RADIOLOGY MOSCOW
ENTERPRISE IMAGING

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

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Yekaterinburg, 2019

Technical potential for automation in Healthcare

Automation potential

pharma distribution supply chain — >75%

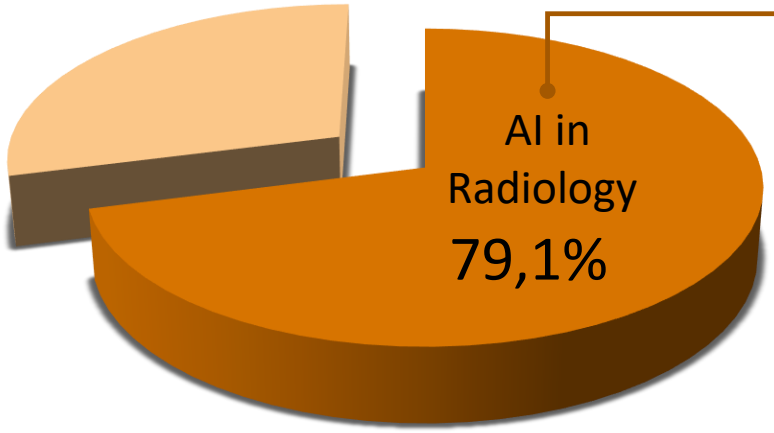
management of patient medical information — >50%

medical image analysis — ≈30%

handling time-consuming nurses'responsibilities — <30%

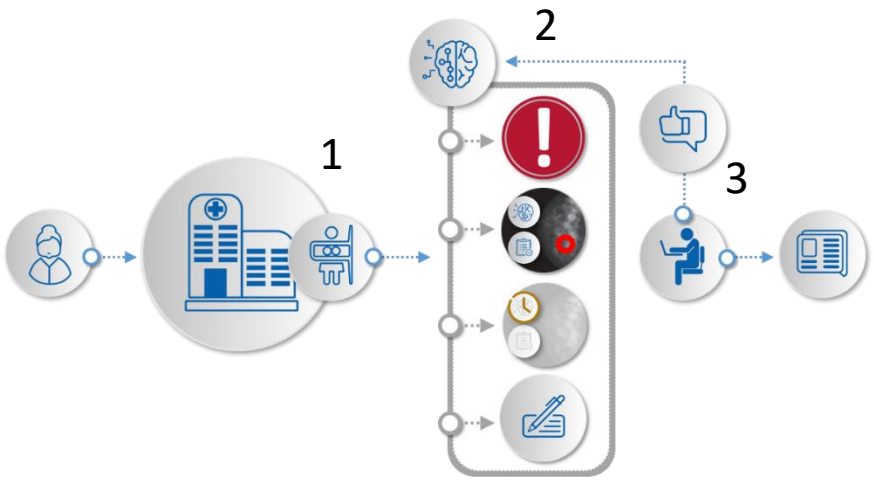
Mckinsey, 2017

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

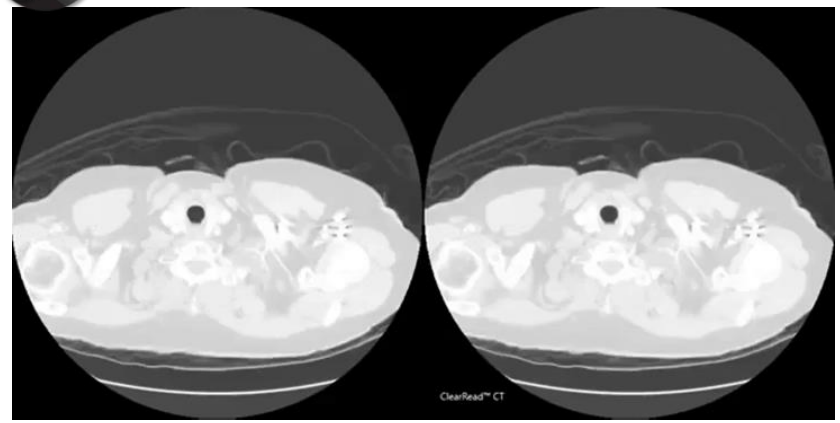


1. **Conducting a diagnostic study**
2. **Processing the study by using of algorithm**
3. **Description of the study by a physician using the algorithm**

