

Resolution based on the results of the conference: "RWD/RWE – Research Tools of Real-World Clinical Practice Today and Tomorrow"

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On behalf of the RWD/RWE Working Group in Russian Federation

Abstract

On September 16, 2021, the Association of Health Technology Assessment Professionals, the Association of Russian Clinical Pharmacologists, St. Petersburg Branch of ISPOR organized the II annual scientific and practical conference with international participation: "RWD/RWE – Research Tools of Real-World Clinical Practice Today and Tomorrow". The topic of the conference brought together leading Russian and world experts in the field of RWD/RWE.

Keywords: real-world data; real-world evidence; RWD; RWE; resolution; Russian Federation

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Introduction

On September 16, 2021, the Association of Health Technology Assessment Professionals, the Association of Clinical Pharmacologists, the St. Petersburg Chapter of the International Society for Pharmacoeconomic and Outcomes Research (ISPOR) organized and held the II annual scientific and practical conference with international participation "RWD/RWE – Research Tools of Real-World Clinical Practice Today and Tomorrow".

The topic of the conference brought together leading Russian and world experts in the field of RWD/RWE. Within the framework of the event, the Chief Clinical Pharmacologist of Russia V.I. Petrov, Deputy Minister of Health, S.V. Glagolev, Deputy Head of the FAS Russia T.V. Nizhegorodtsev, and Deputy Director General of the Federal State Budgetary Institution "Scientific Centre for Expert Evaluation of Medicinal Products" of the Ministry of Health of the Russian Federation V.A. Merkulov.

As part of the plenary session, panel discussion and discussion session on practical experience, speeches were made by leading Russian and international experts in the field of RWD/RWE D.A. Rozhdestvensky, M.Yu. Frolov, D.A. Sychev, R.S. Kozlova, J. Juhaeri (CIOMS) and R. Willke (ISPOR).

Practical issues of working with RWD/RWE were discussed by G.R. Galstyan, L.S. Namazova-Baranova, S.K. Zyryanov, V.V. Ryazhenov, A.L. Khokhlov, E.N. Imyanitov, O.A. Sukhorukikh.

The business position was presented by M. Borzova (Trubor), O.A. Loginovskaya (Flex Databases), T.I. Galimov (Data Management 365), A. Spannheimer (IQVIA), M. Leer (Takeda), T. Goldina (AIPM), M.Yu. Samsonov

(R-Pharm), Gracy Crane (Roche), V.V. Kukava (Infarma), A.V. Gusev, and A.V. Artyomov (Aston Health), as well as other colleagues.

The conference participants discussed tools for researching real clinical practice, the growing importance of RWE in modern healthcare, legislation, as well as global perspectives in the world and in Russia. Last but not the least, the technological changes happening during the COVID period were addressed during discussion sessions.

There were 30 reports presented at the conference.

In September 2022, the III international conference is planned dedicated to the modern aspects of RWD/RWE.

We offer you the Resolution of the Conference.

RESOLUTION

Based on the results of the conference "RWD/RWE – Research Tools of Real-World Clinical Practice Today and Tomorrow", which took place on September 16, 2021.

I. Translations and RWD/RWE terms

1. RWD (Real-World Data) – data of real clinical practice (RCP) - data related to the patient's state of health and (or) to the process of providing medical care, obtained from various sources;
2. RWE (Real-World Evidence) – evidence obtained from data from real clinical practice - clinical evidence regarding the use and potential benefits or risks of using a medicinal product, obtained from the collection and analysis of data from real clinical practice.

II. During the conference, the following limitations were identified for the implementation of the RWD.

In legal regulation in Russia at the national level:

1. The lack of definition at the legislative level of the term “real clinical practice,” “real-world data,” “real real-world data research” and “real-world evidence”, as well as the rules governing the procedures for collecting and analyzing data from the RWD.
2. The lack of well-developed regulatory approaches in relation to the implementation of RWD and/or RWE and their use in conjunction with the results of clinical trials within the framework of scientific justification when updating data on the safety and efficacy of drugs.
3. The lack of tools to correlate data on a specific drug with patient data, since data from the federal registry and data from clinical trials do not interact with drug movement monitoring systems.
4. The procedures for registering RWD studies as a post-marketing clinical trial or other study have not been developed.

