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the Chief Regional Radiology and Instrumental Diagnostics Officer of the Moscow Health Care Department

_____ S.P. Morozov

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REGULATIONS ON DATASET PREPARATION AND APPROACHES TO REPRESENTATIVE DATA SAMPLING

Part 1

Guidelines No. 1

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Authors:
Prof. **S.P. Morozov**, MD, PhD, MPH, Chief Officer of Regional Radiology and Instrumental Diagnostics of the Moscow Healthcare Department and the Chief Freelance Specialist-Radiologist for the Central Federal District of the Russian Federation CEO, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Health Care Department
A.V. Vladzymirskiy, MD, PhD, Chief Research Officer, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
A.E. Andreychenko, PhD, Head of the Department of Medical Informatics, Radiomics, and Radiogenomics, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
E.S. Akhmad, Junior Researcher, Standardization and Quality Assurance Sector, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
I.A. Blokhin, Junior Researcher, Radiology Research Sector, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
V.A. Gombolevsky, MD, PhD, Managing Director of Key Research Programs, Artificial Intelligence Research Institute
V.V. Zinchenko, Head of Clinical and Technical Testing Sector, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
N.S. Kulberg, PhD, Head of the Department of Medical Imaging Tools Development, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
V.P. Novik, Researcher, Department of Medical Imaging Tools Development, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department
N.A. Pavlov, Project Leader, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies, Moscow Healthcare Department

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Reviewers:
E.I. Kremneva, PhD, Senior Researcher, Radiology Department, Research Center of Neurology
A.V. Mishchenko, MD, PhD, Deputy Chief Medical Officer, City Clinical Oncological Hospital No. 1, Moscow Health Care Department

This guidance document provides recommendations to all healthcare professionals who curate and perform labeling of medical datasets.

The guideline was developed as part of the research project "Scientific substantiation for the application methodology and methods of quality assessment of intelligent technologies (artificial intelligence) in diagnostics".

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CONTENTS

REGULATORY REFERENCES

1. GOST ISO 13485-2017 "Quality management systems. Requirements for regulatory purposes".

2. Regulation of the Moscow Government No. 1543-PP of November 21, 2019 "On conducting the Experiment on the application of innovative computer vision technologies for the analysis of medical images and further use in the Moscow healthcare system".

3. Order of the Moscow Healthcare Department No. 51 of January 26, 2021 "On approval of the Procedure and conditions to conduct the Experiment on the application of innovative computer vision technologies for the analysis of medical images and further use in the Moscow healthcare system" (as revised on April 30, 2021 under No. 413, as revised on June 23, 2021 under No. 588).

4. Order of the Federal Service for Supervision in the Sphere of Telecom, Information Technologies, and Mass Communications (Roskomnadzor) of Moscow No. 996 of September 5, 2013 "On approval of requirements and methods for personal data anonymization".

5. Decree of the President of the Russian Federation No. 490 of October 10, 2019 "On the development of artificial intelligence in the Russian Federation".

6. Federal Law No. 323-FZ of November 21, 2011 "On the Basics of Health Protection of the Citizens in the Russian Federation".

7. Federal Law No. 152-FZ of July 27, 2006 "On Personal Data".

GLOSSARY

The document contains the following terms and correspondent definitions:

1. **Anonymization** (de-identification) refers to removing the connection between identifiable data and the data subject. For this purpose, all attributes are deleted from the record or irreversibly altered in such a way that the data subject can no longer be identified (irreversible de-identification).
2. **Life cycle** refers to the evolution of a system, product, service, project, or other man-made entity from conception through retirement.
3. **AI service** refers to special software based on artificial intelligence (computer vision) algorithms that solves specific medical diagnostic tasks in diagnostic radiology.
4. **Artificial intelligence (AI)** is a set of technological solutions simulating human cognitive functions (including self-learning and finding solutions without a predetermined algorithm) and obtaining results of performed specific tasks that are at least comparable to the results of human intellectual activity. The complex of technological solutions includes information and communication infrastructure, software (including those that use machine learning methods), data processing and data solutions services.
5. **Metadata** refers to information about a dataset, that is means for classifying, sorting, and describing data.
6. **Dataset** refers to an ordered collection of data and corresponding metadata organized according to the certain rules.
7. **Reverse process**, i.e. de-anonymization (reverse personification), refers to the processing of data in such a way that anonymous data can be attributed to a specific data subject, as a result of which anonymous data becomes personal data.
8. **Pseudonymization** refers to a particular type of anonymization that removes a direct association with a data subject and creates an association between a particular set of characteristics relating to the data subject and one or more pseudonyms.
9. **Data labeling (annotation)** refers to the process of assigning data type identifiers to structured and unstructured data (such as text, images, and videos), i.e., data classification, and/or data interpretation in order to solve a specific task, including by using artificial intelligence technology.