Prioritization

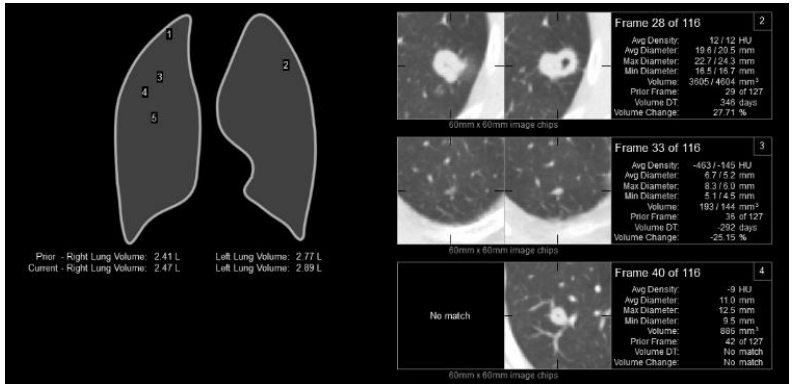
Источник: https://www.aidoc.com/

Localization



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

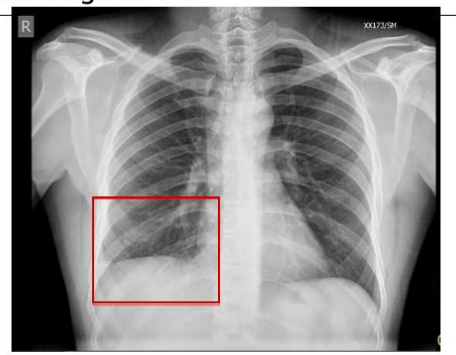
Dynamic assessment



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

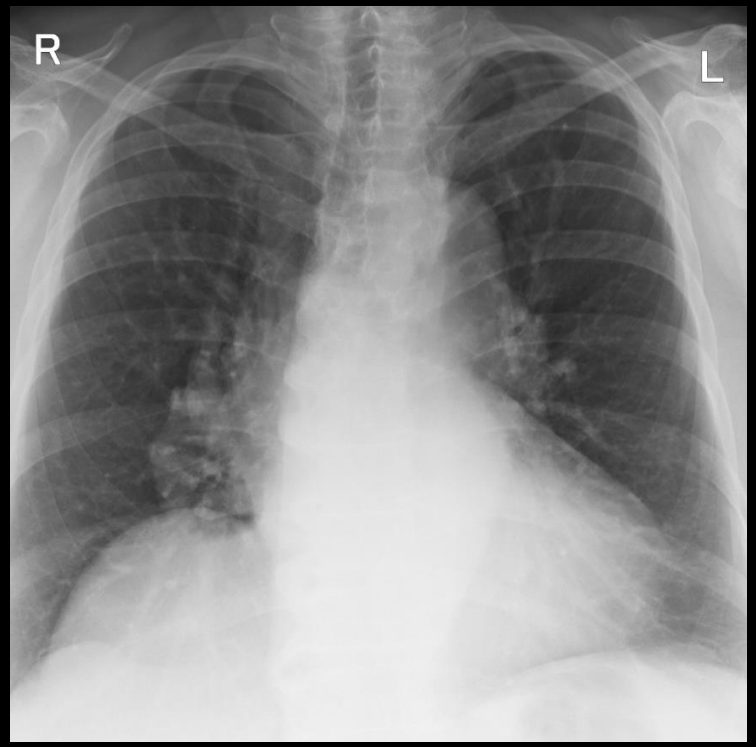
Template of protocol

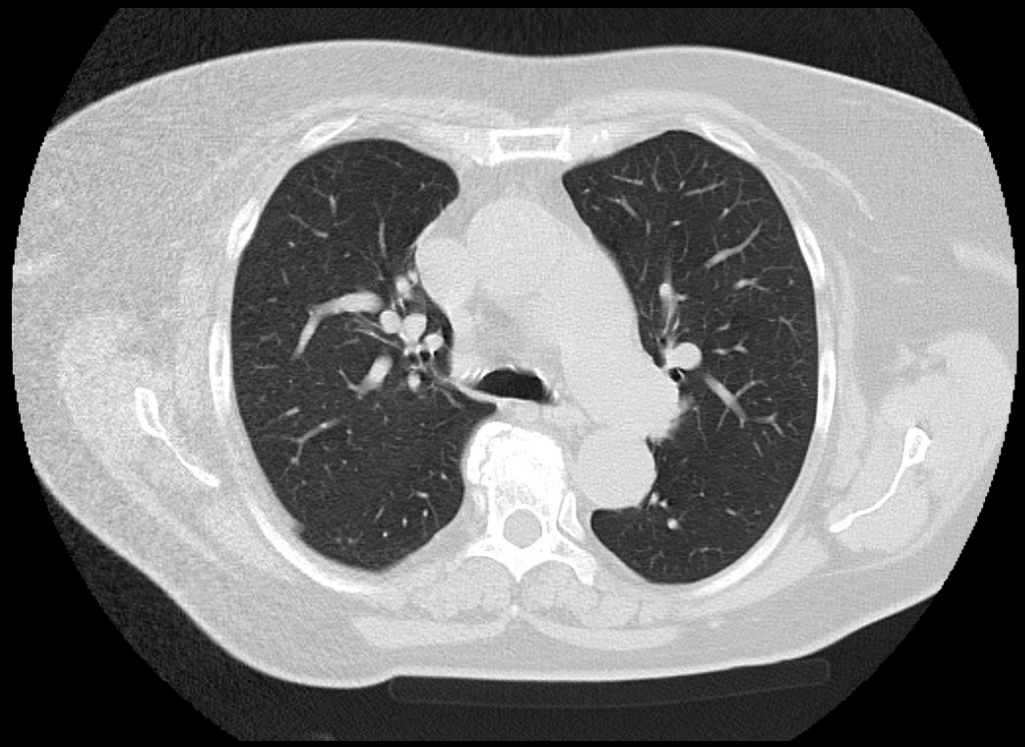
Impression:
Abnormal study.
Preliminary Findings :
Pleural Effusion detected on the right.



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

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.

