



RADIOLOGY MOSCOW  
ENTERPRISE IMAGING

# EXPERIENCE IN TESTING AND COMPARING DIFFERENT SOLUTIONS BASED ON ARTIFICIAL INTELLIGENCE FOR THE MOSCOW HEALTH SERVICE

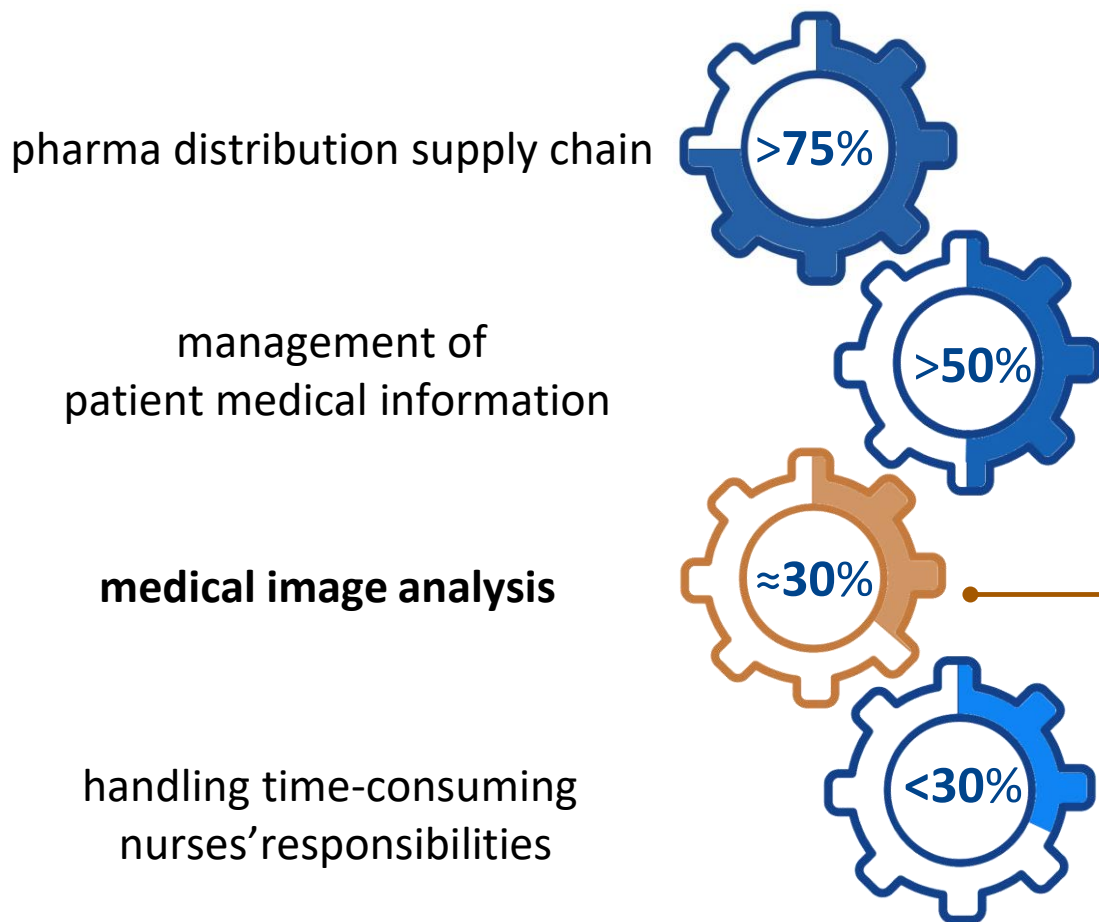
Morozov S.P., Sergunova K.A., Vladzimirskyy A.V., Klyashtornyy V.G., Andreychenko A.E., Kulberg N.S., Gombolevisky V.A.

Scientific and Practical Clinical Center for Diagnostics and Telemedicine Technologies of  
the Moscow Health Department, Russia  
Yekaterinburg, 2019

# Technical potential for automation in Healthcare

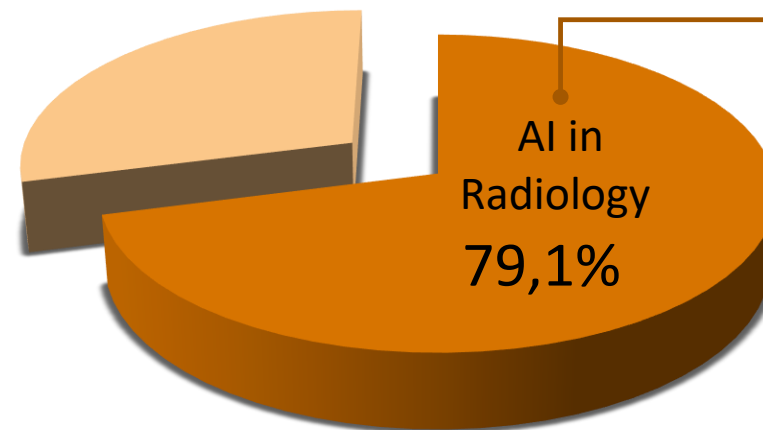


## Automation potential



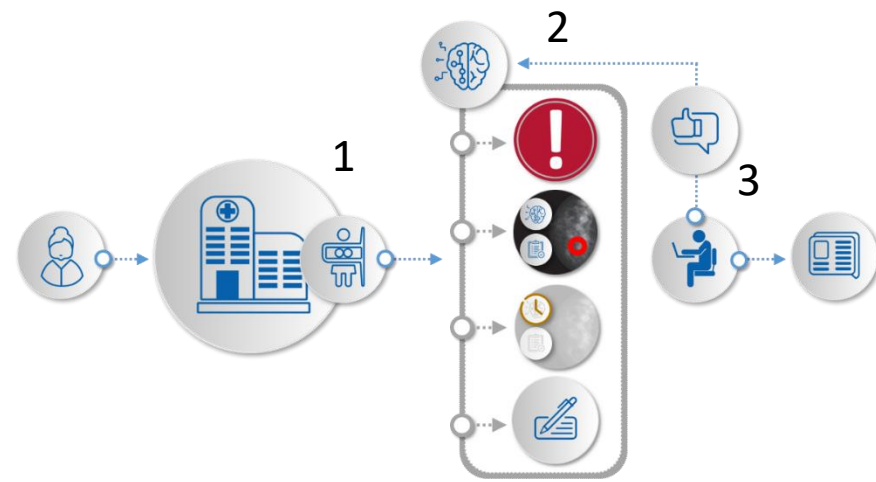
Mckinsey, 2017

from 516 articles (2018)  
investigated the performance of AI algorithms  
that analyze medical images  
to provide diagnostic decisions



