Basic principles of the procedure 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 in 2021, approved by the Order No. 51 of the Moscow Healthcare Department dated January 26, 2021

3. The Experiment is carried out in order to investigate the possibility of using advanced innovative technologies for clinical decision support system based on the data analysis results in the Moscow healthcare.

4. The Experiment is a scientific and practical study with the assessment and comparative analysis of services in the categories listed below.
   4.1. Diagnostic accuracy (including that estimated on the identical sample of images for concurrently operating services).
   4.2. Practical applicability.
   4.3. Convenience of use.
   4.4. Work efficacy (including the impact on labor productivity, speed of image analysis).

5. The Experiment involves developers and representatives of software services based on computer vision technologies designed to analyze medical images of a certain type of radiological examination (hereinafter referred to as the Services).

6. Requirements for the Services:
   6.1. Availability of functions in accordance with the basic functional requirements approved by the Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow Healthcare Department (hereinafter referred to as the CDT) and published on the Experiment website www.mosmed.ai
   6.2. Compliance with the basic requirements for the operation results, approved by the CDT and published on the Experiment website www.mosmed.ai
   6.3. Compliance with the diagnostic accuracy indicators approved by the CDT and published on the Experiment website www.mosmed.ai
   6.4. Data obtained during a participation in the Experiment will be stored, analyzed and used only on the territory of the Russian Federation.

7. The Moscow Healthcare Department (hereinafter referred to as the Department) has exclusive rights to the data obtained during the Experiment and its results (including the rights to publications and reports in the mass media, scientific periodicals and at conferences, as well as for registration of intellectual property).

8. Participation in the Experiment is based on the application of a legal entity that developed and/or has the right to provide the Service to participate in 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 referred to as the Application).

9. The applicant for participation in the Experiment (hereinafter referred to as the Applicant) submits the Application in accordance with the form (see Annex 1) and required documents to the CDT at the following address: The Center for Diagnostics and Telemedicine, 24 Petrovka Street, office 240, Moscow, 127051, Russia. The Applicant also emails copies at: ai@npcmr.ru. The following documents should be attached to the Application:
   9.2. Documents confirming the development and/or the right to provide the
proposed computer vision-based Service for the analysis of medical images.

9.3. A report on preliminary clinical and technical tests in accordance with the Guidance 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) and a report on testing on medical images of citizens of the Russian Federation and/or persons of the Caucasian and Mongoloid races.

9.3.1. The report on preliminary clinical and technical trials should indicate:
- classic ROC - curve, area under the curve (AUC);
- indicators of sensitivity, specificity and accuracy;
- four-field table of comparing the results of the index and reference tests;
- duration of a study analysis.

9.3.2. The report on preliminary clinical and technical trials should be certified by a signature of the authorized person and a seal of the medical organization that prepared the report.

9.4. Documentation describing and confirming the availability of the Service functions corresponding to the basic functional requirements specified in the clause 6.1 of this Procedure, as well as describing the technical architecture and characteristics, provided scenarios for using the Service, and its hardware and software requirements.

9.5. A report on the clinical implementation and/or testing of the proposed Service in medical organizations of the Russian Federation or other countries, indicating the duration of its testing, as well as a number of medical institutions where the proposed Service was tested (if available).

9.6. Certified copies of the certificate of conformity of the Service quality proposed by the Applicant to FDA, CE standards and their regional analogues in other countries, or the state registration as a medical device (if available).

9.7. Copies of scientific articles on the assessment of accuracy and efficacy of the proposed Service in peer-reviewed journals indexed in Scopus and/or Web of Science (if available).

9.8. A valid certificate of conformity of a quality management system to the ISO standard (if available).

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

9.10. Other documents that the Applicant for participation in the Experiment considers necessary to submit.

11. Diagnostic studies enter into URIS UMIAS from connected diagnostic devices. The technical means of URIS UMIAS anonymize studies, send them to the Service for analysis, return studies to URIS UMIAS and de-anonymize the analysis results. A diagnostic study may contain a different number of images or cases of image slices, depending on the type of examination.

12. A technical integration of the Service is carried out in the URIS UMIAS testing hardware software complex (hereinafter referred to as THSC URIS UMIAS). The term of its implementation is no more than 14 working days from the moment of sending an informational e-mail to the Applicant to commence a procedure for the technical integration in URIS UMIAS. The integration period can be extended at the request of the Applicant for participation in the Experiment.

12.1. A technical integration is a technical configuration of the access to the URIS UMIAS system and verification of the correctness of data exchange between the Applicant's Service and URIS UMIAS. In the technical integration process, functional and
calibration testing of the Service is carried out. A description of the technical integration process is published on the Experiment website www.mosmed.ai

15. A technical integration of the Service is considered passed if the functional and calibration testing have been successfully completed.

15.1. Upon successful completion of the technical integration, the Service operation is transferred to the industrial hardware-software complex URIS UMIAS (hereinafter referred to as IHSC URIS UMIAS).

16. The Experiment is conducted on the types of studies listed below.

16.1. Chest computed tomography and/or low-dose computed tomography for the diagnosis of various diseases, including lung cancer (CT LC), coronavirus disease COVID-19 (CT COVID-19), spinal osteoporosis (CT SO), coronary artery disease (coronary calcium (CT CC), pericardial fat), emphysema.

16.2. Brain computed tomography for the diagnosis of various diseases, including strokes (CT B).

16.3. Brain magnetic resonance imaging to detect various diseases, including malignant neoplasms, multiple sclerosis, Alzheimer's disease (MRI B).