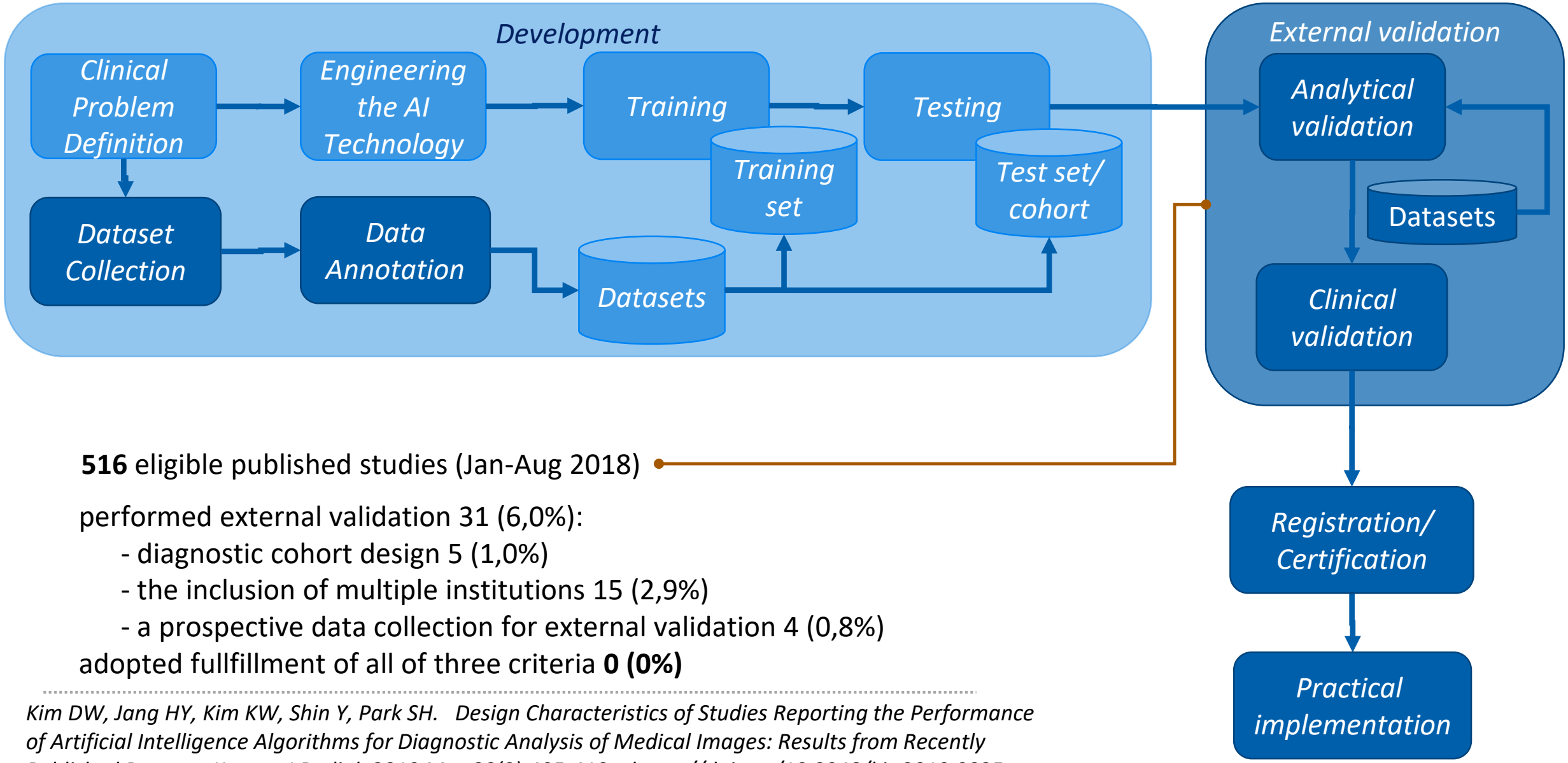
Patient was referred for an unnecessary CT scan:
- radiation dose of 19,6 mSv on CT;
- the cost of CT 1153 rubles according to the CHI;

The questions

How accurate is your AI?

Can we trust AI ?

Total product lifecycle and QA approach on AI workflow



516 eligible published studies (Jan-Aug 2018)

performed external validation 31 (6,0%):

- diagnostic cohort design 5 (1,0%)
- the inclusion of multiple institutions 15 (2,9%)
- a prospective data collection for external validation 4 (0,8%)