In the use of RWD in health technology assessment:

1. The lack of regulatory frameworks for the use of RWD does not allow the widespread use of data in decision-making in health technology assessment.
2. The process of comprehensive assessment of medicines in the formation of lists of drugs does not include the analysis of RWD.

In the use of RWD in the development of clinical guidelines:

3. There is no mechanism for the use of RWD in the development / updating of clinical guidelines.
4. There are no special norms allowing professional non-profit organizations to use RWD contained in the information system legally provided in the development / revision of clinical guidelines.
5. There are no special rules for processing this information when creating systems to support medical decision-making (including the use of artificial intelligence technologies) and providing access to this information for medical specialists.

In the use of RWD in the implementation of innovative models of drug provision:

1. The absence of the RWD paradigm in the domestic health care system does not allow the introduction of a value-oriented approach to innovative models of drug provision. At the same time, to launch a pilot project on the introduction of innovative models of drug provision, it is necessary, amongst other things, to analyze data on the clinical efficacy of a drug for public procurement using innovative models (for example, the “risk sharing” model).

In the use of the RWD when using information systems:

1. The quality of the data collected by laboratory information systems and medical information systems and their incompatible format does not allow systematic processing and use of RWD in decision-making in the health care system.

In using RWD when creating registries:

1. The federal registry unites data on individual categories of patients (cross-sectional nosologies and persons eligible for state social assistance).
2. In Russia, there is no unified registry of patients receiving medical care within the framework of the state health care system, i.e. a registry that would combine all registries.

In legal regulation at the EAEU level:

1. There is no definition of the term “Real-world data” and/or the term “Real-world evidence” at the level of regulatory legal acts.
2. There are no approaches developed at the level of concepts, strategies or methodological recommendations for using RWD and/or RWE in making regulatory decisions.
3. There are no regulatory approaches regarding the cross-border transfer of data / acceptability of the RWD and/or RWE sources.
4. There are no special regulatory approaches regarding the implementation of RWD and/or RWE as part of the scientific justification or part of the scientific justification when updating data on the safety and efficacy of drugs / registration of new drugs.
5. There are no special approaches regarding the use of RWD and/or RWE in post-marketing clinical trials and/or in organizing pharmacovigilance.

III. During the conference, the following solutions were proposed for the implementation of the RWD.

In legal regulation in Russia at the national level:

1. Amendments to the Federal Law of 12.04.2010 No. 61-FZ "On the Circulation of Medicines": to supplement Art. 4 with definitions of “real clinical practice”, “real-world data”, “real-world data research”, “real-world evidence”.
2. Development of a Decree of the Government of the Russian Federation on the procedure for processing and analyzing RWD. Consolidation of requirements for methods of collecting and analyzing RWD for further assessment of their quality and transparency; consolidation of requirements for methods of working with possible medical errors and data entry errors; consolidation of requirements for sources of information that can be used for research purposes.

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3. RWD and/or RWE and their use in conjunction with the results of clinical trials will provide scientific justification for making regulatory decisions when making changes to the instructions for medical use in relation to the safety and efficacy of previously registered drugs or decisions about suspension of the use of a drug, on inclusion / exclusion from restrictive lists, and also to confirm the validity of the results of a clinical trial for making regulatory decisions.
4. Amendments to the Decree of the Government of the Russian Federation of November 28, 2013 No. 1086 “On approval of the Rules for the formation of a list of medicines, the purchase of which is carried out in accordance with their trade names”: add clause 5 with the following wording: “the results of non-interventional studies of the use of drugs for medical use in real-world clinical practice”.
5. The need to create a national standard, requirements and ethical principles for the collection, storage and processing of data from real-world clinical practice.
6. Creation of a body (committee) to control the quality of tools for collecting and processing real-world data.
7. Assistance in accelerating the adoption of international requirements of the rules of good clinical practice ICH GCP E6 (R2) in the Russian Federation.