ABBREVIATIONS

The document contains the following abbreviations:

1. **DICOM** – Digital Imaging and Communications in Medicine
2. **URIS UMIAS** – Unified Radiological Information Service of the Unified Medical Information and Analytical System of Moscow
3. **AI** – Artificial Intelligence
4. **FDA** – Food and Drug Administration
5. **GDPR** – General Data Protection Regulation
6. **EHR** – Electronic Health Record
7. **HIS** – Health Information System
8. **QMS** – Quality Management System

INTRODUCTION

The purpose of these guidelines is to describe the main stages of medical dataset creation for machine learning, indicating the required staff resources, tools, and infrastructure.

The guidelines incorporate a practical experience and expertise acquired by the Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow Healthcare Department (hereinafter, Center for Diagnostics and Telemedicine) in creating medical datasets for testing, validation, and training of intelligent systems in healthcare, including as part of the Experiment on the application of innovative computer vision technologies for the analysis of medical images and further use in the Moscow healthcare system (Regulation of the Moscow Government No. 1543-PP of November 21, 2019; Order of the Moscow Healthcare Department No. 51 of January 26, 2021 (as revised on April 30, 2021 under No. 413, as revised on June 23, 2021 under No. 588)). The guidelines also provide an analytical summary of the world's best practices in the planning, creation, and management of medical imaging datasets for artificial intelligence and machine learning. The guidelines reflect all aspects of health data management to ensure that created datasets are fit-for-purpose and meet the requirements of interested persons. These include technical, medical, and regulatory (standards) aspects of preparation and application of datasets for artificial intelligence-based software (hereinafter, the AI services) in healthcare. These guidelines present a general-purpose approach that can be used in any field of healthcare where AI is applicable.

PURPOSE AND RELEVANCE OF GUIDELINES

The diagnosis, treatment, and prevention of diseases based on intelligent analysis of medical big data is one of the promising areas in today's healthcare. For this purpose and to standardize and improve the accuracy of medical interpretation and diagnosis, artificial intelligence-based algorithms and services are being developed. However, the advancement in this field is highly dependent on the availability of high-quality structured datasets collected from medical big data.

The amount of primary digital (machine-readable) electronic health records grows annually and includes both clinical data (results of the examination) and laboratory and instrumental findings, including diagnostic imaging tests (magnetic resonance imaging, computed tomography, radiography, mammography, fluorography, etc.) and bio-signal methods (electrocardiography, electroencephalography, electroneuromyography, etc.).

A key limitation for straightforward use of collected data for a successful development of artificial intelligence (hereinafter, AI) is the fact that electronic health records are compiled during routine medical practice and are not originally indented for data harvesting and machine processing, which leads to unstructured data and different data presentation formats. Although artificial intelligence in healthcare is rapidly developing, the process of health data collection and combining it into a single structure with a set of predefined parameters enabling further manipulations and calculations has not yet been regulated.

Some challenges inherent to artificial intelligence in healthcare are listed below.