~ 40% MRI  
~ 27% CT  
~ 6% Ultrasound  
~ 4% Mammography  
~ 3% X-ray  
~ 1% PET

# Integration of AI into PACS and RIS



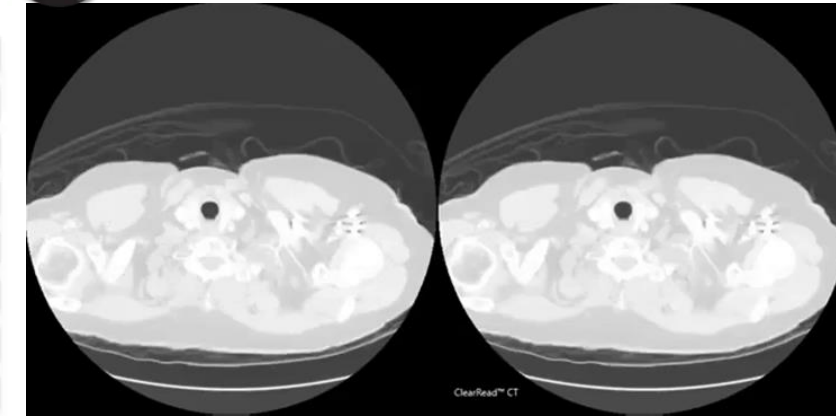
## Prioritization

| Priority | STAT | Patient Name | Patient MRN | Modality | Study Time | Hospital Location | Procedure |
|----------|------|--------------|-------------|----------|------------|-------------------|-----------|
|          |      |              |             |          |            |                   |           |
|          |      |              |             |          |            |                   |           |
|          |      |              |             |          |            |                   |           |
|          |      |              |             |          |            |                   |           |
|          |      |              |             |          |            |                   |           |
|          |      |              |             |          |            |                   |           |
|          |      |              |             |          |            |                   |           |

Источник: <https://www.aidoc.com/>



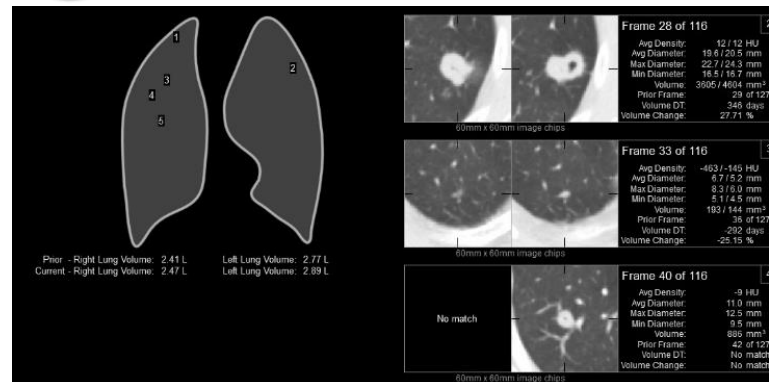
## Localization



Источник: <https://www.riveraintech.com/clearread-ct/>



## Dynamic assessment

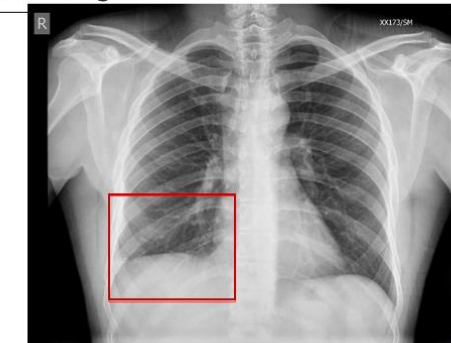


Source: <https://www.riveraintech.com/clearread-ct/>



## Template of protocol

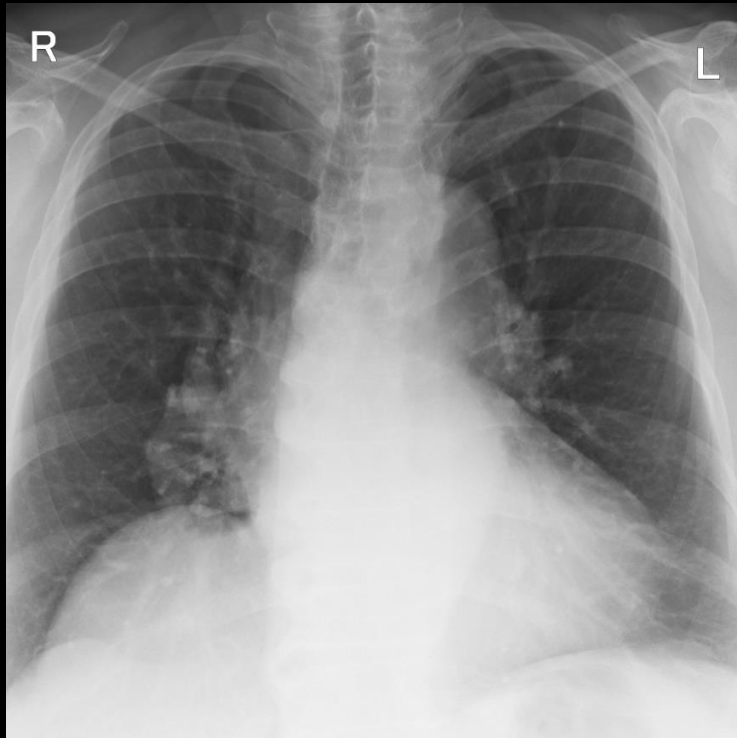
**Impression:**  
Abnormal study.  
**Preliminary Findings :**  
Pleural Effusion detected on the right.