adopted fullfillment of all of three criteria **0 (0%)**

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

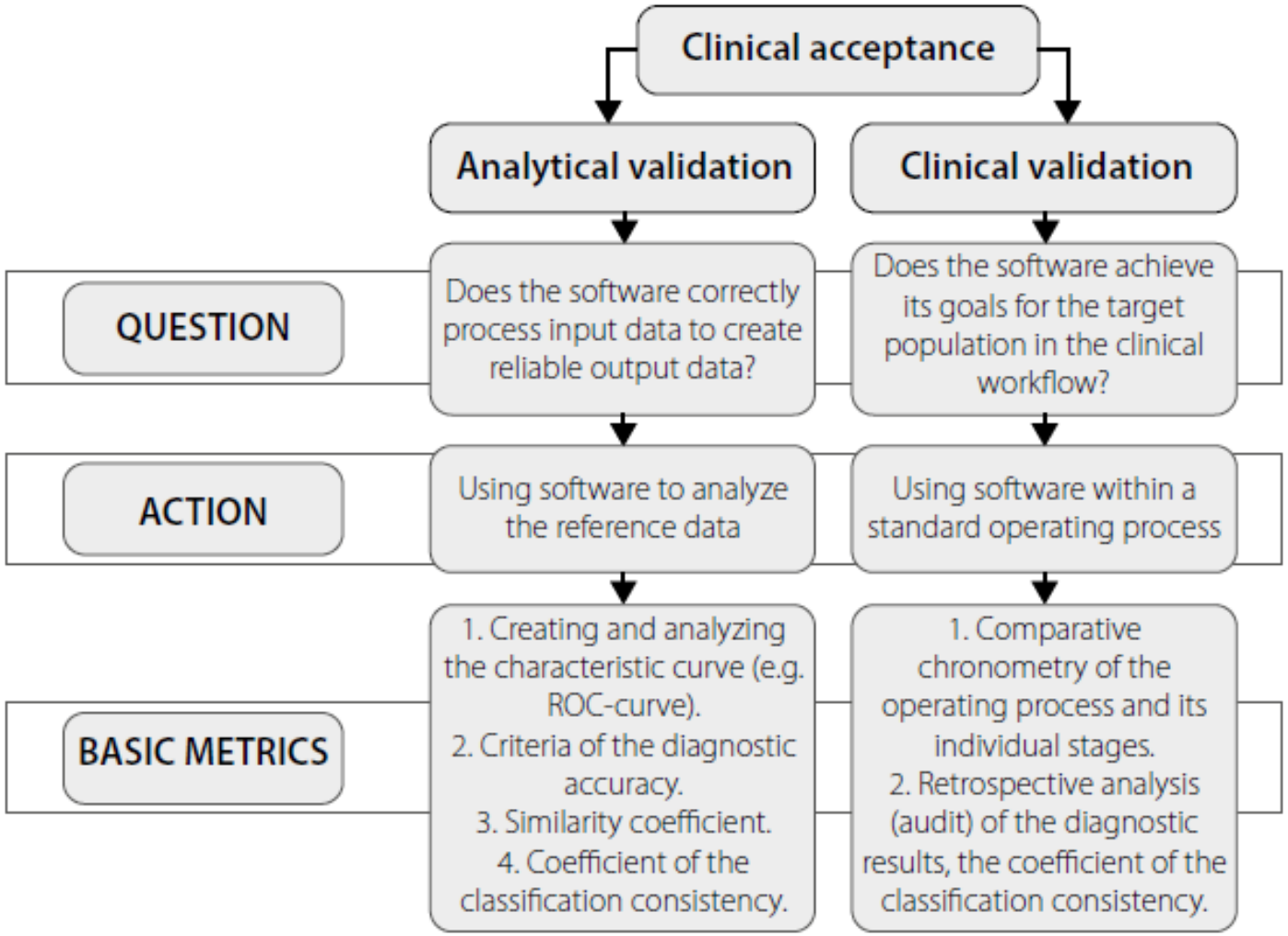
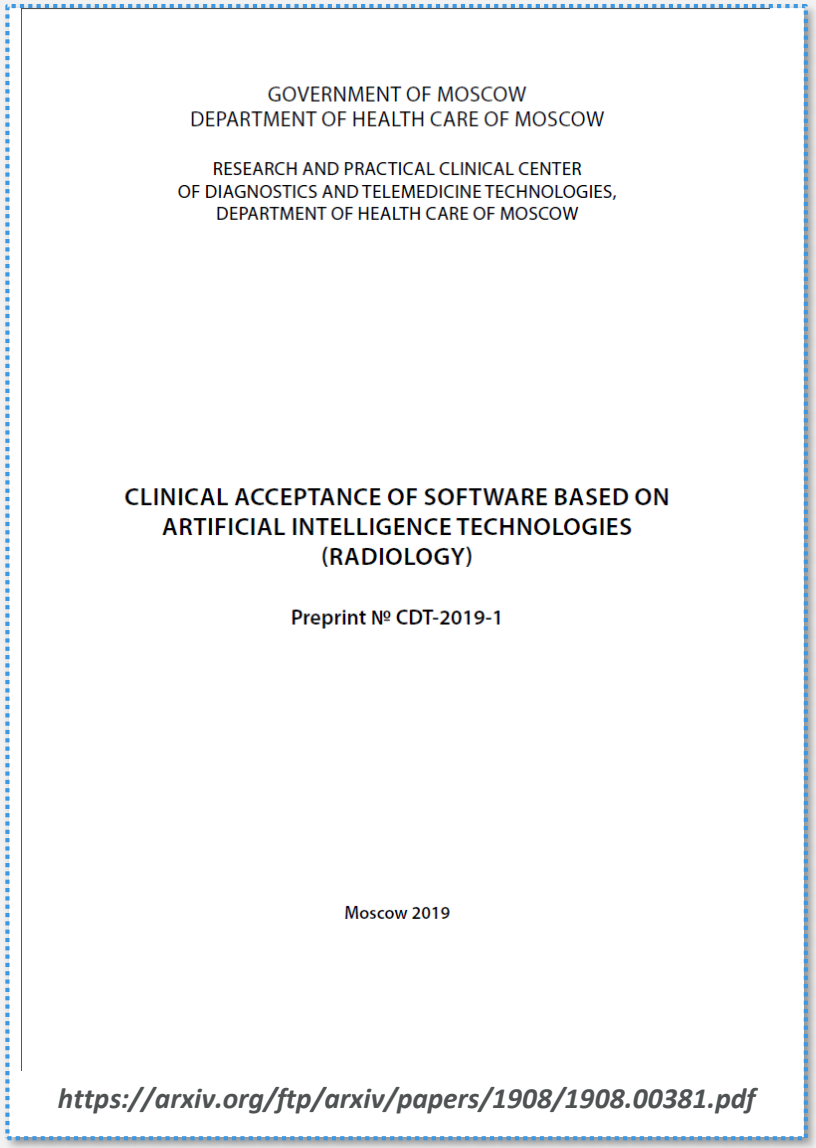


Figure 1 – Flowchart for a clinical evaluation of the AI-based software in radiology.



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

Analytical validation

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:

