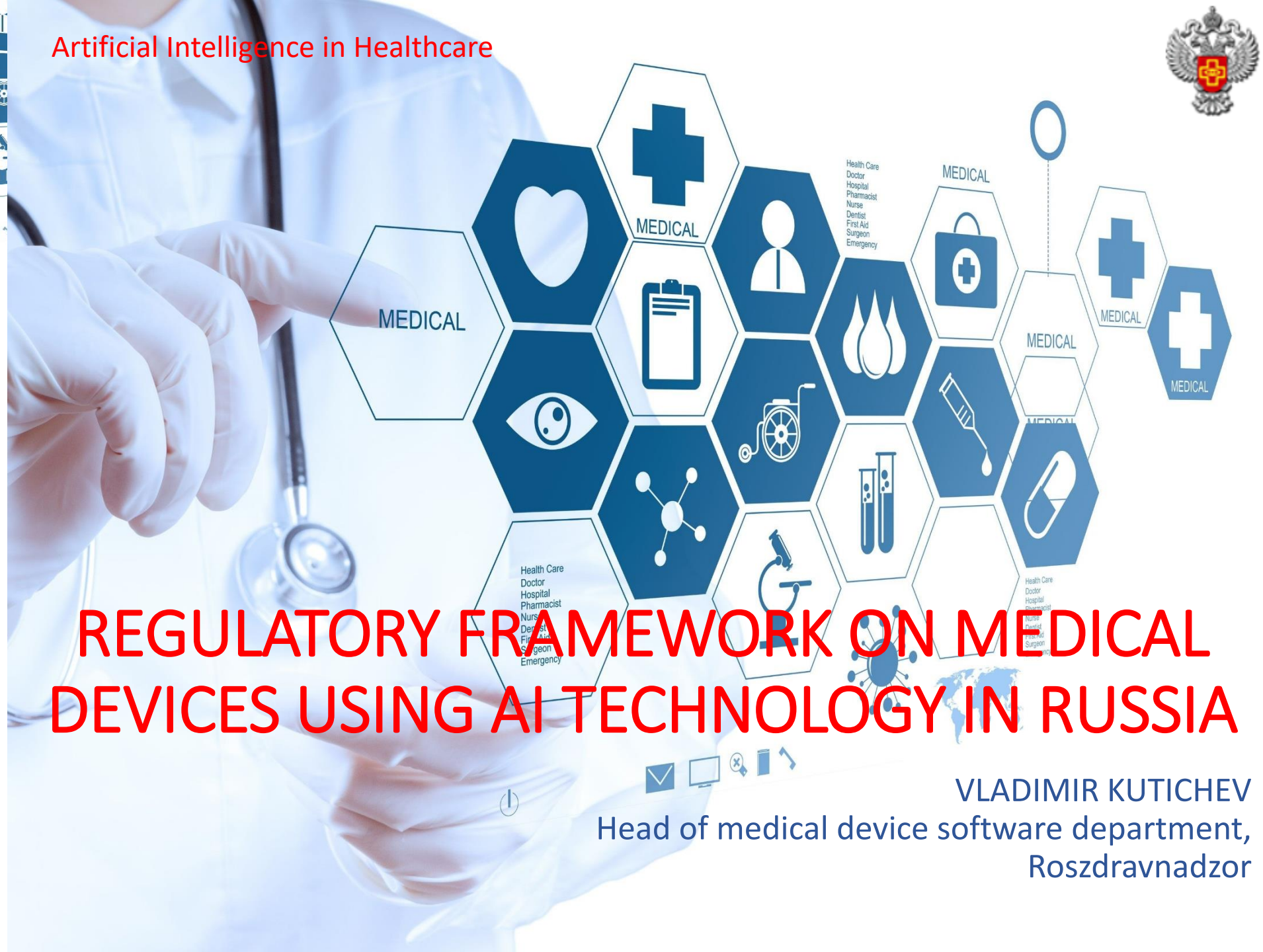
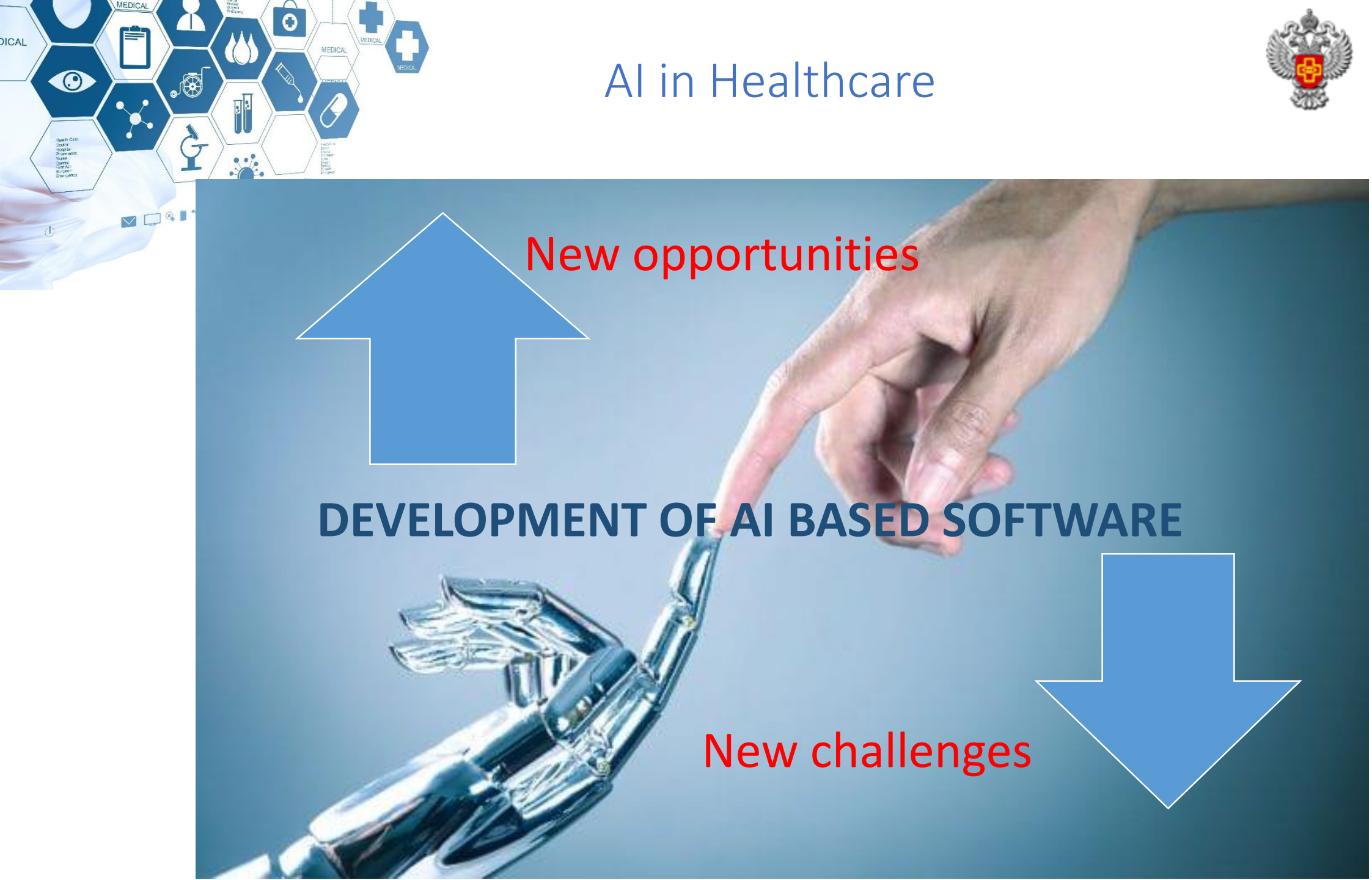
Artificial Intelligence in Healthcare



