automatic checks performed on the data entered in the electronic Case Report Form (eCRF) and offline and manual checks done on the database extracted at defined stages of each study during the cleaning waves (figure 3).
- The integration between the data analysis performed on the quality of database in terms of data entry, the queries raised and resolved, the consistency of data collected with the study objectives and the oversight on the investigational sites driven by the information provided by the analysis performed on the database itself contribute to the quality of RWD.
- The statistical processing of data with the choice of the suitable methodology is fundamental also for the generation of valuable RWE.
- Based on the above considerations, it has not been established a relevant relationship between the study design setting including the number of patients, the countries involved and investigational sites, the number of monitoring visits and the number of checks implemented in the eCRF study with the quality of RWD.
- The key factors that contribute to the quality of RWD are reported in figure 4.

CONCLUSIONS

- **It follows that to produce RWE valuable for the decision-making process at least the following elements have to be considered:**
  - ✓ **the definition of standardized processes aimed to ensure the GxP compliance of the processes at the Contract Research Organization (CRO);**
  - ✓ **the use of validated computerized systems at investigational sites and by the CRO and the Sponsor;**
  - ✓ **the definition of process indicators useful for the monitoring of the quality of RWD on-site, during Source Data Verification (SDV), and off-site by centralized monitoring and data analysis;**
  - ✓ **the training of the study team, Investigators and site staff on ICH-GCP requirements and ALCOA++ principles;**
  - ✓ **the collaboration with the Investigators responsible for the oversight at the investigational sites and for the data collection.**

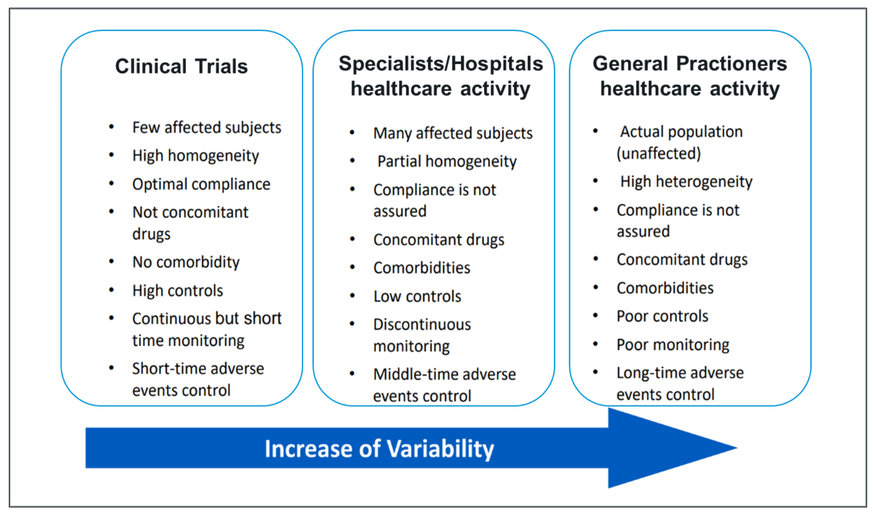

Figure 1: Variability from data collected in experimental studies versus clinical practice

