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Russia enacts law to enable Real-World Evidence research for pharma companies

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Russian president Vladimir Putin signed Federal Law which establishes a regulatory sandbox for digitally innovative projects. Data MATRIX, a sole Real-World Evidence solutions provider in Russia, is among the 7 projects that can operate within this legal regime.



Under the law, Data MATRIX will be able to conduct retrospective clinical studies without signing informed consent and obtain anonymized data from healthcare facilities and data integrators.

As a result, pharmaceutical and biotech companies will have a legally compliant provider of Real-world data (RWD) and the opportunity to conduct RWE studies derived from millions of EHRs.

Excerpt from Federal Law No. 258-FZ of July 31, 2020 "On Experimental Legal Regimes for Digital Innovation in the Russian Federation."

"Real-world evidence (RWE) studies are widely used abroad and are fundamental both in terms of accumulating scientific and medical data and in terms of forming a comprehensive evaluation of diagnostic methods, drug and non-drug treatments, prevention and rehabilitation. The use of research results allows to evaluate and optimize clinical guidelines and standards of care to improve their clinical and economic efficiency, as well as in the framework of pharmacovigilance measures".

In the nearest future, Data MATRIX will also demonstrate a tool for predictive data analysis. This is one of many products that can be created based on validated RWD. The tool allows to estimate survival to progression within 5 years based on individual patient parameters and compare it to the best treatment option for patients with the same baseline data.

More information can be found here: https://dm-matrix.com/