REGULATORY FRAMEWORK ON MEDICAL DEVICES USING AI TECHNOLOGY IN RUSSIA

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Regulatory Framework on AI Software in Russia

- Existing rules of medical devices regulation, including medical software
- AI Regulation Challenges
- Prospects activities in the field of artificial intelligence
"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose.


"Medical devices" any instrument, apparatus, appliances, equipment, materials and other devices used for medical purposes alone or in combination with each other as well as with other accessories required for use of these devices for their purpose, including special software and designed by the manufacturer for the prevention, diagnosis, treatment and rehabilitation of diseases, monitoring the state of the human body, for medical research, rehabilitation, replacement, changes of anatomical structure or physiological functions, prevention or termination of pregnancy, which function is not implemented by pharmacological, immunological, genetic or metabolic effects on the human body.
“Software as a Medical Device” is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.
Criteria for classifying software as medical devices

Recommendation of the Board of Eurasian Economic Commission dated 12.11.2018 No. 25

Information letter of Roszdravnadzor dated 30 December 2015 No. 01Н-2358/15
Circulation of medical devices


The circulation of medical devices and software includes:

- Technical testing
- Toxicity testing
- Clinical trials
- Official registration
- Production
- Manufacturing
- Import to the territory of the Russian Federation
- Export from the territory of the Russian Federation
- Conformity assessment
- State Control
- Storage
- Transportation
- Sales
- Installation
- Calibration
- Intended use
- Maintenance
- Utilization & Disposal

Intended use, including maintenance, required by regulatory, technical and (or) operational manufacturer's documentation

Expertise of quality, effectiveness and safety of medical devices

Only registered medical devices can be used in the territory of the Russian Federation
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Software as a Medical Device Guideline

Recommendations for the Expertise of Quality, Efficiency and Safety of SaMD

- Recommendations on criteria for classifying software as medical devices
- Recommendations on medical purpose of the Software
- Recommendations for the risk classification of Software
- Recommendations for the list of standards used for conformity assessment
- Recommendations on the content of technical documentation
- Recommendations on the content of operational documentation
- Recommendations for evaluating software technical tests
- Cybersecurity recommendations
Revision of Existing Regulatory Practices

- Harmonization of risk classification with IMDRF
- Update criteria how to classify software as medical devices
- Update requirements for technical and operational documentation content
- Update Software as a Medical Device Guideline
AI Registration Experience

Artificial Intelligence system registration case

Automatic analysis of medical data, including electronic medical records

Identification of risk factors for diseases, risk stratification of patients

Formation of individual prognosis of fatal and nonfatal complications of diseases in different nosologies

Medical decision support system based on artificial intelligence

Formation of recommendations on patient management tactics on the basis of generally accepted clinical recommendations, medical standards and evidence-based medicine

Facilitate clinical research and search for unknown dependencies in electronic medical data

Population analysis and forecasts
AI Registration Challenges

No specific regulatory requirements for AI

Black box testing

The absence of national or international databases containing validated clinical information

Inaccurate medical data recorded in the medical old records on which the AI learns can produce incorrect results
AI Registration Challenges

We have integrated the AI system with the medical information system.

We used a database provided by the manufacturer which contained accumulated patient data.

The database consisted of depersonalized patient data, which contained raw data, so the personal data privacy was not violated.

The product provides the doctor only advice, and does not make an independent clinical decision. The final decision is made by the doctor.
Technical Committee (TC) 164 "Artificial intelligence" was approved by Federal Agency for technical regulation and Metrology at the end of July 2019.

The technical Committee was established to improve the efficiency of the development of the national regulatory and technical base in the field of artificial intelligence.

The first meeting of the Technical Committee was held on August 6.

Roszdravnadzor became as an official member of TC 164.
Structure of TC 164

Working Groups of the Technical Committee 164

- WG 01: Terms & Definitions
- WG 02: Big Data
- WG 03: Quality of Artificial Intelligence Systems
- WG 04: Applied Artificial Intelligence Technologies
- WG 05: Artificial Intelligence Technologies in Education
Objectives:

1) Development of classification criteria (types, classes of potential risk) of software using artificial intelligence/machine learning technologies

2) To formulate a clear terminology: what is artificial intelligence/machine learning, etc.

3) Development of proposals to national standards and other regulatory documents for software using artificial intelligence/machine learning technologies

4) Development of the criteria of responsibility - in which cases the doctor can rely on the data obtained from the software based on artificial intelligence/machine learning, whether it is entitled to use them for diagnosis, and whose opinion is more important

5) Development of proposals to the regulatory framework for the organization of the collection of unified verified clinical data to configure and verify the effectiveness of artificial intelligence systems

6) Development of approaches to regulation of software using artificial intelligence and machine learning technologies, including a transparent approach to regulation to confirm the quality, effectiveness and safety
THANK YOU FOR ATTENTION

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