Appendix 1
to the Order N 160
of the Moscow Healthcare Department
of February 24, 2022

PROCEDURE FOR THE EXPERIMENT ON THE USE OF INNOVATIVE COMPUTER VISION TECHNOLOGIES FOR THE ANALYSIS OF MEDICAL IMAGES AND FURTHER APPLICATION IN THE MOSCOW HEALTHCARE SYSTEM IN 2022

(as amended by orders of the Moscow Healthcare Department N 276 of 25.03.2022, N 540 of 08.06.2022, N 748 of 29.07.2022, N 896 of 16.09.2022)

1. Terms, Abbreviations and Definitions

1.1. For the purposes hereof, the following definitions and abbreviations are used:

DD – diagnostic device of a medical facility subordinated to the Moscow state healthcare system, and connected to the Unified Radiological Information Service of the Unified Medical Information and Analytical System of Moscow;

URIS UMIAS – Unified Radiological Information Service of the Unified Medical Information and Analytical System of Moscow.

USNEI – Unified System of Notifications for External Interactions;

application – an application for the participation in the Experiment from a legal entity that has developed and/or is entitled to provide a service;

CS – comprehensive service;

CT – calibration testing of the software based on computer vision technologies designed to analyse medical images obtained by means of certain types of radiological examinations;

Commission – a commission of the Moscow Healthcare Department to review applications from the legal entities applying for a grant, and to evaluate the operation of the services based on computer vision technologies;

CTT – control and technical testing of the software based on computer vision technologies designed to analyse medical images obtained by certain types of radiological examinations;

MF – medical facility of a state healthcare system of the city of Moscow;

monitoring – monitoring over the operational parameters of the software based on computer vision technologies designed to analyse medical images obtained by means of certain types of radiological examinations;

IHSC URIS UMIAS – Industrial Hardware-Software Complex URIS UMIAS;

applicant – a legal entity that has developed and/or is entitled to provide the software based on computer vision technologies designed to analyse medical images obtained by means of certain types of radiological examinations;

service – a piece of software based on computer vision technologies designed to analyse medical images obtained by certain types of radiological examinations;

THSC URIS UMIAS – Testing Hardware-Software Complex URIS UMIAS;

participant – an applicant, whose Service successfully passed the functional and calibration testing and has been integrated into IHSC URIS UMIAS;

FT – functional testing of the Service;

target pathology – signs of a disease or a pathology, that the Service should detect during the analysis of radiological studies.

2. General Provisions

2.1. This Procedure defines the terms and conditions for conducting the Experiment on the use of innovative computer vision technologies for the analysis of medical images and further application in the Moscow healthcare system (hereinafter, the Experiment) in 2022.

2.2. The organization and support of the Experiment is carried out by the Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow Healthcare Department (hereinafter, the Center for Diagnostics and Telemedicine).

2.3. The Experiment is designed to evaluate the prospects of using results of data analysis based on advanced innovative technologies for the clinical decision support methods in the Moscow healthcare system.

2.4. The Experiment is a prospective research and practical study designed to assess and compare the services in the following categories:

- diagnostic accuracy (estimated, among other things, using identical samples of studies for the services that operate simultaneously);

- applicability;

- ease of use;

- operation efficiency (including the impact on operational productivity and the time reading images).

2.5. The Moscow Healthcare Department (hereinafter, the Department) shall hold the exclusive rights to the data and the results obtained during the Experiment (including the rights to publications and reports in the media, the academic periodicals, conferences, as well as registration of intellectual property rights, and excluding the rights to the intellectual property of the Participants).

2.6. The Experiment covers the following imaging modalities:

- chest computed tomography and/or low-dose computed tomography to detect malignant neoplasms of the lungs, lung involvement in COVID-19, compression fractures of the vertebral bodies, ischemic heart disease (coronary calcium, paracardial fat), emphysema, thoracic aortic aneurysms which includes measurement of the thoracic aorta diameter, dilation of the pulmonary trunk which includes measurement of the pulmonary trunk diameter, free fluid (effusion) in the

pleural cavities, enlarged lymph nodes (lymphadenopathy), pulmonary tuberculosis, sarcoidosis and bronchiectasis;

- computed tomography of the brain to detect ischemic stroke and intracranial hemorrhage;

- computed tomography of the abdomen to detect urolithiasis, adrenal lesions, liver lesions, kidney lesions, compression fractures of the vertebral bodies, aneurysm of the abdominal aorta which includes measurement of the abdominal aorta diameter;

- magnetic resonance imaging of the brain to detect malignant neoplasms and multiple sclerosis;

- magnetic resonance imaging of the lumbosacral spine to detect spinal stenosis and protrusions and herniations of the intervertebral discs;

- mammography to detect breast cancer;

- chest X-ray to detect various pathologies;

- chest photofluorography to detect various lung pathologies;

- head X-ray to detect sinusitis;

- X-ray of the musculoskeletal system to detect various pathologies of the spine (osteochondrosis, scoliosis, spondylolisthesis, fracture of the vertebral bodies), bone fractures of the upper and lower extremities (wrist, shoulder, hip and ankle joints), arthrosis (hip, knee), longitudinal flat feet.

