

## **2. Grant application submission procedure**

2.1. To receive a grant, legal entities shall submit a grant application (hereinafter, the application) to the Department. The following documents shall be attached to the application:

2.1.1. Certified copies of the legal entity's statutory documents.

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

2.1.3. Certified copies of the state certification as a medical device (if available).

2.1.4. Certified copies of certificates of quality compliance of the service proposed by the participant to local standards of FDA, CE, and their equivalents in other countries (if available).

2.1.5. Copies of scientific articles on evaluating the accuracy and efficacy of the proposed service (if available).

2.1.6. Originals or copies of reports on clinical implementation or application of the proposed service in medical centers of the Russian Federation or other countries (if available).

2.1.7. Documents confirming the right to provide the proposed service based on computer vision for the analysis of medical images as well as describing the functions, technical architecture and characteristics, intended use scenarios of the service, and its hardware and software requirements.

2.1.8. Report on preliminary clinical and technical tests performed 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 Health Care Department, Protocol No. 8 of June 25, 2019).

2.1.9. Other documents that the applicant considers necessary to provide in order to receive the grant.

2.2. The Department shall appoint a Commission to review applications and select legal entities applying for the grant and to make decisions on grant allocation.

2.3. The composition and rules of procedure of the Commission shall be established by the Department.

2.4. Requirements for the form and content of applications and deadlines for their submission shall be established by the Department and posted on its official website on the Internet.

2.5. Submitted applications with the attached documents shall be registered by the Department.

2.6. Applications of medical centers shall be sent to the Commission no later than 10 calendar days from the date of application registration by the Department.

## **3. Application review and grant allocation procedure**

3.1. Each application shall be reviewed by the Commission. Commission meetings are held as applications are received.

3.2. The deadline for application review by the Commission must not exceed 10 calendar days from the date of receipt of the application by the Commission.

3.3. The Commission makes a decision on grant allocation based on the following criteria:

3.3.1. The applying legal entity has documents confirming its right to provide the proposed service based on computer vision for the analysis of medical images.

3.3.2. The applying legal entity has certified copies of certificates of quality compliance of the service proposed by the participant to local standards of FDA, CE, and their equivalents in other countries or state registration as a medical device.

3.3.3. The applying legal entity has copies of scientific articles on evaluating the accuracy and efficacy of the proposed service published in peer-reviewed journals indexed in Scopus and/or Web of Science.

3.3.4. The applying legal entity has originals or copies of reports on clinical implementation or acceptance of the proposed service in medical centers of the Russian Federation or other countries.

3.3.5. Duration of acceptance testing of the proposed service in medical centers of the Russian Federation or other countries.

3.3.6. The number of medical centers where the acceptance testing of the proposed service was carried out.

3.3.7. Quality and completeness of the provided documentation describing the functions, technical architecture and characteristics, intended use scenarios of the service, and its hardware and software requirements.

3.3.8. The proposed service has passed preliminary clinical and technical tests performed 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 Health Care Department, Protocol No. 8 of June 25, 2019) with a test report issued.

3.3.9. Availability and quality of implementation in the proposed service of the functionality of an automated analysis of medical images, indicating localization of pathological findings detected by the service and providing notification of the results.

3.3.10. Availability and quality of implementation in the proposed service of the possibility to form a DICOM series as a result of analysis, which contains information on the presence or absence of pathologies and analysis results visualizing the findings on the original images.

3.3.11. Support of the HealthLevel7 (HL7)/FHIR standard by the proposed service.

3.3.12. Availability and quality of implementation in the proposed service of the possibility to automatically provide information to prioritize studies in the radiologist worklist.

3.3.13. Availability and quality of implementation in the proposed service of the functionality of comparative analysis of studies of one patient performed at different times (evaluating the dynamics of pathological processes).

3.3.14. Availability and quality of implementation in the proposed service of the functionality of automated preparation of the draft radiology report.

3.3.15. The time required to analyze one study using the proposed service.

3.3.16. Availability of the results of testing the diagnostic accuracy of the proposed service on depersonalized medical images of citizens of the Russian Federation and/or European and Asian subjects.

3.3.17. Diagnostic accuracy metrics of the proposed service, including:

3.3.17.1. Classic ROC curve, area under the curve (AUC).

3.3.17.2. False-negative rate.

3.3.17.3. False-positive rate.

3.3.17.4. Other diagnostic accuracy parameters as per Guidelines No. 43 “Clinical Acceptance of Software Based on Artificial Intelligence Technologies (Radiology)” (recommended by the Expert Council for Science of the Moscow Health Care Department, Protocol No. 8 of June 25, 2019).

3.4. The Commission shall form a consolidated list of grant applicants and conclusions based on application review results to be executed as per the procedure established by the Moscow Health Care Department.

3.5. Based on the conclusions made by the Commission upon application review, the Department shall make a decision on grant allocation, confirm the grant recipient status and the

amounts of grants provided by adopting a legal act, and publish the corresponding information on the official website of the Department on the Internet.

3.6. Grants shall be provided by the Department based on a grant contract (agreement) concluded between the grant recipient and the Department, which regulates the procedure and deadlines for the grant transfer.

3.7. The grant contract (agreement) template shall be approved by the Department.

3.8. No later than 15 working days from the date of the Department's decision specified in paragraph 3.5 hereof, the Department shall send the grant recipient a draft grant contract (agreement) and compile data on the grant contract (agreement) in the Automated City Financial Management System of Moscow (hereinafter, the ACFMS).

3.9. The grant recipient shall submit the grant contract (agreement) signed by the grant recipient to the Department no later than 5 working days from the date of receipt of the draft grant contract (agreement).

3.10. No later than 7 working days from the date of signing the grant contract (agreement) by the parties, the Department shall submit via ACFMS to the Moscow Finance Department data on the grant contract (agreement) signed with an enhanced qualified electronic signature, enclosing an electronic image of the grant contract (agreement).

3.11. As per legislation of the Russian Federation, the grant recipient shall be responsible for the inaccuracy of data provided to the Department and state financial control authorities.

3.12. The Department shall monitor the grant recipient's compliance with the goals, conditions, and grant allocation procedure set out in the grant contract (agreement).

#### **4. Grant amount calculation procedure**

4.1. The grant is provided in parts based on the results of reporting periods to be established by the Department and posted on its official website on the Internet no later than the publication date of the requirements for the form and contents of grant applications.

4.2. The procedure and deadlines for the grant transfer shall be set out in the grant contract (agreement).

4.3. The grant amount for the reporting period is determined as the product of the number of medical images analyzed by the service provided by the grant recipient by the cost of analyzing each study depending on its type according to the Annex hereto.