Source: <http://qure.ai/qxr.html>

1. Conducting a diagnostic study
2. Processing the study by using of algorithm
3. Description of the study by a physician using the algorithm

# Artificial intelligence helps radiologist

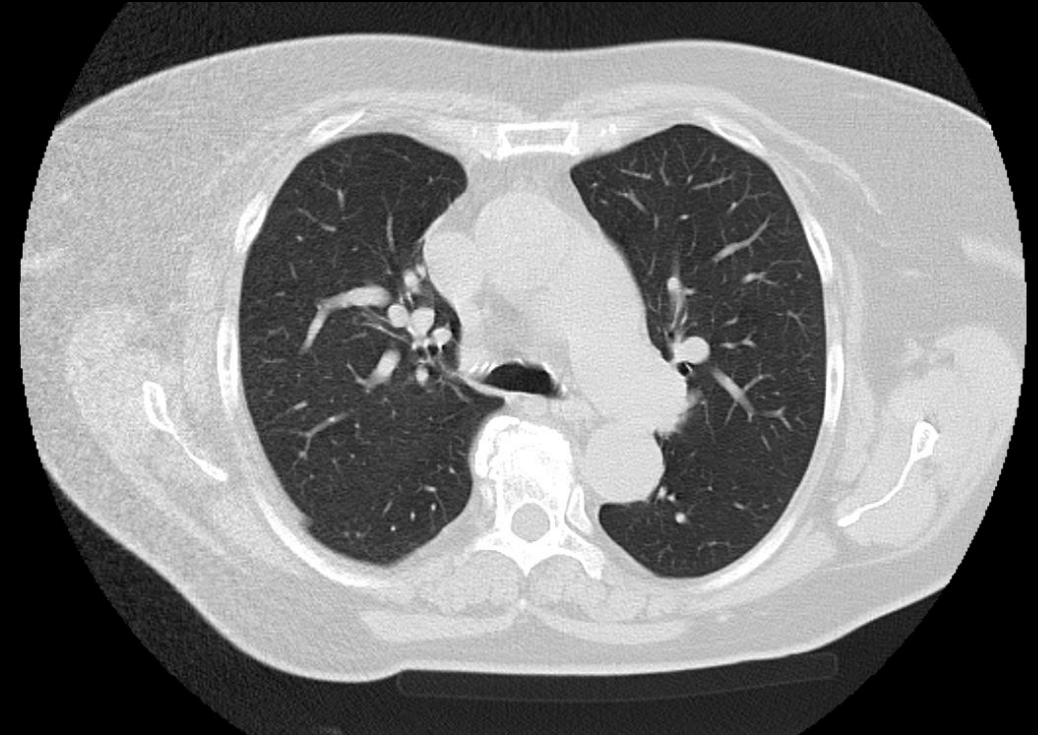


## The conclusion of radiologist:

The mass in the root of right lung. CT in recommended

## The conclusion of AI:

No pathology (abnormality 7%).



## The conclusion of radiologist:

The pulmonary hypertension. No mass lesion was detected.

## Patient was referred for an unnecessary CT scan:

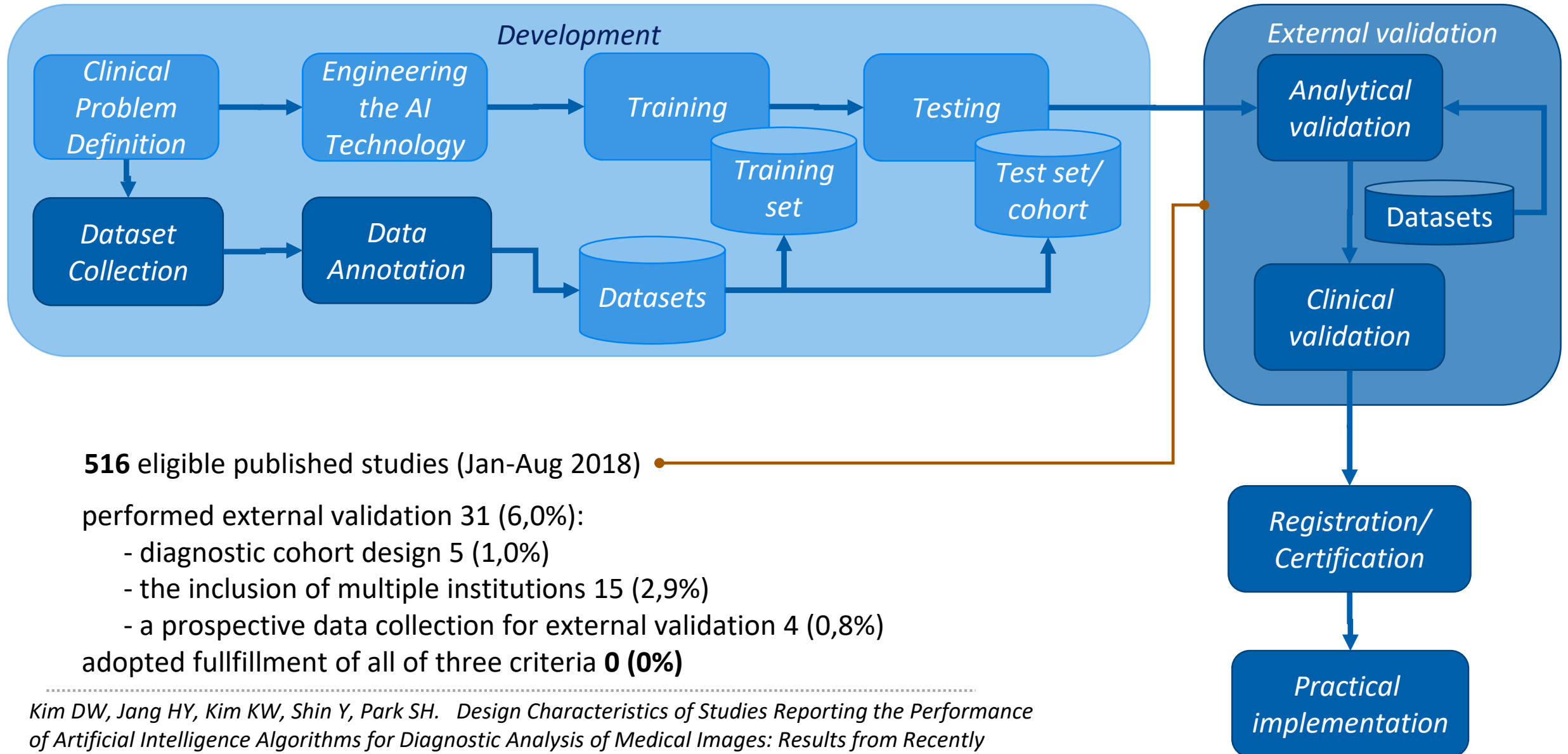
- radiation dose of 19,6 mSv on CT;
- the cost of CT 1153 rubles according to the CHI;