2.7. During the Experiment the introduction of the modalities specified in clause 2.6 will be carried out on a step-by-step basis. Stages and time frames for the introduction are published and updated on the Experiment's website www.mosmed.ai.

The Center for Diagnostics and Telemedicine has the right to change the stages and time frames for the introduction of the imaging modalities of the Experiment, including reviewing the applications from the applicants and participants.

3. Requirements for Participants and Services

3.1. Service developers and their legal representatives participate in the Experiment.

3.2. Depending on the number of target pathologies to be detected using one of the imaging modalities, the following services may participate in the Experiment:

3.2.1. A service that analyzes medical images to identify one target pathology within the framework of either imaging modality.

3.2.2. A comprehensive service that analyzes medical images to identify a set of target pathologies established by this Procedure within the framework of either imaging modality.

3.3. Requirements to the Services:

- availability of functions that match the baseline functional requirements approved by the Center for Diagnostics and Telemedicine and published on the Experiment's website:

www.mosmed.ai;

- compliance with the baseline diagnostic requirements to the deliverables, approved by the Center for Diagnostics and Telemedicine and published on the Experiment's website: www.mosmed.ai;

- compliance with the diagnostic accuracy indicators specified in clause 7.1.5 hereof.

3.4. A Participant of the Experiment is obliged to guarantee:

- observe the terms and conditions of the Experiment;

- observe the rules related to the confidentiality of personal data and other legally protected information;

- the data obtained during the course of participation in the Experiment will be stored, processed and used only on the territory of the Russian Federation and strictly for the purposes of the Experiment, and will not be transferred to third parties (which includes prevention of access to studies by the third parties);

- all image data and analysis results will be deleted upon completion of the Experiment.

6. Application for Participation

4.1. Participation in the Experiment is carried out on the basis of an application.

4.2. An applicant for participation in the Experiment shall submit a formal application (see the application form in Appendix 1 hereto) and supporting documents to the Center for Diagnostics and Telemedicine at the following address: Moscow, 24 Petrovka Str. The copies of the above-mentioned documents should be sent either to the Experiment's email address ai@npcmr.ru, and/or by means of the applicant’s personal user account on the Experiment's website: www.mosmed.ai.

4.3. The following supporting documents shall be attached to the application:

4.3.1. Certified copies of the documents evidencing state registration of the applicant's legal entity on the territory of the Russian Federation.

4.3.2. Documents evidencing the development and/or the right to provide the proposed Service based on the computer vision technologies for the analysis of medical images.

4.3.3. A report on preliminary clinical and technical testing conducted using medical images obtained from citizens of the Russian Federation and/or persons of Caucasian and Mongoloid races, prepared in accordance with the Guidelines No. 43 “Clinical Acceptance of Software Based on Artificial Intelligence Technologies (Radiology)” (recommended by the Expert Council for Science of the Moscow Healthcare Department, Protocol No. 8 of June 25, 2019).

The report on preliminary clinical and technical testing should be certified by the signature of an authorized person and the seal of the medical facility that prepared the report.

The report on preliminary clinical and technical testing shall contain the following information:

- classic ROC curve and area under the curve (AUC).

- data on sensitivity, specificity and accuracy;

- a four-section spreadsheet that compares the results of index- and reference testing;

- a reading time for a study.

4.3.4. Documentation outlining and evidencing the availability of the Service functionality that meets the baseline functional requirements specified in clause 3.3 hereof, along with the technical architecture and characteristics, use case scenarios, and requirements to the software and hardware for the service operation.

4.3.5. Report on the clinical implementation and/or acceptance testing of the Service across medical facilities of the Russian Federation or other countries, indicating the testing duration and the number of medical facilities where the service was tested (if available).

4.3.6. Certified copies of the certificates for the Service compliance with the regional quality standards of FDA, CE, and their equivalents in other countries or a certified copy of the certificate of state registration as a medical device (if available).

4.3.7. Copies of scientific articles evaluating the accuracy and efficacy of the Service published in peer-reviewed journals indexed in Scopus and/or Web of Science (if available).

4.3.8. Valid certificate of conformity of the quality management system to the ISO standard (if available).

4.3.9. Certified copies of the certificate of state registration as a medical device (if available).

4.3.10. Other documents that the applicant may consider appropriate.

4.4. If the original document is issued in a language other than Russian, it should be accompanied by a translation into Russian, certified by an authorized person and stamped by the applicant.

4.5. The Center for Diagnostics and Telemedicine, within three business days from the date the application is hand-delivered to the Center for Diagnostics and Telemedicine's address specified in clause 4.2 hereof, shall review the application for compliance with the requirements set out in clauses 4.2 - 4.3 hereof. During the review, the Center for Diagnostics and Telemedicine is entitled to request clarification from the applicant regarding the submitted application, along with the other attached documents and information. The review of the application shall be suspended until a clarification is provided.

4.5.1. Should the application fail to meet the requirements set up in clauses 4.2 - 4.3 hereof, the applicant will receive a corresponding notice at the email address specified in the application within three business days upon completion of the review and finalization of the decision.