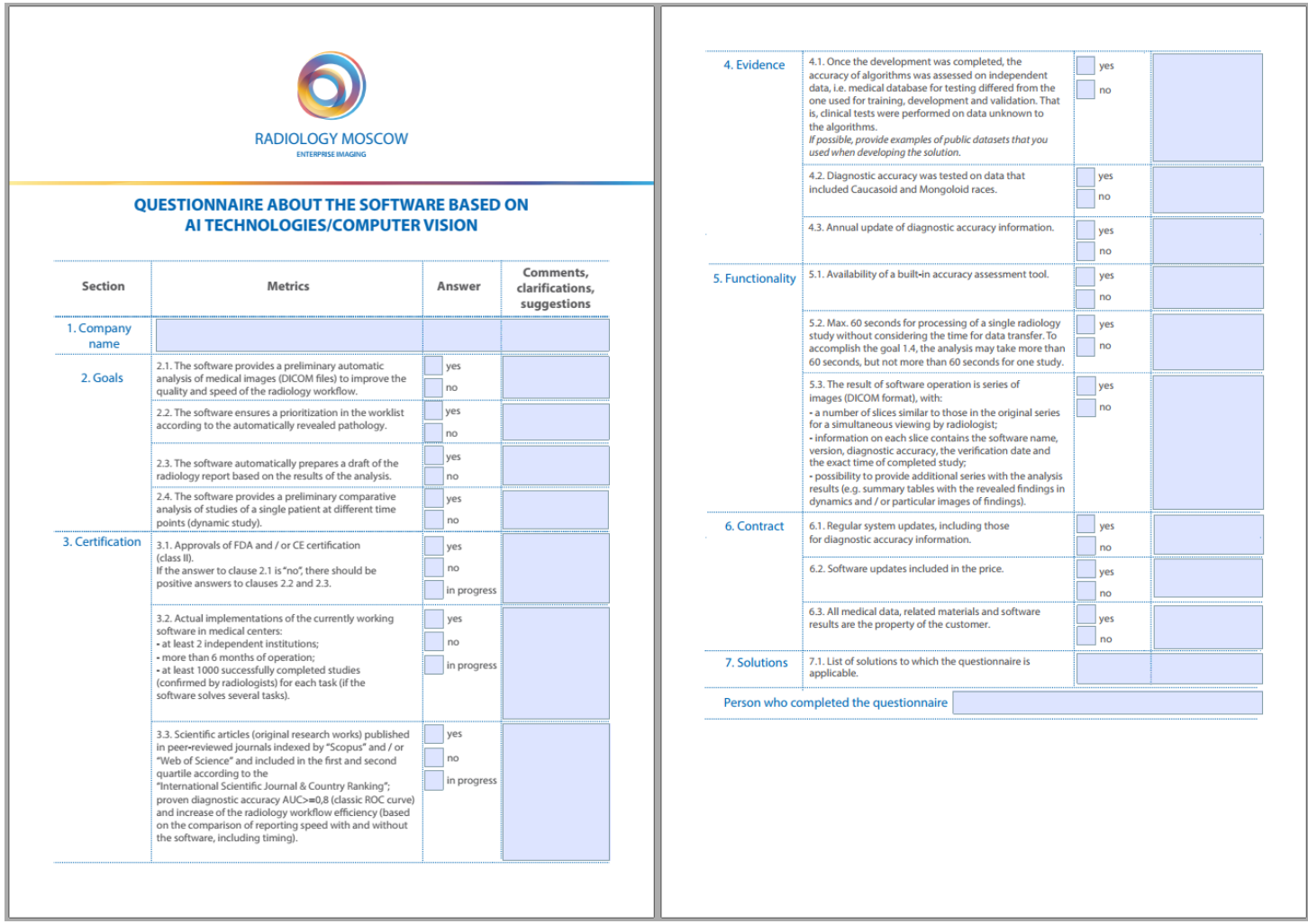
1. Approvals of FDA and / or CE certification

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.



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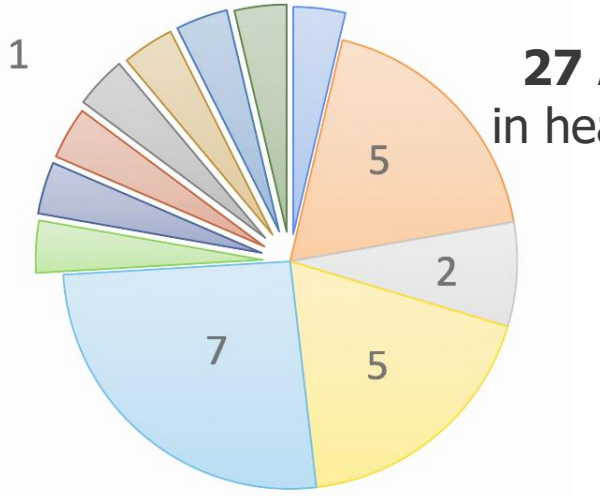
QUESTIONNAIRE ABOUT THE SOFTWARE BASED ON AI TECHNOLOGIES/COMPUTER VISION

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.	☐ yes ☐ no	
	2.2. The software ensures a prioritization in the worklist according to the automatically revealed pathology.	☐ yes ☐ no	
	2.3. The software automatically prepares a draft of the radiology report based on the results of the analysis.	☐ yes ☐ no	
	2.4. The software provides a preliminary comparative analysis of studies of a single patient at different time points (dynamic study).	☐ yes ☐ no	
3. Certification	3.1. Approvals of FDA and / or CE certification (class II). If the answer to clause 2.1 is "no", there should be positive answers to clauses 2.2 and 2.3.	☐ yes ☐ no ☐ in progress	
	3.2. Actual implementations of the currently working software in medical centers: - at least 2 independent institutions; - more than 6 months of operation; - at least 1000 successfully completed studies (confirmed by radiologists) for each task (if the software solves several tasks).	☐ yes ☐ no ☐ 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).	☐ yes ☐ no ☐ 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. *If possible, provide examples of public datasets that you used when developing the solution.*	☐ yes ☐ no	
	4.2. Diagnostic accuracy was tested on data that included Caucasoid and Mongoloid races.	☐ yes ☐ no	
	4.3. Annual update of diagnostic accuracy information.	☐ yes ☐ no	
5. Functionality	5.1. Availability of a built-in accuracy assessment tool.	☐ yes ☐ 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.	☐ yes ☐ no	
	5.3. The result of software operation is series of images (DICOM format), with: - a number of slices similar to those in the original series for a simultaneous viewing by radiologist; - information on each slice contains the software name, version, diagnostic accuracy, the verification date and the exact time of completed study; - 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).	☐ yes ☐ no	
6. Contract	6.1. Regular system updates, including those for diagnostic accuracy information.	☐ yes ☐ no	
	6.2. Software updates included in the price.	☐ yes ☐ no	
	6.3. All medical data, related materials and software results are the property of the customer.	☐ yes ☐ 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*