How accurate is your AI?

Can we trust AI ?



# Total product lifecycle and QA approach on AI workflow



Kim DW, Jang HY, Kim KW, Shin Y, Park SH. Design Characteristics of Studies Reporting the Performance of Artificial Intelligence Algorithms for Diagnostic Analysis of Medical Images: Results from Recently Published Papers. Korean J Radiol. 2019 Mar;20(3):405-410. <https://doi.org/10.3348/kjr.2019.0025>

# Stages of clinical evaluation

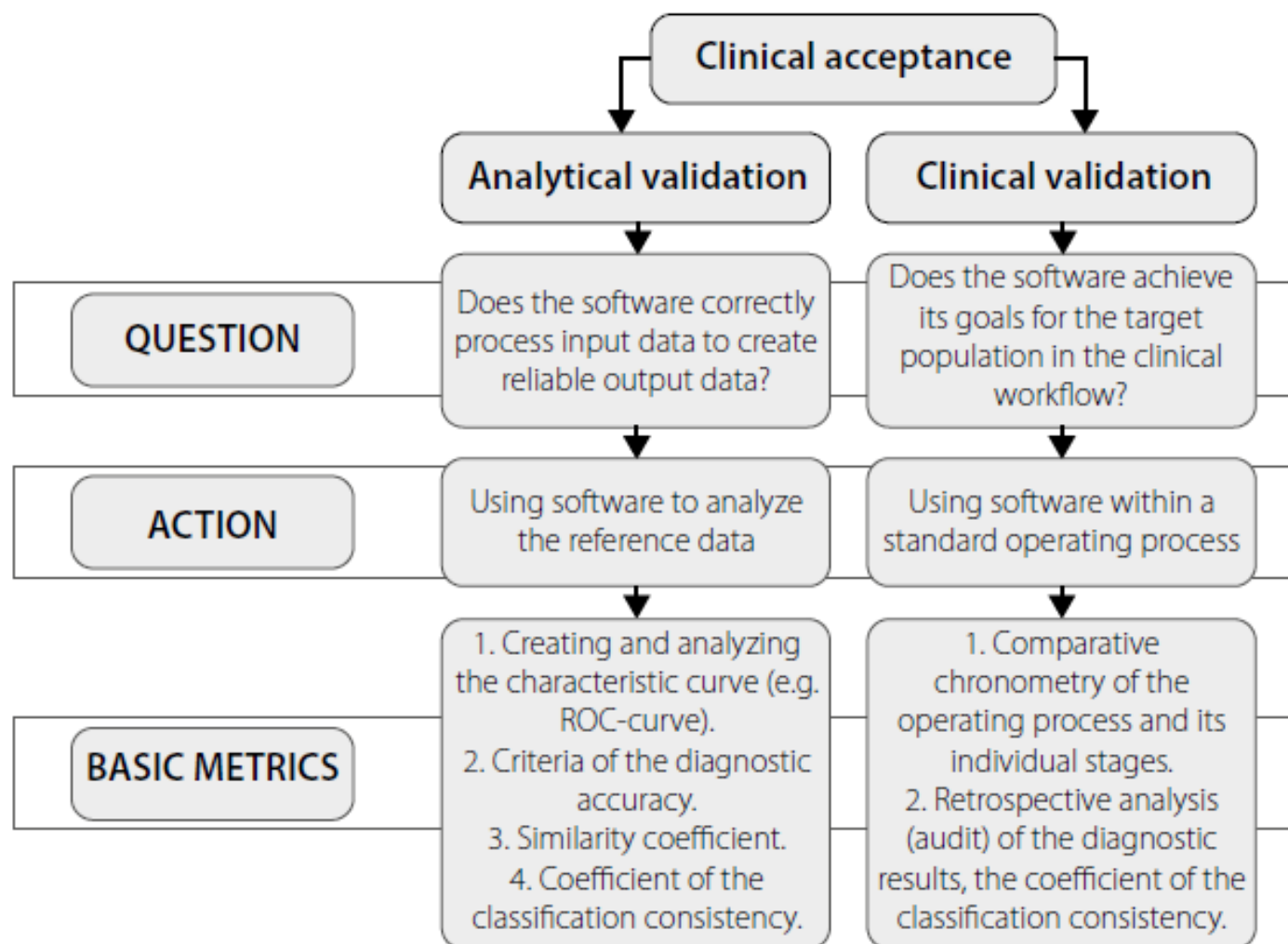


Figure 1 – Flowchart for a clinical evaluation of the AI-based software in radiology.