4.5.2. An applicant shall bear all the risks related to the delivery of the correspondence on all emerging issues during the Experiment to the email address specified in the application.

4.5.3. An applicant shall have the right to re-submit the application after correcting discrepancies associated with the completeness of supporting documentation and/or compliance with the requirements specified in clauses 4.2 - 4.3 hereof.

4.5.4. If the application meets the requirements set up in clauses 4.2 - 4.3 hereof, a technical integration into URIS UMIAS shall begin within one business day. An acceptance letter and a

need to proceed with the technical integration shall be sent to the applicant to the email address specified in the application.

4.5.5. Applications approved in 2021 that meet the requirements of the Experiment (established by this Procedure) in terms of the imaging modalities (clause 2.6) shall be considered valid for 2022.

5. Technical Integration

5.1. Technical integration of the Service is carried out in THSC URIS UMIAS. A time limit of the integration shall not exceed 15 calendar days from the date of sending an information letter concerning the initiation of the technical integration into URIS UMIAS to the applicant's e-mail.

5.2. The integration period may be extended upon a request from the applicant sent to the e-mail address of the Experiment: ai@npcmr.ru.

5.3. The technical integration procedure consists of the configuration of access to the URIS UMIAS and verification of the consistency of data exchange between the applicant's Service and URIS UMIAS. Where applicable, the applicant shall make the necessary improvements to the Service to complete the integration process. Once the technical integration is completed, the Service shall undergo the FT and CT procedures. A description of the technical integration process is published on the Experiment’s website: www.mosmed.ai.

6. Functional Testing

6.1. FT of the Service operation is carried out in stages:

6.1.1. Up to 5 studies are sent to the Service for analysis to the THSC URIS UMIAS.

6.1.2. The Service shall analyze these studies one by one and submit the results to THSC URIS UMIAS.

6.1.3. Based on the FT outcomes, the applicant shall complete Table 1 of Appendix 2 to this Procedure and submits it to the Center for Diagnostics and Telemedicine.

6.1.4. The experts of the Center for Diagnostics and Telemedicine evaluate the data from Table 1 for compliance of the parameters stated in the application with the baseline functional and diagnostic requirements for the deliverables expected from the Service in accordance with clause 4.2.4 hereof. The assessment results shall be documented in an FT protocol using the form provided in Appendix 3 to this Procedure.

6.1.5. The Center for Diagnostics and Telemedicine sends a completed protocol to the applicant’s email address specified in the application and (or) to the personal user account on the Experiment’s website: mosmed.ai. In case of any critical discrepancies, Table 2 of Appendix 2 to this Procedure is sent additionally.

6.1.6. The discrepancies shall be considered critical if they directly or indirectly affect the life and health of patients, as well as negatively affect the doctor's work processes.

6.1.6.1. In the absence of critical discrepancies with the declared parameters listed in Table 1 of Appendix 2 to this Procedure, the Service shall proceed to the CT outlined in clause 7 hereof.

6.1.6.2. In case of any critical discrepancies in the parameters stated in the application and the baseline functional and diagnostic requirements for the Service deliverables specified in clause 4.2.4 of this Procedure, the applicant shall eliminate these remarks and notify the Center for

Diagnostics and Telemedicine on the timing of their elimination.

6.1.6.3. Upon the elimination of identified discrepancies, the applicant shall complete a table of eliminated discrepancies in the Service operation (see Table 2 of Appendix 2) and submit it to the Center for Diagnostics and Telemedicine.

6.1.7. Should the Service require improvements that neither alter its initially declared functions and technical architecture, nor affect the diagnostic accuracy metrics, the applicant is allowed to proceed to the CT phase outlined in clause 7 of this Procedure that involves supervision over the Service improvements.

6.1.7.1. Should the applicant make improvements that alter the initially declared functions and technical architecture, and affect the diagnostic accuracy metrics, the Service should undergo a repeated FT that outlined in clauses 6.1.1 - 6.1.5, once the applicant submits a notification about the introduction of these changes.

6.2. The applicant is allowed to take the FT no more than twice. In case the repeated FT has been unsuccessful, the Service is sent for revision. The Service has the right to undergo FT again no earlier than 3 months after receiving the last protocol with unsatisfactory test results.

7. Calibration Testing

7.1. CT of the Service is carried out in stages:

7.1.1. At least 100 studies of a certain imaging modality are sent to the Service to THSC URIS UMIAS for analysis.

7.1.2. The Service shall analyze these studies one by one and submit the results to THSC URIS UMIAS.

7.1.3. A reading time for each study is recorded for further comparison with the standard reading time in accordance with clause 8.4 of this Procedure.

7.1.4. Upon returning the analysis results to THSC URIS UMIAS, Table 3 of Appendix 2 is to be completed containing the study identification numbers, probability of pathological findings in each study, and the time spent by the Service on the analysis of this study.

