Why do we need
"Real-World Data & Evidence", the new scientific electronic journal?

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The modern request of the global healthcare system is the collection and analysis of the information obtained during the analysis of data collected in research of routine medical practice, namely real-world data (RWD), and the evidence based on it, real-world evidence (RWE).

FDA defines the term **"real-world data"** as follows *– the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.*

In turn, the term **"real-world evidence"** is interpreted by the FDA as *"the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD."*

The evidence from real clinical practice is characterized by the actual use of drugs in practice and conclusions that can be generalized to the target population. In formulating the above definitions, the difference between the terms "data" and "evidence" is emphasized. The rationale was that "data" only meant factual information, while "evidence" meant organizing information to support a conclusion or decision.

RWD collection objectives can be divided into two broad categories: clinical and organizational.

Clinical objectives are to collect information on the efficacy and safety of the use of medicines. The study of safety consists primarily of the analysis of safety signals, which can be converted into data from real clinical practice in the process of active surveillance, which is a systematic approach to the authorisation and analysis of the safety of drugs. Real-life clinical data obtained this way can provide evidence by integrating observational studies (retrospective or prospective) and pragmatic clinical studies.

Organizational goals in the field of drug use policy: include obtaining information on adherence, treatment costs, creating clinical guidelines, changing instructions for the use of drugs, and correcting the design of pre-authorisation randomized clinical trials (RCTs). The study of the above indicators is necessary in order to create a system of drug supply, as well as to maximize the effective use of drugs or to assess their impact on the health care budget.

The effectiveness is measured in the course of RWD studies. Often, the effect of a drug in routine medical practice differs from the results of the RCT on the basis of which the drug was approved (i.e. its efficacy). This problem is called the **"efficacy-effectiveness gap"** (EEG) *– it is the difference in the risk-benefit ratio obtained at the stage of clinical trials and at the stage of drug use in routine medical practice.*

The EEG is an issue of variability in drug action, which can be related to biological and behavioral factors, how the effect is measured, and the characteristics of the health care system.

To bridge the gap between efficacy and effectiveness, studies are being conducted in real clinical practice with the analysis of the data obtained both prospectively and retrospectively. Although the different design of real-life clinical trials will have different advantages and disadvantages, the selection of an appropriate design should be based on the purpose of the data collection and provide the required level of confidence.

The evidence collected in real-life clinical practice studies does not oppose RCTs, but complements them by providing missing information on efficacy and safe-

ty, health-related quality of life, adherence, as well as clinical and economic characteristics of drugs.

By analyzing the data obtained from real clinical practice, it is possible to assess changes in almost any number of points and outcomes (clinical, surrogate, and composite) and see the effects of drugs in their entirety.

According to the research methodology, RWD can be:

- interventional studies:
  - large simple trials,
  - pragmatic clinical trials;
- non-interventional studies:
  - post-authorisation safety studies,
  - observational studies,
  - cohort studies,
  - case-control studies,
  - registers,
  - analysis of insurance databases,
  - health survey questions,
  - analysis of electronic medical records,
  - study of Internet resources,
  - information from medical mobile resources and mobile applications.

Benefits of real-life clinical practice research:

- assessment of effectiveness rather than efficacy;
- multiple comparisons of alternative drug options in order to make a decision about the optimal therapy;
- evaluating a new drug on a ris k-benefit basis, including long-term clinical benefits or harm (including rare adverse reactions);
- the outcomes reach a diverse study population, which reflects the range and distribution of patients observed in routine medical practice;
- a wider range of results than traditionally obtained in RCTs;
- data on the use of resources for determining the costs of medical services and conducting cost-effectiveness analysis and/or budget impact analysis;
- obtaining information on how the drug is dispensed and used in routine medical practice;
- obtaining data on adherence to treatment;
- collecting data in situations where RCTs are not possible;
- obtaining data on the clinical effect or economic impact after the drug is included in clinical guidelines, standards of care, restrictive lists or other healthcare programs.

Indeed, there are also significant limitations to real-life clinical practice research. For all non-randomized data, the most serious problem is the likelihood of bias.

Uncertainty about the internal validity of RWD: arises from inaccurate medical records, missing data, and obscure reporting of research and results.

Some of the information needed to answer a question, may not be available in electronic medical records, but even if the information is recorded, the way data is documented in electronic medical records may limit their availability.

In the context of routine medical practice, in addition to low adherence, there are cases of polypharmacy, diagnostics based on the assessment of the results of therapy, and other cases that complicate the differentiation of the effects of a particular drug.

Summarizing the above, it can be argued that there are not nearly enough scientific journals dedicated to RWD and RWE which cover all aspects – from pharmacoepidemiology, pharmacoeconomic, and pharmacovigilance to biostatistics and biomedical ethics.

The electronic scientific journal "Real-World Data & Evidence", registered by the Federal Service for Supervision of Communications, Information Technology and Mass Media in 2021, was created as a new international resource for academic researchers, decision-makers in the healthcare system, healthcare organizers and pharmaceutical company specialists who publish articles on the latest aspects and methods of RWD and RWE.

The journal "Real-World Data & Evidence" main focus is on modern methodological trends in both the conduct and the analysis of RWD.

When creating the journal "Real-World Data & Evidence", we developed a few main priorities, namely:

1. All published articles are peer reviewed. In order for a publication to make it onto the pages of "Real-World Data & Evidence", it needs to have obtained at least two positive reviews from specialists from similar institutions. All reviewers remain anonymous. These requirements are aimed at improving the quality of published works.
2. All published materials become available in the public domain immediately after being accepted for publication – free of charge for the reader. Quick, easy, and convenient access to the full text of the work will immediately provide the scientific community and medical practitioners with information concerning research in the field of RWD around the world.

Thus, by creating a new electronic scientific journal, we plan to quickly and efficiently cover the main problems and achievements in the field of RWD and RWE. The main goal of the editorial office is to bring the journal "Real-World Data & Evidence" to the international level with its inclusion in the main international citation bases: MEDLINE, Web of Science, Scopus, and Springer. MyRWD

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