1. Abundance of patient data, in particular diagnostic imaging data, resulting in the need to regulate the process of data collection to create datasets for machine learning.
2. Emergence of unregistered medical cases that require a prompt response and creation of new datasets to be investigated by doctors and researchers (the recent example is a detection of the novel coronavirus disease 2019 (COVID-19)).
3. Rapid creation and advancement of machine-learning algorithms that require reference datasets for their validation.
4. Reference datasets should have the structure and parameters that enable machine learning applications. Moreover, they should be fit-for-purpose of both computer science and medical perspectives. This requires interdisciplinary professionals qualified to collect and prepare requested data.

The purpose of these guidelines is a systematic review of the global practical experience and expertise acquired by the Center for Diagnostics and Telemedicine in the preparation of medical datasets for the development and validation of AI in healthcare. The guidelines will be structured in two parts: Part 1 (this document)

comprises methodological issues of medical dataset preparation; Part 2 describes technical details of dataset creation.

Concept of datasets and labeling

A dataset is a logically structured set of information suitable for machine processing by computer methods of data analysis, which is characterized by four main stages:

1) content (observations, parameter values, records, files, etc.);
2) purpose (e.g., knowledge base, particular application);
3) grouping (aggregation and organization of contents into sets, collections, etc.);
4) cohesion (relation to the subject, integration, logical collection of the content, etc.).

Data labeling (annotation) refers to the process of adding data type identifiers to structured and unstructured data (such as text, images, and videos), i.e., data classification and/or data interpretation in order to solve a specific task, including by using artificial intelligence systems.

Goals of dataset creation

Datasets intended for one domain or solving the same clinical/practical task may vary depending on the ultimate goal of their application. The proposed dataset classification is as follows:

1) self-testing for technical compliance of AI service;
2) testing AI service on local data for validation and calibration;
3) transfer learning to retrain an existing AI model;
4) machine learning for training new models and solving new clinical tasks.

Concept of dataset lifecycle

The dataset lifecycle model is shown in Figure 1. It provides an overview of the main phases of dataset planning, creation, modification, and use. It was adapted from the CRISP-DM model [1] for data mining.

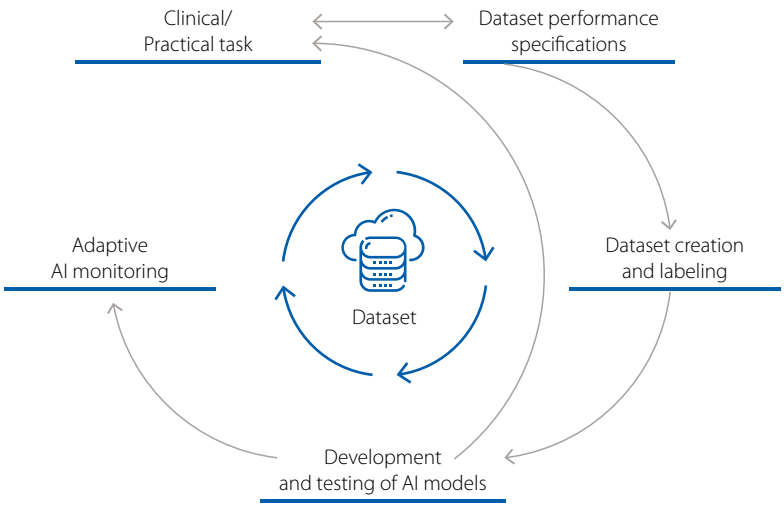

Figure 1 – Dataset lifecycle for artificial intelligence systems in healthcare

While preparing a dataset, the following should be kept in mind: changing the access level to third-parties, update frequency, support period, and a method of destroying (destruction).

Some categories of datasets are subject to regular updates. This may concern both supporting information (e.g., for verification purposes when follow-up studies become available) and dataset units (e.g., when adding new cases in a specific epidemiological context). In these cases, the principles of obtaining new data and making changes, including the version number, can be described separately.

The dataset can be programmed to change the data access level from closed/restricted to open after a certain while (e.g., one calendar year from the date of publication).

On the contrary, a dataset can have its expiration date, after which it should be either removed from access (from open to restricted/closed access or from restricted to closed access) or archived for long-term storage without a possibility to quickly restore it.

A complete deletion of the dataset is discouraged as, in the future, it may be necessary to restore the source of missing studies.