7.1.5. Based on the data from Table 3 of Appendix 2 to this Procedure, the Center for Diagnostics and Telemedicine evaluates the obtained CT results for compliance with the following requirements

- optimal activation threshold as shown on the study data in URIS UMIAS (Youden index), based on the Report on preliminary clinical and technical testing;

- time spent by the Service on the study analysis (in accordance with clause 8.4 of this Procedure);

- diagnostic accuracy parameters as shown on the reference dataset in THSC URIS UMIAS.

The values of the area under the ROC curve (AUC) obtained with the reference dataset:

- for chest computed tomography and/or low-dose computed tomography to diagnose malignant neoplasms of the lungs – at least 0.91;

- for chest computed tomography to diagnose the lung involvement in COVID-19 – at least 0.90;

- for chest computed tomography and/or low-dose computed tomography to diagnose compression fractures of the vertebral bodies, ischemic heart disease (coronary calcium, paracardial fat), emphysema, thoracic aortic aneurysms with a measurement of the thoracic aorta diameter, dilation of the pulmonary trunk with a measurement of the pulmonary trunk diameter, free fluid (effusion) in the pleural cavities, enlarged lymph nodes (lymphadenopathy), pulmonary tuberculosis, sarcoidosis and bronchiectasis – at least 0.81;

- for computed tomography of the brain to detect ischemic stroke and intracranial hemorrhage – at least 0.81;

- for computed tomography of the abdomen to detect urolithiasis, adrenal lesions, liver lesions, kidney lesions, compression fractures of the vertebral bodies, aneurysm of the abdominal aorta with a measurement of the abdominal aorta diameter – at least 0.81;

- for magnetic resonance imaging of the brain to detect intracranial neoplasms and multiple sclerosis – at least 0.81;

- for magnetic resonance imaging of the lumbosacral spine to detect spinal stenosis, protrusions and herniations of the intervertebral discs – at least 0.81;

- for mammography to diagnose breast cancer – at least 0.81;

- for chest X-ray and photofluorography to detect various pathologies – at least 0.86;

`- for head X-ray to detect sinusitis – at least 0.81;

- for X-ray of the musculoskeletal system to detect various pathologies of the spine (osteochondrosis, scoliosis, spondylolisthesis, fracture of the vertebral bodies), bone fractures of the upper and lower extremities (wrist, shoulder, hip and ankle joints), arthrosis (hip, knee), longitudinal flat feet – at least 0.81;

- for a comprehensive chest computed tomography to detect various pathologies – at least 0.81.

A reduction of diagnostic accuracy parameters as compared to the reference dataset should not exceed 10% of the values specified in the report on preliminary clinical and technical testing.

For the numerical indicators evaluated by the Service, additional metrics can be calculated to quantify the diagnostic accuracy of the Service.

7.1.6. The assessment results shall be documented in a CT protocol using the form provided in Appendix 4 to this Procedure.

7.1.7. The Center for Diagnostics and Telemedicine sends a completed protocol to the applicant’s email address specified in the application and (or) to the applicant’s personal user account on the Experiment’s website: www.mosmed.ai.

7.1.8. If the requirements outlined in clause 7.1.5 of this Procedure are met, the applicant receives a Participant status; a respective notification to be sent to the email address specified in the application and (or) to the applicant’s personal user account on the Experiment’s website: mosmed.ai. Afterwards, the Participant shall proceed with the integration of the Service into the

IHSC URIS UMIAS. In this case, a version and/or modification of the Service is integrated into the IHSC URIS UMIAS, corresponding to a permission indicated in the CT protocol. Changing the indicators of diagnostic accuracy and functionality of the integrated Service is possible only after performing the procedure described in Section 12 hereof.

7.1.9. If there are any discrepancies with the requirements described in clause 7.1.5 hereof, the Center for Diagnostics and Telemedicine sends a notification concerning a need to improve the Service to the applicant's email address specified in the application.

7.1.10. Upon revision of the service, the applicant notifies the Center for Diagnostics and Telemedicine by e-mail about the works performed and then proceeds to a repeated CT procedure that outlined in clauses 7.1.1 - 7.1.8 hereof.

7.2. An applicant is allowed to take the CT no more than twice. If the repeated CT fails, the Service is sent for revision. The Service has the right to repeat a CT procedure at least three months after receiving the last protocol with unsatisfactory test results.

7.3. In case if a repeated testing was unsuccessful (clause 6.27.2 of this Procedure), the applicant may be offered to consider an alternative option for scientific and practical collaboration. Within the framework of such collaboration, the applicant will receive an opportunity to use the database containing de-identified (anonymized) study results, while the Center for Diagnostics and Telemedicine shall have the right to use the service free-of-charge (with all its updates, improvements and modifications) on the territory of the Russian Federation on the terms of a simple non-exclusive license.

8. Processing of diagnostic studies in IHSC URIS UMIAS

8.1. Upon successful completion of the functional and calibration testing, the Service is integrated into IHSC URIS UMIAS. During the integration phase the following factors are taken into account:

- testing results in THSC conducted no earlier than 2021 that meet the requirements of clauses 3.3, 7.1.5;

- Service operation stage in IHSC in 2021.