In the use of RWD in health technology assessment:

1. Amendments to clause 55 of Art. 4 of the Federal Law of 12.04.2010 No. 61-FZ “On the Circulation of Medicines” “... analysis of information on the comparative clinical efficacy and safety of a drug, including on the basis of real-world data”.
2. Amendments to the Rules for the formation of lists of drugs for medical use and the minimum assortment of drugs required for the provision of medical care, approved by Decree of the Government of the Russian Federation of August 28, 2014 No. 871, in terms of taking into account real-world data in the formation of lists of drugs.

In the use of RWD in the development of clinical guidelines:

1. Amendments to Appendix 1 to the Order of the Ministry of Health of Russia dated February 28, 2019 No. 103n “On the approval of the procedure and terms for the development of clinical guidelines, their revision, the standard form of clinical guidelines and requirements for their structure, composition and scientific validity of information included in the clinical guidelines” in terms of the possibility of taking into account RWD in the formation of clinical guidelines, as well as

the use of such data by professional non-profit organizations in the development / revision of clinical guidelines.

In the use of RWD in the implementation of innovative models of drug provision:

1. Optimization of antitrust legislation to eliminate the risks of unjustified application of existing norms to innovative models of drug provision.
2. Implementation of a mechanism for recording RWD when analyzing data on the clinical efficacy of a drug for public procurement using innovative models.
3. Implementation of a mechanism for RWD accounting when assessing the effectiveness of treatment in the model of an agreement on payment based on the results of therapy.

In the use of RWD when using information systems:

1. Implementation of interim measures to control the quality of data collected / entered within the framework of MIS and LIS.
2. Integration of MIS and LIS, specializing in the collection of structured medical data.

In the RWD, when creating registries:

1. It is necessary to revise approaches to maintaining patient registries in order to transform registries into sources of reliable scientific information about the patient population, the prescribed and applied therapy, treatment outcomes, etc., and, accordingly, provide for the maintenance of a single register for all nosologies.
2. Develop a procedure for interdepartmental interaction with the aim of maintaining and processing the data of such a registry, as well as the possibility of providing limited access for the formation of RWD from the medical and scientific community.
3. To establish the obligatory use of registries in clinical practice, as well as in the framework of technology assessment in health care.
4. At present, a draft resolution of the Government of the Russian Federation “On the unified state information system in the field of healthcare” is being discussed, which establishes new rules for the functioning of the unified state information system in the field of health care (USISH). In addition, the order of accessing it, the procedure and terms for providing information to it are specified. It is advisable to provide for the organization of a system access to it, including RWD (and not to its individual subsystems), to medical specialists, experts, scientists, non-governmental companies (IT-sector, pharmaceutical industry, manufacturers of medical and diagnostic equipment).

In legal regulation at the EAEU level:

1. 1. Develop approaches at the level of concepts, strategies or guidelines for the use of RWD and/or RWE in making regulatory decisions.
2. Develop regulatory approaches with regard to cross-border transfer of RWD / acceptability of RWD and/or RWE sources.
3. Develop special regulatory approaches in relation to the implementation of RWD and/or RWE and their use in conjunction with the results of clinical trials for scientific justification and making appropriate regulatory decisions on amending the general characteristics of the drug, when making changes to the instructions for medical use in relation to the safety and efficacy of previously registered drugs and registration of new drugs.

4. Develop special approaches to the use of RWD and/or RWE when conducting post-registration clinical trials and/or when organizing pharmacovigilance.

In the organization of interdepartmental and expert interaction:

1. Create working groups to address the above issues in order to quickly implement the RWD approach.

Association of Health Technology Assessment Professionals, Association of Clinical Pharmacologists, St. Petersburg Chapter of the International Society for Pharmacoeconomic and Outcomes Research (ISPOR)

September 16, 2021, Moscow, Russian Federation