GOVERNMENT OF MOSCOW  
DEPARTMENT OF HEALTH CARE OF MOSCOW  
  
RESEARCH AND PRACTICAL CLINICAL CENTER  
OF DIAGNOSTICS AND TELEMEDICINE TECHNOLOGIES,  
DEPARTMENT OF HEALTH CARE OF MOSCOW

CLINICAL ACCEPTANCE OF SOFTWARE BASED ON  
ARTIFICIAL INTELLIGENCE TECHNOLOGIES  
(RADIOLOGY)

Preprint № CDT-2019-1

Moscow 2019

<https://arxiv.org/ftp/arxiv/papers/1908/1908.00381.pdf>

1

Questionnaire for the admission of software based on AI  
to a preliminary test operation

to evaluate whether the algorithm meets the key criteria

2

Self-test

to check technical compatibility of an AI product with the  
radiology equipment's output DICOM files and PACS/RIS/HIS

3

Proof-test

for evaluating the performance of an AI product with  
reference data (sensitivity, specificity , accuracy , .. )



# Criteria for the admission of AI to a preliminary test



## Key criteria:

1. Approvals of FDA and / or CE certification

or

Actual implementations of the currently working software in medical centers


&

Scientific articles (original research works) in Q1/Q2

2. Availability of tools for integration with PACS

## Metrics of application in Moscow:

Diagnostic accuracy was tested on data that included Caucasoid and Mongoloid Races.



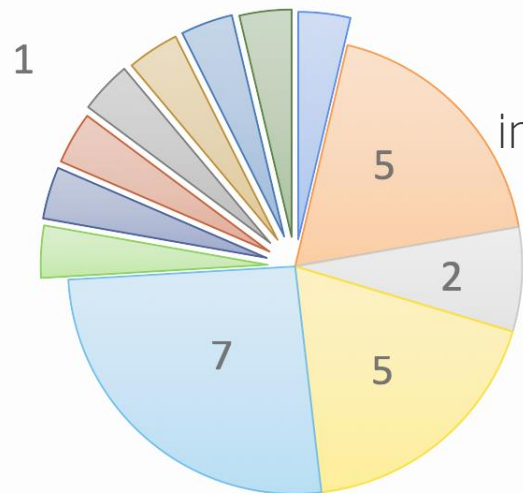
### QUESTIONNAIRE ABOUT THE SOFTWARE BASED ON AI TECHNOLOGIES/COMPUTER VISION

| Section          | Metrics   | Answer  | Comments, clarifications, suggestions |
|------------------|---|---|---------------------------------------|
| 1. Company name  |   |   |                                       |
| 2. Goals         | 2.1. The software provides a preliminary automatic analysis of medical images (DICOM files) to improve the quality and speed of the radiology workflow.   | <input type="checkbox"/> yes<br><input type="checkbox"/> no   |                                       |
|                  | 2.2. The software ensures a prioritization in the workflow according to the automatically revealed pathology.   | <input type="checkbox"/> yes<br><input type="checkbox"/> no   |                                       |
|                  | 2.3. The software automatically prepares a draft of the radiology report based on the results of the analysis.  | <input type="checkbox"/> yes<br><input type="checkbox"/> no   |                                       |
|                  | 2.4. The software provides a preliminary comparative analysis of studies of a single patient at different time points (dynamic study).  | <input type="checkbox"/> yes<br><input type="checkbox"/> no   |                                       |
| 3. Certification | 3.1. Approvals of FDA and / or CE certification (class II).<br>If the answer to clause 2.1 is "no", there should be positive answers to clauses 2.2 and 2.3.  | <input type="checkbox"/> yes<br><input type="checkbox"/> no<br><input type="checkbox"/> in progress |                                       |
|                  | 3.2. Actual implementations of the currently working software in medical centers:<br>• at least 2 independent institutions;<br>• more than 6 months of operation;<br>• at least 1000 successfully completed studies (confirmed by radiologists) for each task (if the software solves several tasks).   | <input type="checkbox"/> yes<br><input type="checkbox"/> no<br><input type="checkbox"/> in progress |                                       |
|                  | 3.3. Scientific articles (original research works) published in peer-reviewed journals indexed by "Scopus" and / or "Web of Science" and included in the first and second quartile according to the "International Scientific Journal & Country Ranking"; proven diagnostic accuracy AUC>=0.8 (classic ROC curve) and increase of the radiology workflow efficiency (based on the comparison of reporting speed with and without the software, including timing). | <input type="checkbox"/> yes<br><input type="checkbox"/> no<br><input type="checkbox"/> in progress |                                       |

|  |   |   |  |
|--|---|---|--|
| 4. Evidence                            | 4.1. Once the development was completed, the accuracy of algorithms was assessed on independent data, i.e. medical database for testing differed from the one used for training, development and validation. That is, clinical tests were performed on data unknown to the algorithms.<br><i>If possible, provide examples of public datasets that you used when developing the solution.</i>   | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
|  | 4.2. Diagnostic accuracy was tested on data that included Caucasoid and Mongoloid races.  | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
|  | 4.3. Annual update of diagnostic accuracy information.  | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
| 5. Functionality                       | 5.1. Availability of a built-in accuracy assessment tool.   | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
|  | 5.2. Max. 60 seconds for processing of a single radiology study without considering the time for data transfer. To accomplish the goal 1.4, the analysis may take more than 60 seconds, but not more than 60 seconds for one study.   | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
|  | 5.3. The result of software operation is series of images (DICOM format), with:<br>- a number of slices similar to those in the original series for a simultaneous viewing by radiologist;<br>- information on each slice contains the software name, version, diagnostic accuracy, the verification date and the exact time of completed study;<br>- possibility to provide additional series with the analysis results (e.g. summary tables with the revealed findings in dynamics and / or particular images of findings). | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
| 6. Contract                            | 6.1. Regular system updates, including those for diagnostic accuracy information.   | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
|  | 6.2. Software updates included in the price.  | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
|  | 6.3. All medical data, related materials and software results are the property of the customer.   | <input type="checkbox"/> yes<br><input type="checkbox"/> no |  |
| 7. Solutions                           | 7.1. List of solutions to which the questionnaire is applicable.  |   |  |
| Person who completed the questionnaire |   |   |  |

*\*Questionnaire for the admission of software based on "AI" / computer vision to a preliminary test operation*