8.2. The Center for Diagnostics and Telemedicine shall notify the Commission members about a successful completion of the testing before integrating the Service into IHSC URIS UMIAS.

8.3. URIS UMIAS receives diagnostic studies from connected DDs. Using the URIS UMIAS technical capacities, the studies shall be de-identified, routed for the processing by the Service, and then the results are returned to URIS UMIAS for reverse de-identification. Each study may contain a various number of images or scan sections depending on the imaging modality.

8.4. A standard time for a study analysis is the time elapsed from the moment of notice that a study has become available for downloading and processing by the Service in USNEI, and until the Service alerts USNEI that the analysis results are available in URIS UMIAS. The standard reading time should not exceed 6.5 minutes.

8.5. Upon completion of the integration into the IHSC URIS UMIAS, the participant proceeds to the acceptance testing.

8.6. During the acceptance testing, each participant shall receive the necessary number of

studies for analysis in order to evaluate the Service performance and to see if a transition to the operation testing is possible. A duration of this stage is at least three months for each Service, not including the periods of the Service suspension outlined in clauses 10.11, 10.11.1, 10.11.4 hereof.

8.7. During the acceptance testing, the studies are routed from all DDs to the Service on the principle of "chessboard routing".

"Chessboard routing" means automated submission of the studies to the Service, that ensures alternate interaction of the Service with all DDs for each particular imaging modality. To secure the approach across all imaging modalities, the Experiment design gathers of MFs into groups based on the total number of DDs. The periods and sequence of the Service operation with each group are determined by the Center for Diagnostics and Telemedicine.

8.8. Once the three month period is over, the automated submission of the studies is suspended until the Commission decides if the Service is ready to proceed to the operational testing. A decision on the successful completion of the acceptance testing is based on the Service testing results in THSC, reports on the technological monitoring of Service operation, and the experts' clinical evaluation of the Service performance.

Until the Commission makes a decision, each study is routed to the Service individually upon a request from a radiologist.

8.9. During the trial operation phase, the studies are routed to the Services from DDs based on the following:

- the results of a quarterly survey of radiologists concerning the preferred Services for each imaging modality;

- the use of the Services by medical facilities through their user account on the official website of the Experiment: mosmed.ai (a priority factor);

- submission of an individual study to the Service at the request of a radiologist.

8.10. During the trial operation phase in the quarter I of 2022, the routing of studies to the Services is carried out in accordance with the rules outlined in Appendix 7 to this Procedure; during the quarters II-IV of 2022 the routing shall be guided by the rules outlined in Appendix 8 to this Procedure.

8.11. Services that have passed to the trial operation stage may be involved by the Center for Diagnostics and Telemedicine to participate in the information technological, scientific and practical and other forms of interaction and collaboration within the Experiment on the terms and conditions established by the agreements on such interactions and collaboration. (Clause 8.11 was introduced by the Order of the Moscow Healthcare Department N 748 of July 29, 2022)

9. Control and Technical Testing

9.1. For the first participated Service that successfully completed the integration into the IHSC URIS UMIAS, CTT is performed. For the remaining Services, CTT is carried out upon the participant's request or, if necessary, when updates to the Service require functionality assessment. CTT evaluates a performance of the declared functionality (similar to FT), as well as the absence of technological defects.

9.2. CTT is carried out in IHSC URIS UMIAS. Within 5 calendar days, studies from DD to

the Service are automated sent. Once this period is over, the routing is suspended.

9.3. Within three business days, the Center for Diagnostics and Telemedicine evaluates the testing results. The entire scope of studies is reviewed for the defects pertaining to the “a”-“c” categories in accordance with clause 10.4 of this Procedure. Where necessary, selected studies may be reviewed for the defects pertaining to the “d”-“g” categories in accordance with clause 10.4 hereof. Based on the testing outcomes, for further routing of studies to the Service, the DDs are selected, from which at least 95% of the studies directed to the Service were successfully analyzed in accordance with clause 10.4.

9.4. For the first participated Service that successfully completed the integration into the IHSC URIS UMIAS, the acceptance testing is started after the evaluation of CTT results by the Center for Diagnostics and Telemedicine.

9.5. The CTT Report is drawn up in accordance with Appendix 5 to this Procedure.

10. Monitoring of Technological Parameters of Service Operation

10.1. During the acceptance testing and trial operation phases, the Center for Diagnostics and Telemedicine monitors the technological parameters and conducts a clinical evaluation of the Service operation.

10.2. Monitoring and clinical evaluation of the Service operation is carried out by a retrospective verification of the studies analyzed by the Service in accordance with the data received from URIS UMIAS. Based on the results, a monitoring report shall be drawn up (Appendix 6 to this Procedure).

10.2.1. Monitoring of the technological parameters of the Service operation within the framework of information technological, scientific and practical and other forms of interaction and collaboration within the Experiment is carried out based on the data of the software product of the Center for Diagnostics and Telemedicine – "HUB Telemed" (hereinafter referred to as "HUB Telemed"). Following the results, decisions are made based on the criteria established by the agreements on such interactions and collaboration.