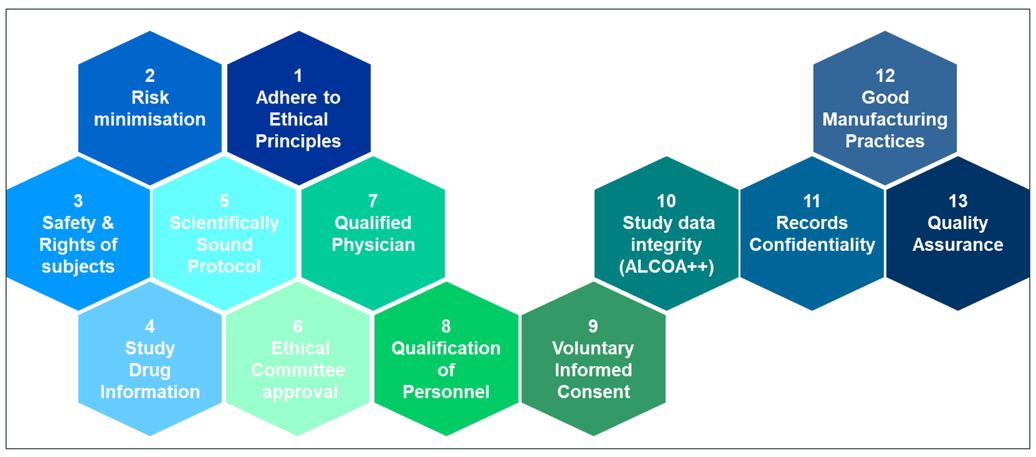

Figure 2: ICH-GCP core principles as applicable in observational research

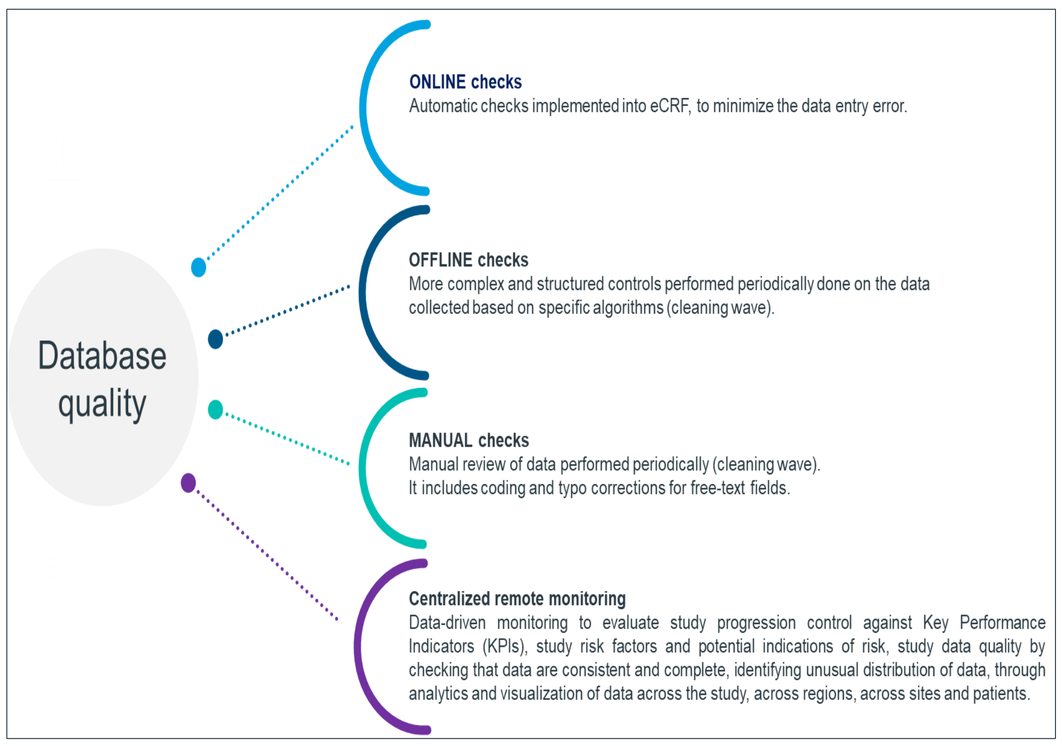

Figure 3: Factors contributing to database quality

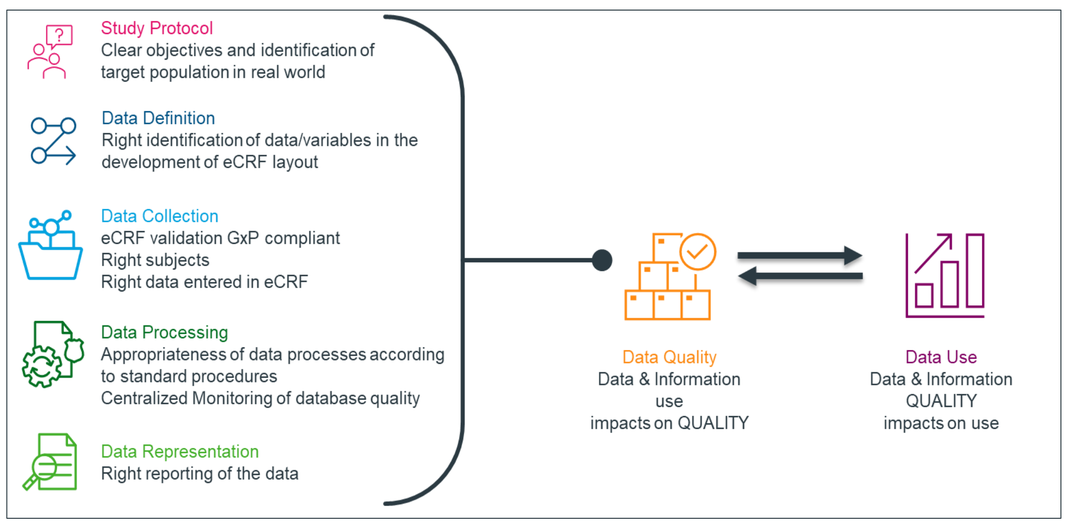

Figure 4: Key factors contributing to data quality

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1. EMA, Use of real-world evidence in regulatory decision making – EMA publishes review of its studies, June 2023
2. EMA, Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence, Draft, May 2024
3. FDA, Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products Guidance for Industry Draft Guidance, March 2024
4. Documento Farmindustria sulla rilevanza della Real World Evidence: strumento innovativo per contribuire al miglioramento della governance sanitaria, November 2022

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