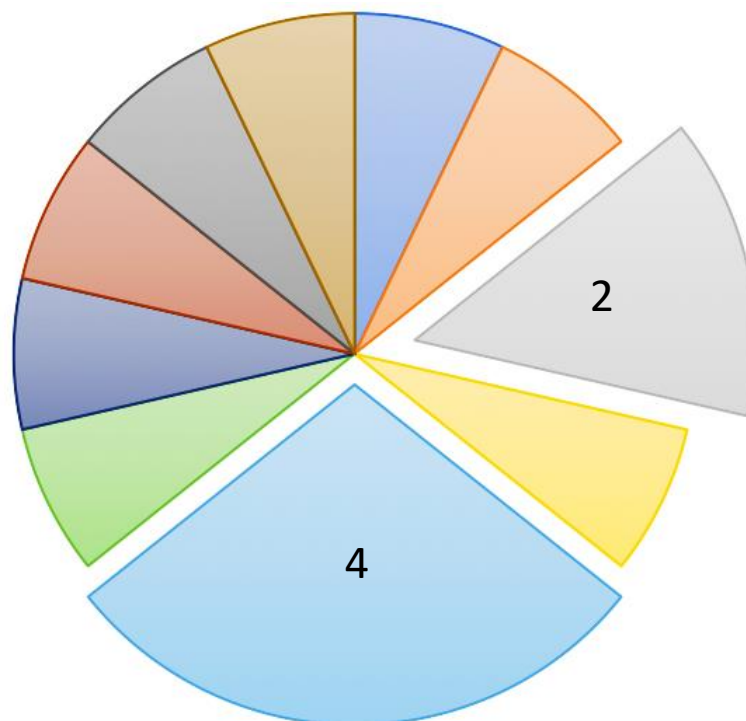
# The results of companies selection



27 AI companies  
in healthcare market



14 AI companies  
agreed to participate in the survey



I stage

5 AI companies

*(Israel, UAE, South Korea, USA, Spain)*

Approvals of FDA and / or CE certification  
or  
Actual implementations in medical centers  
and Scientific articles (Q1, Q2)

II stage

5 AI companies

*(Israel, India, 2 Russia, UK)*

Availability of tools for integration with PACS

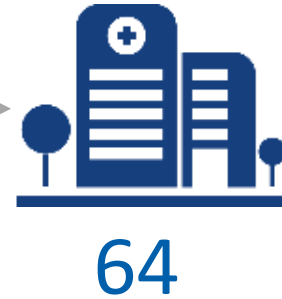
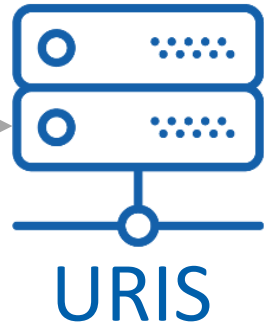
# Directions in the project



| №  | Nosology                                | The number of studies in URIS | AI_3 | AI_7 | AI_8 | AI_9 | AI_11 | AI_12 | AI_14 | AI_18 | AI_19 | AI_25 |
|----|---|-------------------------------|------|------|------|------|-------|-------|-------|-------|-------|-------|
| 1  | Lung cancer                             | 250 000                       | V    | V    |      | V    |       |       |       |       |       |       |
| 2  | Breast cancer                           | 400 000                       |      |      | V    |      |       | V     | V     |       |       |       |
| 3  | Lung pathology                          | 16 000                        |      | V    |      | V    |       |       | V     | V     | V     |       |
| 4  | Tuberculosis                            | 16 000                        |      | V    |      | V    |       |       | V     |       | V     |       |
| 5  | Mass lesion in the adrenal glands       | 480 000                       |      |      |      |      |       |       |       |       |       |       |
| 6  | Mass lesion in the liver                | 100 000                       | V    |      |      |      |       |       |       | V     |       |       |
| 7  | Coronary calcification                  | 250 000                       |      |      |      |      |       |       |       |       |       | V     |
| 8  | Aortic aneurysm                         | 510 000                       | V    |      |      |      |       |       |       |       |       |       |
| 9  | Paracardiac fat                         | 250 000                       |      |      |      |      |       |       |       |       |       |       |
| 10 | Dilation of the pulmonary trunk         | 250 000                       |      |      |      |      |       |       |       |       |       |       |
| 11 | Multiple sclerosis                      | 20 000                        |      |      |      |      | V     |       |       | V     |       |       |
| 12 | Pulmonary emphysema                     | 250 000                       |      |      |      |      |       |       |       |       |       | V     |
| 13 | Fractures of limbs, skull               | 110 000                       | V    |      |      |      |       |       |       |       | V     |       |
| 14 | Brain hemorrhages                       | 78 000                        | V    |      |      |      |       |       |       |       | V     |       |
| 15 | Changes in liver density                | 480 000                       |      |      |      |      |       |       |       |       |       | V     |
| 16 | Vertebral fracture (osteoporosis)       | 592 000                       |      |      |      |      |       |       |       |       |       | V     |
| 17 | Intervertebral disc disease: herniation | 124 000                       |      | V    |      |      |       |       |       |       |       |       |