10.3. Monitoring shall be carried out for all studies analyzed by the Service over the reporting period for the following categories of defects:

"a": the time taken for the study analysis exceeds 6.5 minutes;

"b": the absence of results of the analyzed studies uploaded to IHSC URIS UMIAS according to the URIS UMIAS data.

At least 80 studies processed over the reporting period will be sampled to assess a presence of defects by the following categories:

Technological:

"c": incorrect operation of the Service declared functionality, which complicates a radiologist’s work or makes it impossible to maintain the appropriate quality; divided into subcategories:

c1 - no additional series;

c2 - no DICOM SR;

c3 - 2 or more DICOM SRs;

c4 - Service name is not indicated;

c5 – no information about the Service version;

"d" - defects related to a display of the image area:

d1 - images in the additional series are cropped;

d2 - brightness/contrast of the additional series does not match the original image;

d3 - not all the images are analyzed;

d4 - no warning label “for research purpose only”;

d5 - changes in the original series;

"e": other violations of integrity and content of files containing the study results, limiting their diagnostic interpretation, including:

e1 - labelling is outside the target organ;

e2 - an incorrect anatomical region, projection or series was analyzed.

Clinical:

"f": defects associated with the clinical evaluation of the Service, such as a false positive result, a false negative result or the Service’s incorrect performance from a clinical point of view when labelling the study and providing a report.

10.3.1. Clinical evaluation is generated by assessing the localization of findings (labelling) and providing a report (conclusion) for each study from the sample. The clinical evaluation of the Service's performance is the arithmetic mean of the labelling and conclusion assessments. The labelling and conclusion score is the arithmetic mean of all scores in the sample, expressed as a percentage, according to the criteria listed in the Table of Clinical Evaluation Criteria and Indicators.

TABLE
OF CLINICAL EVALUATION CRITERIA AND INDICATORS

Evaluation criteria	Report	Scores	
		labelling	conclusion
Full compliance	All target findings are labelled or "norm"	1	1
Incorrect evaluation (partial/excessive)	At least 1 finding of the target pathology was noted (or not on all images/projections). Inaccurate contouring of findings. Incorrect estimation of the volume/number of findings.	0,5	0,5

False positive	False/superfluous finding. The finding was noted in the actual complete absence of the target pathology.	0,25	0,25
False negative	Omission of the findings. Not a single finding of the target pathology was noted, when they are actually present.	0	0

The Center for Diagnostics and Telemedicine determines the threshold values for indicators of the clinical evaluation of the Service operation for each direction of the Experiment. Acceptable indicators of the clinical evaluation of the Service operation:

- for chest computed tomography and/or low-dose computed tomography to diagnose malignant neoplasms of the lungs – at least 51%;

- for chest computed tomography to diagnose the lung involvement in COVID-19 – at least 52%;

- for chest computed tomography and/or low-dose computed tomography to diagnose compression fractures of the vertebral bodies, ischemic heart disease (coronary calcium, paracardial fat), emphysema, thoracic aortic aneurysms with a measurement of the thoracic aorta diameter, dilation of the pulmonary trunk with a measurement of the pulmonary trunk diameter, free fluid (effusion) in the pleural cavities, enlarged lymph nodes (lymphadenopathy), pulmonary tuberculosis, sarcoidosis and bronchiectasis – at least 76%;

- for computed tomography of the brain to detect ischemic stroke and intracranial hemorrhage – at least 50%;

- for computed tomography of the abdomen to detect urolithiasis, adrenal lesions, liver lesions, kidney lesions, compression fractures of the vertebral bodies, aneurysm of the abdominal aorta with a measurement of the abdominal aorta diameter – at least 50%;

- for magnetic resonance imaging of the brain to detect intracranial neoplasms and multiple sclerosis – at least 50%;

- for magnetic resonance imaging of the lumbosacral spine to detect spinal stenosis, protrusions and herniations of the intervertebral discs – at least 50%;

- for mammography to diagnose breast cancer – at least 70%;

- for chest X-ray to detect various lung pathologies – at least 50%;

- for chest photofluorography to detect various lung pathologies – at least 50%;

- for head X-ray to diagnose sinusitis – at least 50%;

- for X-ray of the musculoskeletal system to detect osteochondrosis, scoliosis, spondylolisthesis, fracture of the vertebral bodies, bone fractures of the upper and lower extremities (wrist, shoulder, hip and ankle joints), arthrosis (hip, knee), longitudinal flat feet – at least 50%;

- for a comprehensive chest computed tomography to detect various pathologies – at least 55%.

10.3.2. A sample of at least 80 studies for the reporting period is formed if there are 80 or more studies without "a" and "b" type defects over the reporting period. Otherwise, only studies with the “a” and “b” defects are monitored.

10.4. Defects of “f” category are not included into the total number of technological defects when calculating the number of studies analyzed over the reporting period (clause 10.7).

10.5. If, upon receiving a study, the Service determines that its processing is impossible, the Service sends a corresponding error notification. The types of errors are described in the baseline functional requirements for the Service results, published on the website: mosmed.ai. These studies are considered unanalyzed.