REGULATORY FRAMEWORK ON MEDICAL DEVICES USING AI TECHNOLOGY IN RUSSIA

VLADIMIR KUTICHEV
Head of medical device software department,
Roszdravnadzor

AI in Healthcare



Regulatory Framework on AI Software i Russia

Existing rules of medical devices regulation, including medical software

AI Regulation Challenges

Prospects activities in the field of artificial intelligence

Key definitions

IMDRF International Medical Device Regulators Forum

IMDRF/SaMD WG/N10FINAL:2013: Software as a Medical Device (SaMD): Key Definitions

"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.

Paragraph 1 of Article 38 of the Federal Law of November 21, 2011 № 323-FZ "On the basis of public health protection in the Russian Federation"

"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

Key Definitions

Recommendations Of the Board of the Eurasian Economic Commission dated 12.11.2018 No. 25 “Criteria for classifying products as medical devices within the Eurasian economic Union»

IMDRF/SaMD WG/N10FINAL:2013: Software as a Medical Device (SaMD): Key Definitions

“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

“Software as a Medical Device” (SaMD) 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. 01И-2358/15

Circulation of medical devices

The Federal Law 323-FZ dated 21.11.2011 “The basis of health protection in the Russian Federation”

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
- Callibration
- 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

Regulations On Software as a Medical Device

Mandatory Requirements for SaMD Documentation

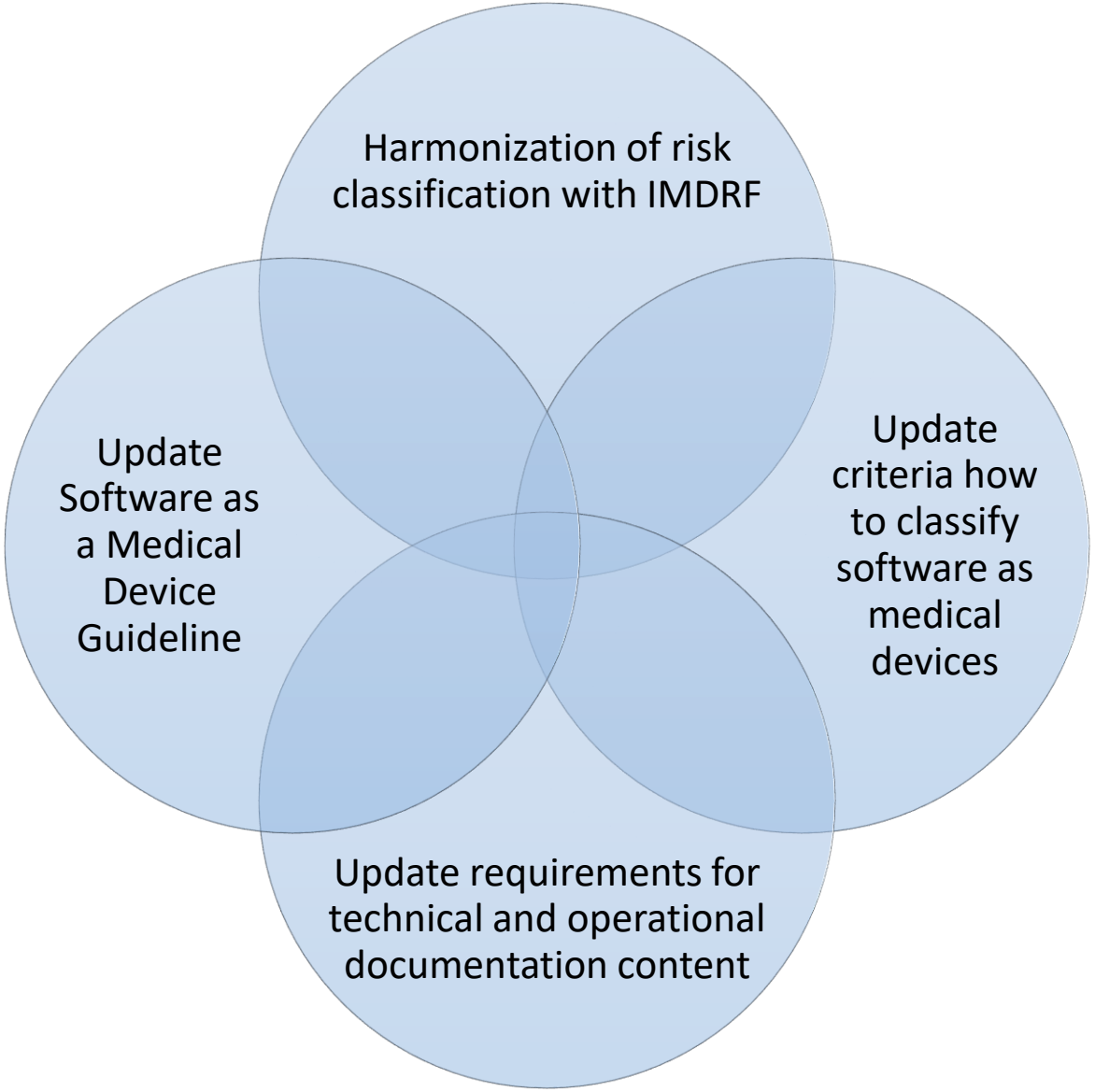
- Software discription
- Software requirement specification
- Software architecture design
- Risk Classification
- Risk management and risk analysis process
- Labeling
- Information about software algorithms based on Published methodologies, standards, or reference guides that have been approved for medical use
- Software Development Environment Description
- Verification and Validation Documentation
- Configuration Management
- Life Cycle Processes
- Cybersecurity
- Unresolved Anomalies (Bugs or Defects)
- Test Plan