1st place  2nd place

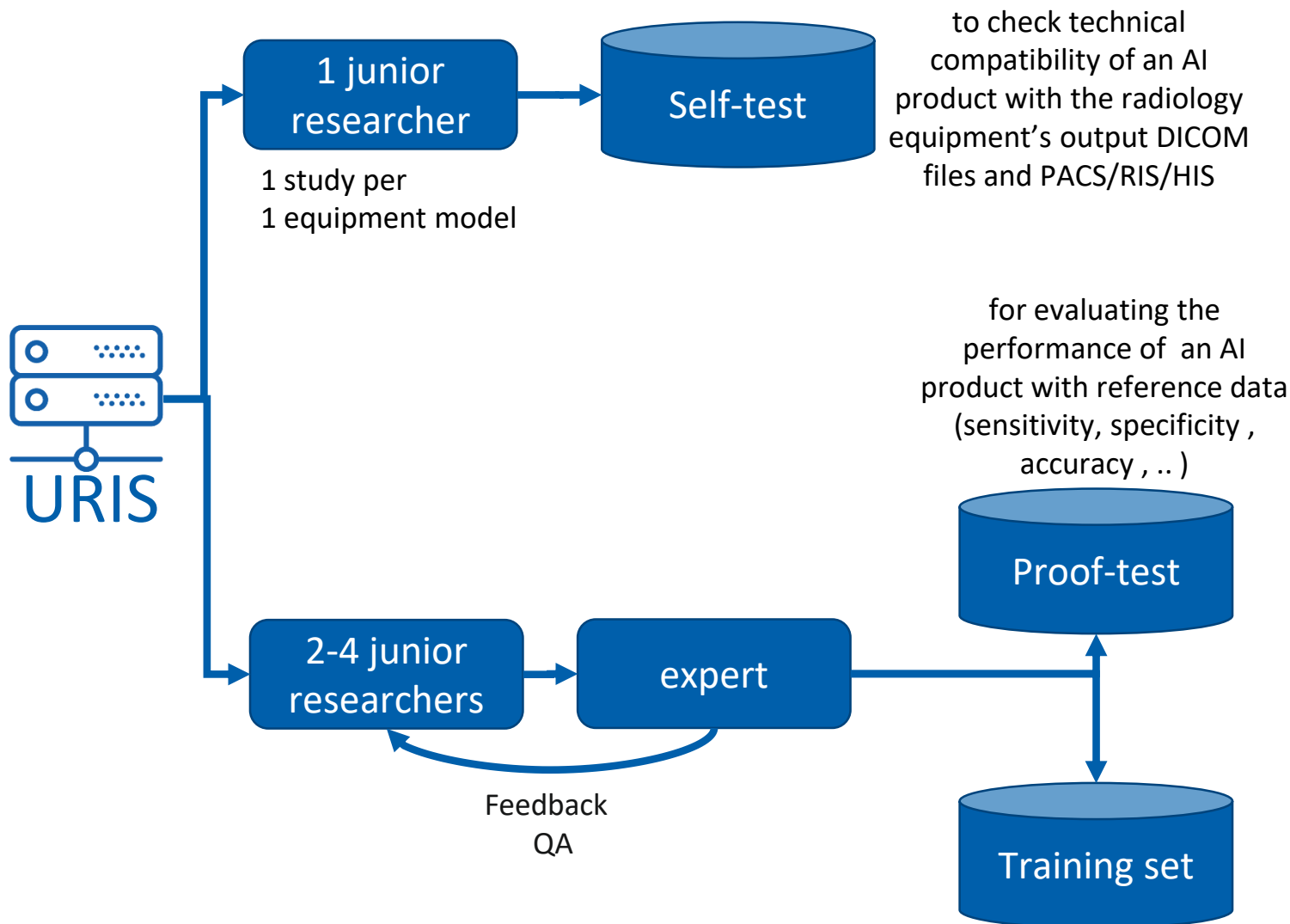
# Unified Radiological Information Service (URIS)



A large number of studies, devices of different manufacturers, as well as the presence of URIS allows to ensure the fulfillment of three main criteria:

- diagnostic cohort design
- the inclusion of multiple institutions
- prospective data collection for external validation

|  | Today | 2020 | 2022 |
|--|-------|------|------|
|  | 60    | 161  | 177  |
|  | 40    | 94   | 117  |
|  | 30    | 106  | 204  |
|  | 9     | 816  | 1067 |
|  | 0     | 25   | 26   |
|  | 0     | 51   | 57   |



## Volume of Datasets

|                              |   |
|------------------------------|---|
| Lung cancer (low-dose CT)    | 4 |
| Lung cancer (CT)             | 4 |
| Breast cancer (mammography)  | 4 |
| Lung pathology (radiography) | 4 |

|                              |     |
|------------------------------|-----|
| Lung cancer (low-dose CT)    | 150 |
| Lung cancer (CT)             | 150 |
| Breast cancer (mammography)  | 150 |
| Lung pathology (radiography) | 150 |

|                              |      |
|------------------------------|------|
| Lung cancer (low-dose CT)    | 500  |
| Lung cancer (CT)             | 3000 |
| Breast cancer (mammography)  | -    |
| Lung pathology (radiography) | -    |



# Data labeling



Разметка

| X   | Y     | Z       | Size(mm) | Type  |
|-----|-------|---------|----------|-------|
| 192 | 255.5 | 119.875 |          | тип ▾ |

Сохранить отметки

Сохраненные тметки

| X | Y | Z | Size(mm) | Type | Удалить строку |
|---|---|---|----------|------|----------------|
|---|---|---|----------|------|----------------|