10.5.1. If the error is not caused by a failure in the Service operations and (or) the participant’s infrastructure, these studies are not included in the number of studies with defects.

10.5.2. If the error is caused by a failure in the Service operations and (or) the participant’s infrastructure, these studies are considered defective; a proportion of defects is estimated relative to the total number of studies sent to the Service over the reporting period.

10.6. The monitoring is performed on a monthly basis until a completion of the Service's participation in the Experiment. A reporting period of the monitoring lasts a calendar month. An interim monitoring report on the defects of "a” and "b” categories is produced on the 10th and 20th day of each month and forwarded to the Participant.

As an exception, the Center for Diagnostics and Telemedicin of the Moscow Healthcare Department may change the reporting period due to changes in the organizational and technological conditions of the Experiment.

10.7. The studies are considered analyzed for the reporting period if they have no defects of “a”-“f” categories as described in clause 10.4 hereof and for which no error notifications were sent in accordance with clause 10.5 hereof.

10.8. Based on the monthly monitoring results, a report of the Center for Diagnostics and Telemedicin indicates one of the following conclusions:

- participation in the Experiment continues;

- the Experiment's participant should make changes into the Service operation;

- participation in the Experiment is suspended until the improvements to the Service has been made.

10.9. Participation in the Experiment continues if all of the following conditions are met:

- all studies analyzed over the reporting period contain less than 10% defects of “a” and “b” categories;

- less than 10% of studies from the sample contain defects of “c”-“e” categories;

- a clinical evaluation indicator meets the requirements of clause 10.3.1 hereof.

10.10. The Service operation should be improved if at least one of the following conditions is met:

- all studies analyzed over the reporting period contain more than 10% defects of “a” and “b” categories;

- more than 10% of studies from the sample contain defects of “c”-“e” categories;

- a clinical evaluation indicator does not exceed the threshold value for this direction of the Experiment.

10.11. Participation in the Experiment is suspended if at least one of the following conditions is met:

- all studies analyzed over the reporting period repeatedly contain more than 10% defects of “a” and “b” categories in comparison with monitoring results for the previous reporting period;

- all studies from the sample repeatedly contain more than 10% defects of “c”-“e” categories in comparison with monitoring results for the previous reporting period;

- a clinical evaluation indicator repeatedly does not exceed the threshold value for this imaging modality of the Experiment in comparison with monitoring results for the previous reporting period.

10.11.1. Participation of the Service is suspended until changes in the Service operation are made in order to eliminate the causes of defects.

10.11.2. When making a decision to suspend the Service's participation in the Experiment, the Center for Diagnostics and Telemedicin is guided by the following: monitoring reports for the current and previous (if any) reporting periods, a confirmation of a number of studies with defects (if any) by the URIS UMIAS operator, and a participant's response to the inquiry regarding the causes of defects (if any).

10.11.3. During the trial operation, when the Service is suspended, the studies routed to it are evenly redistributed among other participants within the same imaging modality of the Experiment.

10.11.4. After eliminating the causes of defects, the participation of the Service may be resumed based on the outcome of consideration of the request for changing the Service status in accordance with clause 12 hereof.

10.12. The Participant has the right to apply to the Center for Diagnostics and Telemedicine for an explanation of the decision made, as specified in clause 10.8 hereof.

11. Comprehensive Service

11.1. The provisions of this section determine a procedure for participation of the CS on the chest computed tomography in the Experiment. The participation procedure for chest X-ray for diagnosing various pathologies and chest photofluorography for identifying various lung pathologies shall comply with the provisions of sections 4 - 10 hereof.

11.2. The list of target pathologies (mandatory and optional) for the CS is specified in the application for participation in the Experiment (Appendix 1 hereto). The requirements to the Service results for each target pathology in the CS are aligned with the baseline diagnostic

requirements for Services results as published on the website: mosmed.ai

11.3. A participant may represent only one CS for each imaging modality of the Experiment. The Services analyzing studies for either imaging modality of the Experiment and included in the CS are excluded from any other routing except for automatic routing to the CS.

11.4. The application procedure for participation of the CS in the Experiment corresponds to the procedure specified in clause 4 hereof. Only the CS, capable of identifying at least 7 mandatory target pathologies, is allowed to participate.

11.5. Functional testing (FT) of the CS operation is performed in accordance with the FT procedure described in clause 6 hereof.

11.6. CT of the CS operations is performed separately for each target pathology identified by the CS in accordance with the procedure described in clause 7 hereof. At the same time, a unified protocol is drawn up with a breakdown of the conclusion for each target pathology, based on the CT results in accordance with clause 7.1.6.

11.7. The CS is transferred to the IHSC with satisfactory test results for all mandatory pathologies.

11.8. A list of the analyzed pathologies for the Service operation in the IHSC may be expanded after considering an application for changing the Service sent by a participant to the Center for Diagnostics and Telemedicine. A procedure for submitting and considering the application for changing the Service corresponds to clause 12 hereof.

11.9. CTT for the CS is performed if the CS is presented by a participant whose Services have not previously operated in IHSC URIS UMIAS. CTT is carried out in accordance with clauses 9.2 - 9.3.