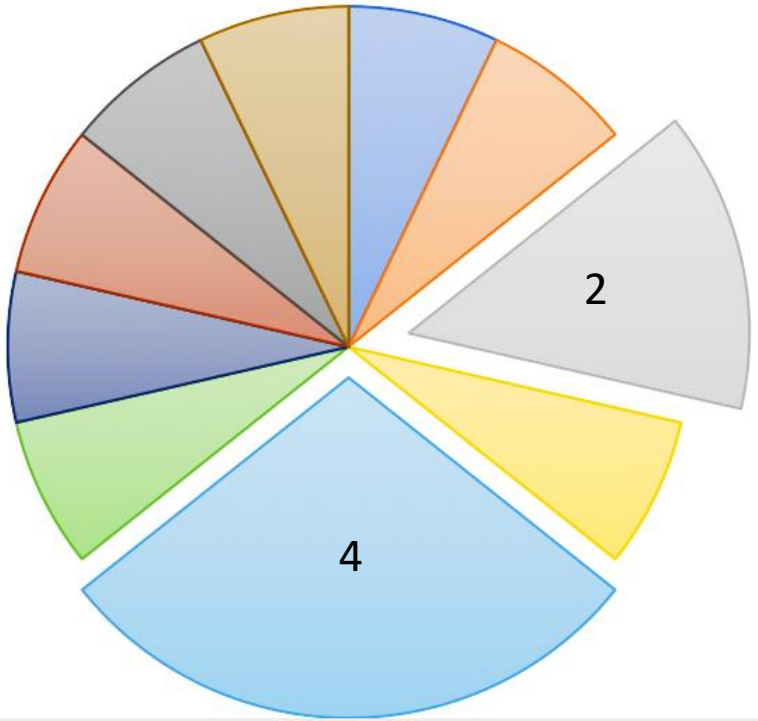
The results of companies selection



27 AI companies
in healthcare market

- Chinese
- Netherlands
- Israel
- USA
- Russia
- UAE
- United Kingdom
- South Korea
- Spain
- India
- Germany
- Singapore

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)

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URIS

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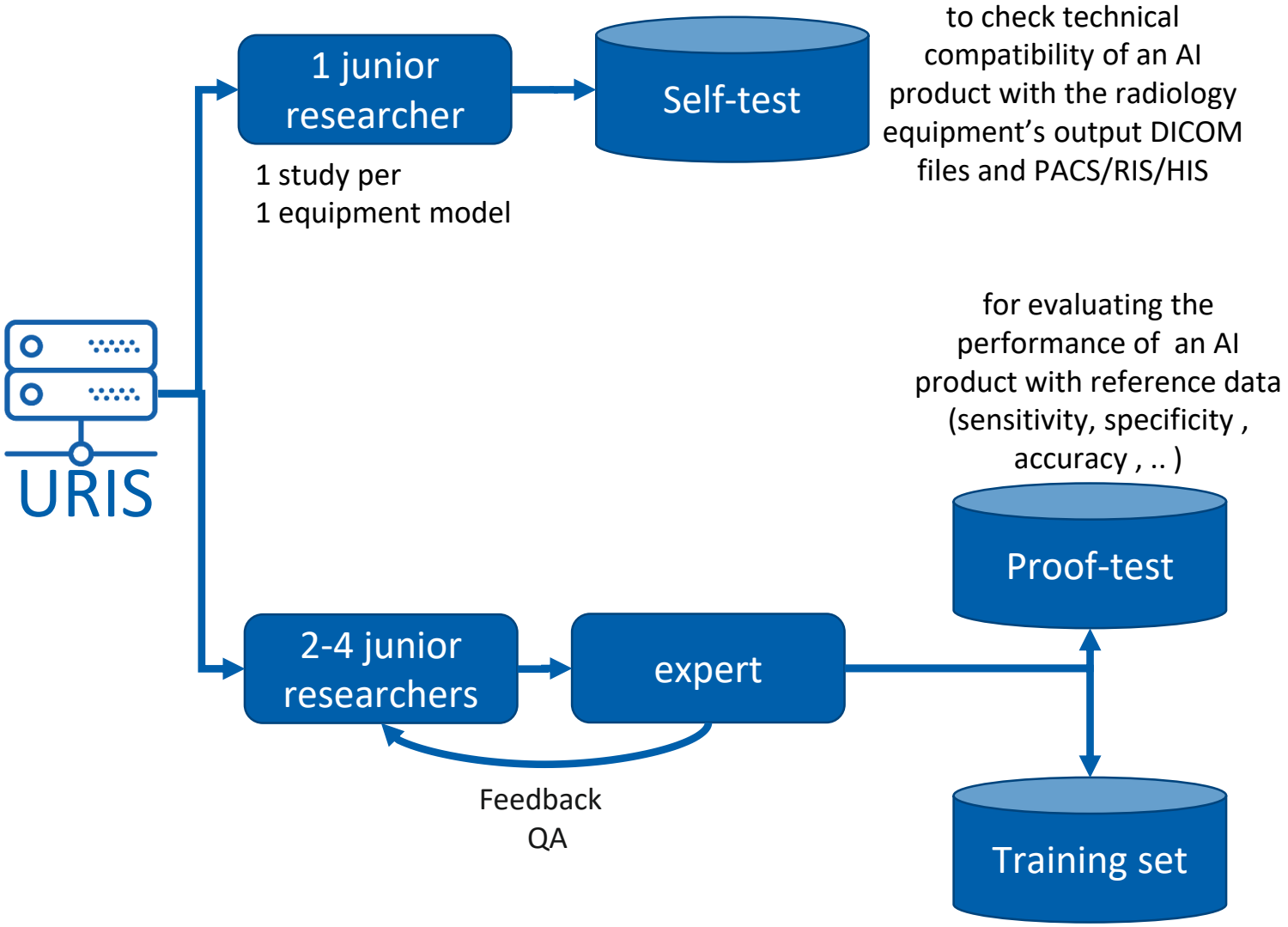
	Today	2020	2022
	60	161	177
	40	94	117
	30	106	204
	9	816	1067
	0	25	26
	0	51	57