MIP

AverageMax valueNo MIP

Black

-140

White

260

Gamma value

Шаблоны

Мягкие тканиСосудыКостиМозг

Легкие

120

256

192

1

2

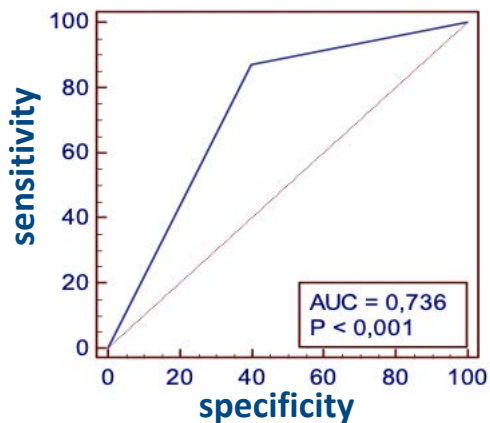
3

4

x: 192 y: 479 z: 172



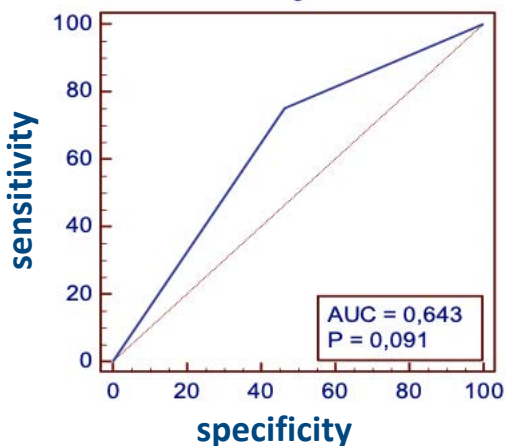
# Examples with low AUC



**Sample №1**  
**n=140**



50% : 50%

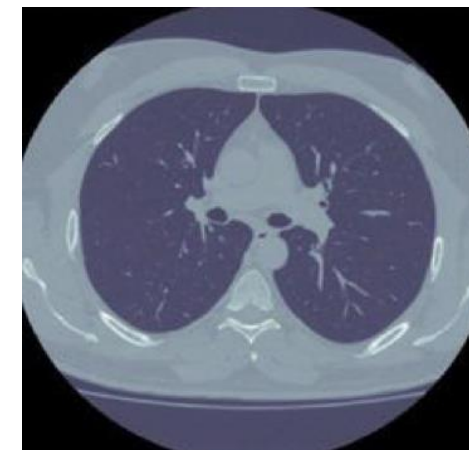


**Sample №2**  
**n=150**

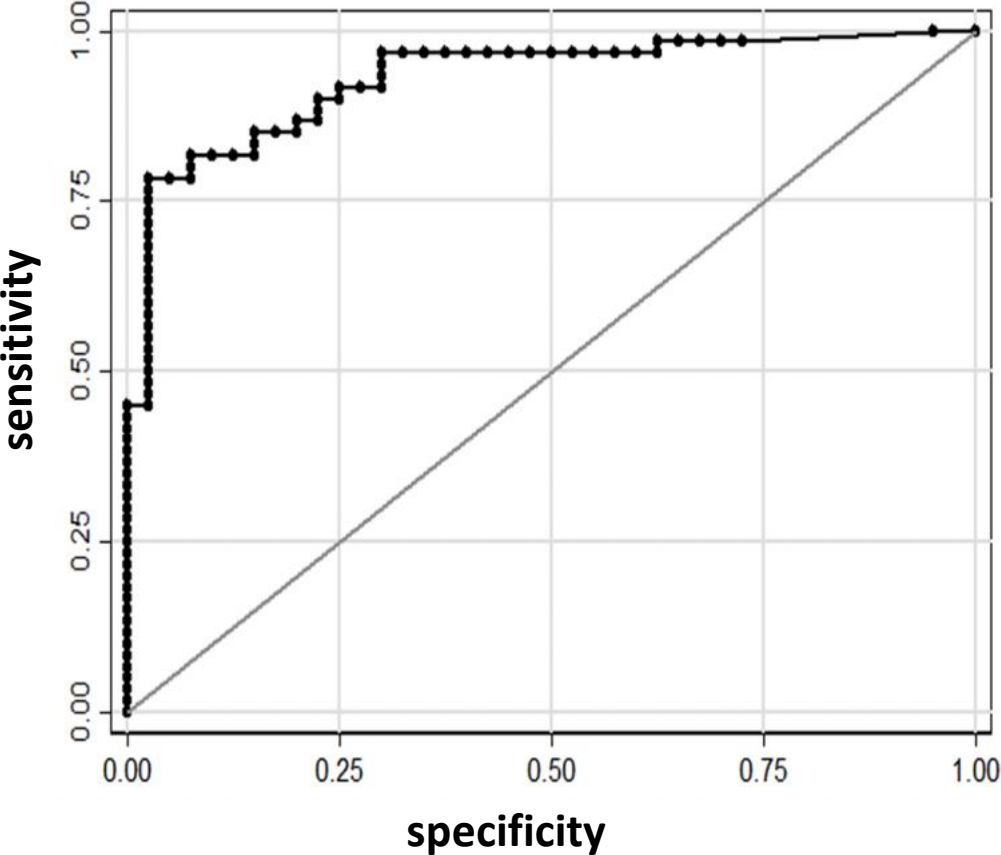


5% : 95%

| Test iteration           | Processing speed, sec. | AUC for assessment the choice "In the study foci presents / no foci" |
|--------------------------|------------------------|--|
| Target value for T3      | 35                     | 0,9  |
| Experiment               | 67                     | 0,8  |
| Experiment (in 3 months) | 35                     | 0,7  |
| Working check 1          | -                      | 0,82   |
| Working check 2          | -                      | 0,64   |
| Working check 3          | -                      | 0,85   |



RESULT: AI solution is applicable only for mass routine health screening in populations with a low pretest probability of pathology presence, which is confirmed by the meaning of the prognostic value of the negative result (97,5%).



|                                       |                      |
|---------------------------------------|----------------------|
| Sensitivity                           | 0,817 (0,696; 0,905) |
| Specificity                           | 0,925 (0,796; 0,984) |
| Accuracy (overall validity)           | 0,860 (0,776; 0,921) |
| Likelihood ratio of a positive test   | 10,9 (3,4;56,6)      |
| Likelihood ratio of a negative test   | 0,20 (0,10; 0,38)    |
| Predictive value of a positive result | 0,942 (0,841; 0,988) |
| Predictive value of a negative result | 0,771 (0,627; 0,880) |

| Evaluation                                  |
|---|
| <0.6 – unsuitable                           |
| 0.61 - 0.8 – revision required              |
| > 0.81 – admissible for clinical validation |

The next stage: to conduct prospective studies on the basis of medical organizations of the Moscow Health Department.

The obtained data confirms the necessity to standardize methodology of testing different solution based on AI

# Technical committee 164 “Artificial Intelligence”



The order of Federal Agency on Technical Regulation and Metrology of July 25, 2019 №1732  
«About creation of technical Committee on standardization of «Artificial intelligence»

| Technical committee 164<br>“Artificial Intelligence”<br>(2019) | Working<br>subgroup |
|--|---------------------|
| WG 01 “Foundational standards”                                 |                     |
| WG 02 “Big Data”   |                     |
| WG 03 “Trustworthiness”  |                     |
| WG 04 “Use cases and<br>applications”                          | AI in Medicine      |
| WG 05 «AI in education»  |                     |



- participates in the activities of artificial intelligence TC 164
- supervises the subgroup of artificial intelligence in health care, which plans to develop standards devoted to clinical and technical trials.



RADIOLOGY MOSCOW  
ENTERPRISE IMAGING

**Kristina Sergunova,**

Head of Technical Monitoring and Quality Assurance Development Department

[sergunova@npcmr.ru](mailto:sergunova@npcmr.ru)

+7 (905) 570-15-28

Thank you for your attention!