11.10. The procedure for processing diagnostic studies in the IHSC URIS UMIAS for CS complies with the provisions of clauses 8.2 - 8.9 hereof.

11.10.1. At the trial operation phase, routing of studies to the CS is carried out in accordance with the routing rules in Appendix 8 hereto.

11.11. The technological parameters of the CS operation are monitored in accordance with clause 10 hereof. At the same time, the clinical defects of "f" category are assessed separately for each target pathology detected by the CS.

12. Changes in the Service

12.1. If any changes to the Service are required, the Experiment participant submits a formal request to the Center for Diagnostics and Telemedicine indicating any modifications or information about the version changes and their consequences (Appendix 9 hereto), however, not more than once every 1.5 months. When making changes affecting the quantitative characteristics, parameters should be specified in the numerical form before and after the changes, where:

- modifications are any operational changes in the software and infoware of the Service that are mandatory for transferring to URIS UMIAS;

- version change is any changes in software and infoware that are mandatory for transferring to URIS UMIAS, allowing to perform the declared or additional functions, as well as ensuring a transition to new operating systems and information environment.

12.2. The current order is due to ensure openness of the practical application of the Service. Openness implies notifications on any changes (modifications, version changes) in the service of interested parties, including the Center for Diagnostics and Telemedicine. The Experiment Participant should ensure, that the application for changes to the Service fully and accurately describes the proposed modifications or version changes.

12.3. The Center for Diagnostics and Telemedicine reviews the application and replies allowing/not allowing to change the current version or make modifications to the Service and, if necessary, any required additional testing (with specification of one or more stages) as part of the Experiment to verify changes to the Service. The application will be reviewed within 10 (ten) business days. The review period may be extended if an incomplete request was submitted or any clarifications were required to determine suitable testings.

12.4. In case of additional testing for changing/modifying the version, a report with the results and a decision on the possibility/impossibility of making changes is generated.

13. Termination of Participation in the Experiment

13.1. A Participant may abandon the Experiment on their own initiative by emailing a notification to the Center for Diagnostics and Telemedicine.

13.2. A participation of the Service in the Experiment may be terminated by a decision of the Healthcare Department Commission if the Service does not re-apply for a participation in the Experiment within 6 months from the date of suspension of the participation, or if a report on unsatisfactory test results is sent to the applicant/participant, and there is no notification about the improvement timing from the participant/applicant, or a presence of a written refusal of the Service to do so.

14. Grants

14.1. A participant may apply for a grant to the Department no more than once a month from the date of transferring studies from connected DDs to the IHSC URIS UMIAS at the acceptance testing and trial operation stages, or to "HUB Telemed" as part of information technological, scientific and practical, and other forms of interaction and collaboration within the Experiment.

14.2. A number of analyzed studies is included in each monitoring report generated by the Center for Diagnostics and Telemedicine in accordance with clause 10 hereof. If a Participant of the Experiment is involved in information technological, scientific and practical, and other forms of interaction and collaboration within the Experiment, the successfully analyzed studies are summarized based on monitoring reports generated in accordance with the criteria established by agreements on such interactions and collaboration.

14.3. A number of analyzed studies to estimate a grant amount is approved by the Commission based on the monitoring reports of the Center for Diagnostics and Telemedicine.

14.4. A grant amount is determined as a product of analyzed studies by the estimated cost of the study analysis, established in Appendix 5 hereto.

15. Clinical and Technical Testing

15.1. A participant may request the Center for Diagnostics and Telemedicine to provide technical testing and clinical trials of the Service in order to register software as a medical device.

15.2. The terms and conditions for provision of the Service, the application form for technical testing and clinical trials, and a list of application documents are published on the website: www.mosmed.ai

16. Evaluation and Comparative Analysis of the Services

16.1. During the Experiment of the Center for Diagnostics and Telemedicine, the evaluation of quantitative and qualitative characteristics of each individual Service and a comparative analysis of all services are performed. The assessment is based on the data obtained during testing and monitoring the Service. The evaluation is carried out over a selected period of time in the form of dynamics of indicators.

16.2. The Experiment results are systematized and analyzed conclusively using data obtained over the calendar year no later than the 1st of April of the year following the reporting one.

16.3. The evaluation shall be carried out, inter alia, in accordance with Guidelines No. 43 "Clinical Acceptance of Software Based on Artificial Intelligence Technologies (Radiology)" (recommended by the Expert Council for Science of the Moscow Healthcare Department, Protocol No. 8 of June 25, 2019).

16.4. The main criteria for evaluation and comparative analysis of the Services:

- diagnostic accuracy;

- applicability;

- ease of use;

- operation efficiency (including the impact on labor productivity and rate of study analysis).

16.5. The criteria shall apply:

- to each Service individually;

- cumulatively to all Services analyzing studies of the certain imaging modality;

- cumulatively to all Services participating in the Experiment.

16.6. The results of evaluation and comparative analysis are issued by the Center for Diagnostics and Telemedicine of the Moscow Healthcare Department in the form of a final report for the calendar year.