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

Preparing Datasets



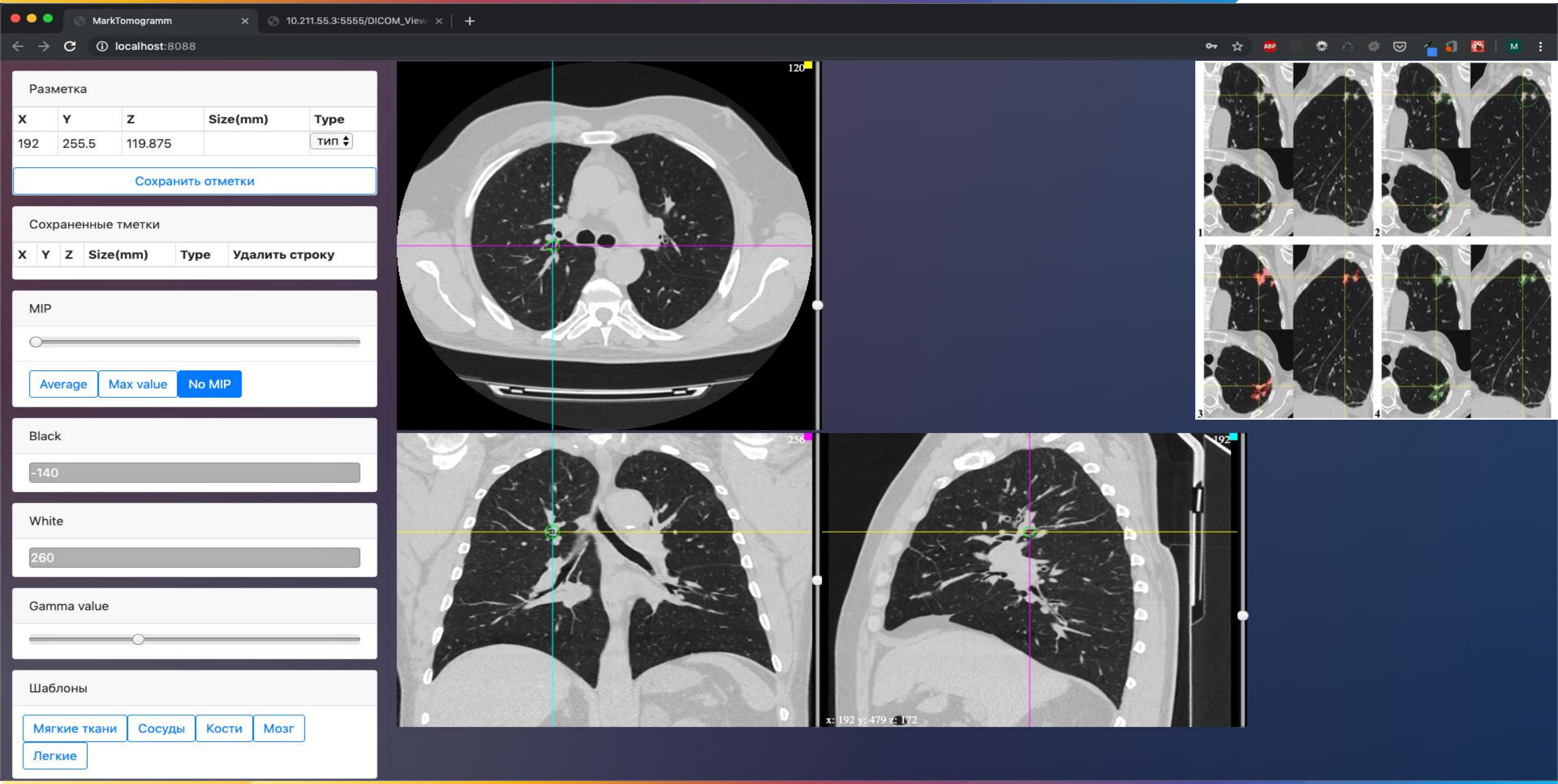
Volume of Datasets

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

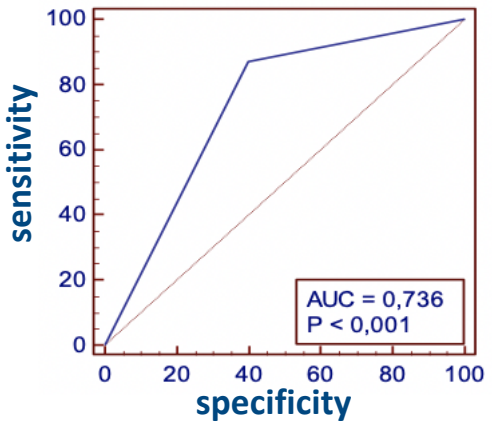
Lung cancer (low-dose CT)	150
Lung cancer (CT)	150
Breast cancer (mammography)	150
Lung pathology (radiography)	150