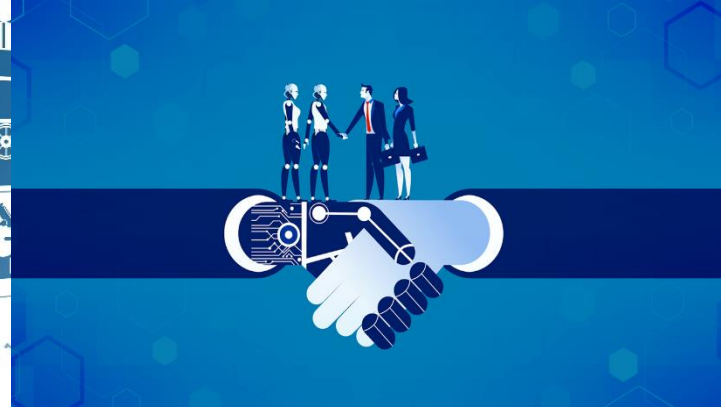
Software as a Medical Device Guideline

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





AI Registration Experience

Artificial Intelligence system registration case

Medical decision support system based on artificial intelligence

- Identification of risk factors for diseases, risk stratification of patients
- Formation of individual prognosis of fatal and nonfatal complications of diseases in different nosologies
- Population analysis and forecasts
- Facilitate clinical research and search for unknown dependencies in electronic medical data
- Formation of recommendations on patient management tactics on the basis of generally accepted clinical recommendations, medical standards and evidence-based medicine
- Automatic analysis of medical data, including electronic medical records

AI Registration Challenges

No specific regulatory requirements for AI

The absence of national or international databases containing validated clinical information

Innacurate medical data recorded in the medical old records on which the AI learns can produce incorrect results

Black box testing

AI Registration Challenges

We have integrated the AI system with the medical information system

We used a database provided by the manufacurer 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

Prospects activities in the field of artificial intelligence

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

National AI Standardization Program 2020

Artificial intelligence systems in medicine. Part 1. Classification, terms and definitions.

Artificial intelligence systems in medicine. Part 2. Areas and boundaries of use.

Artificial intelligence systems in medicine. Part 3. General Provisions. Methods of technical testing.

Artificial intelligence systems in medicine. Part 4. Clinical trials.

Artificial intelligence systems in medicine. Part 5. Application of risk management to pre-training programs. Algorithm Change Protocol.

Artificial intelligence systems in medicine. Part 6. Methods of monitoring and evaluating the operational parameters of continuing education programs.

Artificial intelligence systems in medicine. Part 7. Requirements for the development of a database structure for testing and training artificial intelligence systems.

Artificial intelligence systems in medicine. Part 8: Terms of ensuring the information and cyber security.

Artificial intelligence systems in medicine. Part 9. Requirements for the collection, storage, processing, transfer and protection of data.

Artificial intelligence in medicine. Part 10. Optimization and integration of big data.

Summarize

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

Web: http://www.roszdravnadzor.ru

E-mail: info@roszdravnadzor.ru;
vkutichev@vniiiimt.org