16.4. Magnetic resonance imaging of the lumbosacral spine to detect pathologies, including hernias, protrusions, stenosis (MRI LSS).

16.5. Mammography to diagnose breast cancer (MMG).

16.6. Lung X-ray and/or fluorography to detect various lung pathology (hereinafter referred to as X-r L/ FLG).

16.7. Musculoskeletal X-ray to detect various abnormalities, including arthrosis, flat feet, bone and vertebral fractures (X-r MS).

17. A total of 3 million studies can be analyzed in the Experiment. Studies before being sent to the Services for analysis must be anonymized.

18. After the integration into URIS UMIAS, a participant of the Experiment proceeds to the testing stage. A duration of this stage is no more than 3 (three) months for each Service. During the testing, each Participant receives a necessary amount of studies for analysis in order to evaluate the Service operation and possible transition to the trial operation stage. Studies are routed to the Service from diagnostic devices of medical facilities, that are testing sites. A testing result is the report generated by the CDT, that is sent to the Moscow Healthcare Department. The report indicates the compliance/non-compliance of the Service with the criteria of clause 31.2 of this Procedure.

19. After successful completion of the testing stage, a Participant proceeds to the trial operation stage. Studies are routed to the Service from diagnostic devices connected to the URIS UMIAS system. The volume of studies is distributed among the Services by their types. Routing is also possible upon request from medical facilities.

21. A standard time for analysis of a single study is the time from a publication of a notice of availability of the study for downloading and analysis by the Service in the Unified Notification System for External Interactions (hereinafter referred to as the UNSEI) until the Service publishes in the UNSEI a notice of availability of the study analysis results in URIS UMIAS. The standard time should not exceed 6.5 minutes.

22. At the stages of testing and trial operation, the CDT monitors the technological parameters of the Service operation (hereinafter referred to as monitoring). The first monitoring is conducted in ten working days after passing a technical testing and connecting a diagnostic device to the Service. Subsequent monitorings are carried out monthly until the end of the Service participation in the Experiment.
22.1. Monitoring during the Experiment is carried out by retrospective checking the studies analyzed by the Service in accordance with the data received from URIS UMIAS. The monitoring criteria are described in Table 4 of Annex 2 to this Procedure. Based on the results, a report on monitoring the technological parameters of the Service is issued (Annex 6 to this Procedure).

22.1.1 Monitoring is carried out for all studies analyzed by the Service for the reporting period for the categories of defects listed below.

a) The time spent on a study analysis exceeds 6.5 minutes. A time of a study analysis is the time from a publication of a notice of availability of the study for downloading and analysis by the Service in the UNSEI until the Service publishes in the UNSEI a notice of availability of the study analysis results in URIS UMIAS.

In case if the Service determines during downloading a study, that the duration of the study analysis will exceed 6.5 minutes, the Service does not start the analysis, but sends an error notification "ERROR A". These studies are considered unanalyzed and not included in the number of studies with defects, and they shall not be accounted.

b) The absence of results of the analyzed studies in the IHSC URIS UMIAS according to the URIS UMIAS data. In case if the Service determines during downloading a study, that the image contains a non-target anatomical region, or the image is distorted or not completely present, the Service does not start the analysis, but sends an error notification "ERROR B". These studies are considered unanalyzed and not included in the number of studies with defects, and they shall not be accounted.

At the same time, an assessment is made for a sample of at least 20 studies for the presence of technological defects given below.

c) Images contained in the Service operation results do not correspond to the original images of the study (distorted):
   c1 - images are cropped;
   c2 - brightness/contrast is changed;
   c3 - not all required images were analyzed.

d) Incorrect operation of the declared Service functionality making a radiologist’s work difficult or impossible to produce a proper quality result. This deficiency is divided into the following types:
   d1 - complete absence of the Service operation results;
   d2 - no additional series;
   d3 - no DICOM SR;
   d4 - presence of 2 or more DICOM SR;
   d5 - no Service name;
   d6 - no information about the Service version;
   d7 - no warning notice "For research/scientific purpose only";
   d8 - absence of labeling in the presence of pathology.

e) Other violations of the integrity and content of files containing study results that restrict their diagnostic interpretation, including:
   e1 - contradiction between DICOM SR information and the information in the additional series;
   e2 - labeling outside the target organ;
   e3 - incorrect anatomical region, projection or series is analyzed.

f) Modification of the original study series.

22.2. The studies considered to be analyzed for the reporting period are those that do not reveal the defects listed in clause 22.1.1 of this Procedure.
22.3. Based on the results of monitoring the technological parameters of the Service operation, the CDT indicates one of the decisions in its report:
- participation in the Experiment continues;
- a participant of the Experiment needs to make changes in the Service operation;
- participation of the Service in the Experiment is suspended until changes in the Service operation are made;
- participation of the Service in the Experiment is terminated.

25. A Participant in the Experiment may apply for a grant to the Moscow Healthcare Department no more than once a month, starting from the date of transferring studies from connected diagnostic devices to the IHSC URIS UMIAS at the stages of testing and trial operation.

28. A grant amount is determined as the product of a number of analyzed studies and a price for the study’s type established by the Regulation No.1543-PP of the Moscow Government of November 21, 2019 "On conducting an Experiment on the use of innovative computer vision technologies for the analysis of medical images and further application in the Moscow healthcare system".