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

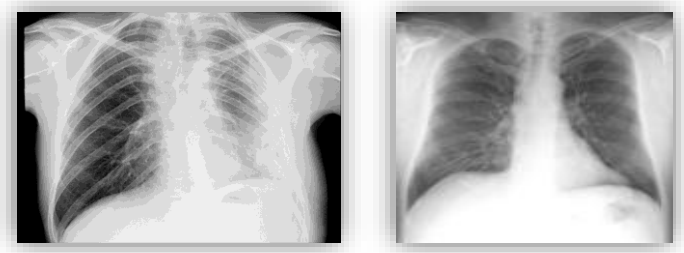
Data labeling



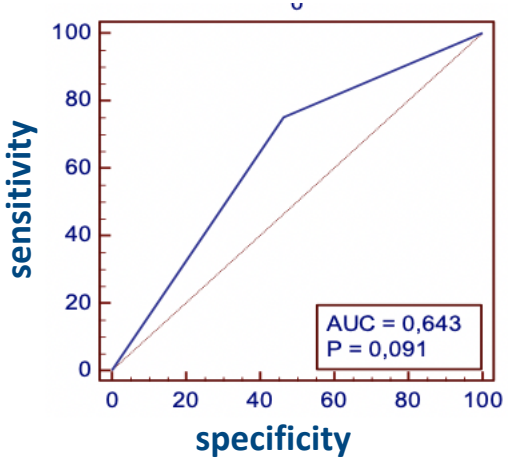
Examples with low AUC



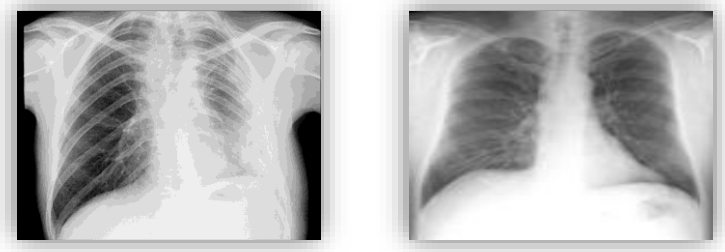
Sample №1
n=140



50% : 50%

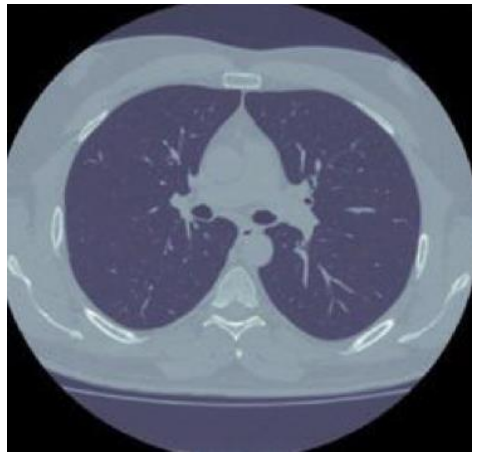


Sample №2
n=150



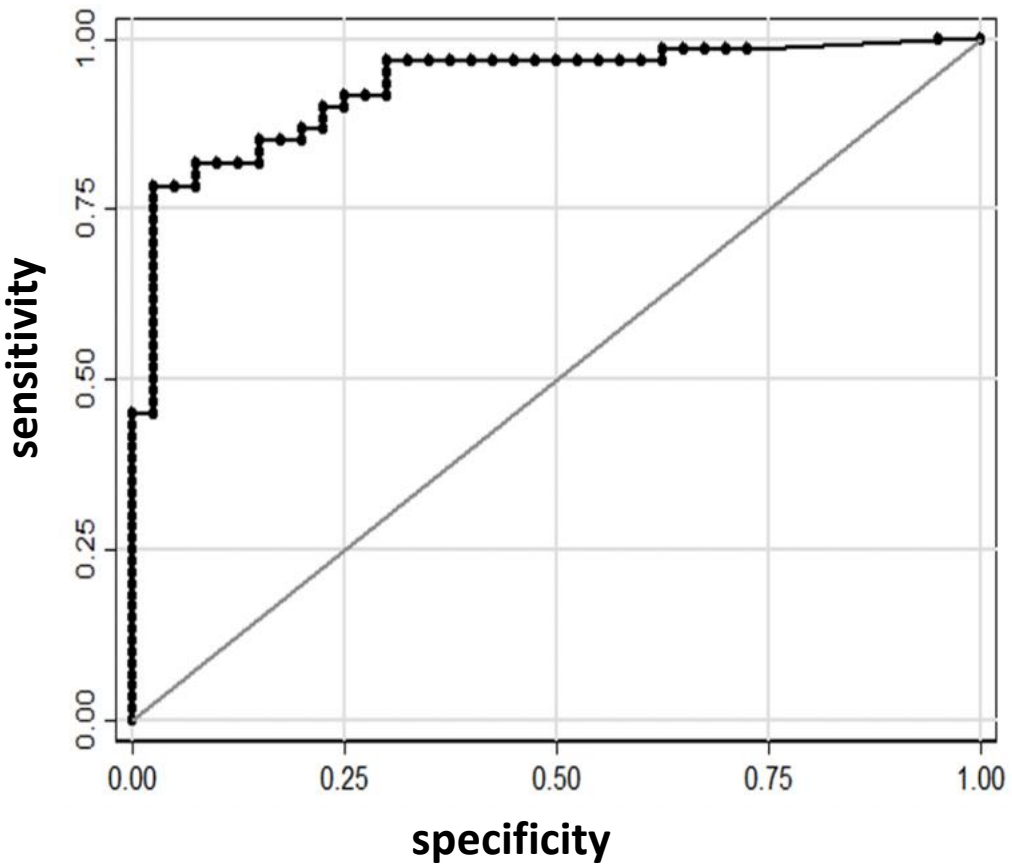
5% : 95%

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%).

Results



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 “Artificial Intelligence” (2019)	Working subgroup
WG 01 “Foundational standards”	
WG 02 “Big Data”	
WG 03 “Trustworthiness”	
WG 04 “Use cases and applications”	AI in Medicine
WG 05 «AI in education»	

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- 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.

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Thank you for your attention!