Concepts of a dataset unit and verified dataset

A dataset unit refers to a paired record of inputs and outputs expected from the AI system after processing and analyzing the inputs (Figure 2). The expected outputs

are generated during labeling; i.e., as a result of labeling, reference (or "correct") responses are obtained, which will then be used to evaluate the responses from the AI system for its further development, testing and/or post- registration monitoring.

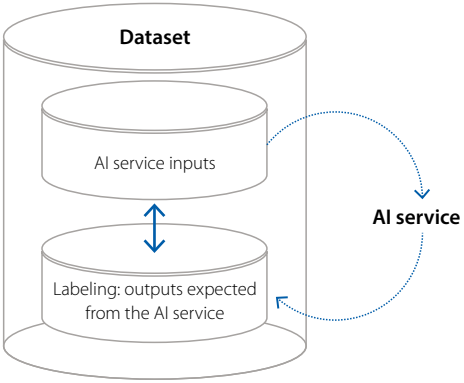

Figure 2 – Dataset sample (the dataset contains paired, unambiguously matching input data and labeling)

Verification of dataset labeling refers to the audit of dataset labeling results using more accurate diagnostic techniques and methods, such as alternative diagnostic tests, clinical diagnosis confirmation (e.g., biopsy or specific laboratory tests), clinical follow-up results and diagnosis, etc. The verification method is determined when planning a dataset and depends on the task solved by the AI service for which this dataset is applicable.

1. HEALTH DATA TYPES AND SOURCES

Health data is broadly defined as any data related to the health status and quality of life of an individual or population. Health data includes clinical metrics along with environmental, socioeconomic, and behavioral information pertinent to health and wellness.

1.1. Health data sources

A lot of health data is collected and used when people interact with health services. Usually, this data is gathered by healthcare providers and includes records related to the services provided, conditions for their provision, and clinical outcomes.

1.2. Health information classification

The types of medical information are summarized in Table 1 [2].

Table 1 – Common types of health data

Data types	Format description	Main features (challenges of use)
Medical records	Data from printed and handwritten texts	Unstructured paper records
Electronic health record	Health information system for the collection, storage, and display of patient information	Unstructured text
Laboratory data	Software and databases used to manage and store laboratory results and pathology data – in quantitative, qualitative, and graphical form	Lack of standardization in data collection, analysis, and storage, and data access control
Medical images	Medical images are obtained for diagnosis, health status, and treatment planning. The most common modalities include PET, CT, CBCT, MRI, and ultrasonography. Medical imaging is regulated by the generally accepted DICOM standard	Inadequate compliance with standards for data collection and analysis; data duplication within a single medical facility; data availability
Genomic data	Individual datasets with large-scale genomic data	Incomplete data; data availability
Auxiliary data	Income, social status, race, ethnicity, education, housing	Unstructured and incomplete data; data availability

Laboratory data: most of the data can be presented in the form of numerical values or categorical estimate. In addition, there is a separate group of pathomorphological tests, which include:

1) electron microscopy;
2) whole mount staining;
3) permanent mount technique;
4) temporary mount technique;
5) tissue culture technique;
6) autoradiography.

Such examinations can also be presented as images in various formats. When preparing a dataset, it is necessary to choose one image format and one format of supporting documentation.

Medical images are the images of internal structures of the human body intended for clinical analysis and medical interventions as well as for visual representation of the functions of certain organs or tissues, which are obtained noninvasively by special devices and sensors. Medical images of the following common modalities are stored in the DICOM format:

EPS – Cardiac Electrophysiology;
CR – Computed Radiography;
CT – Computed Tomography;
DX – Digital Radiography;
ECG – Electrocardiography;
ES – Endoscopy;
XC – External-camera Photography;
IVUS – Intravascular Ultrasound;
MR – Magnetic Resonance;
MG – Mammography;
NM – Nuclear Medicine;
OP – Ophthalmic Photography;
PX – Panoramic X-Ray;
PT – Positron emission tomography;
RF – Radiofluoroscopy;
RG – Radiographic imaging;
US – Ultrasound;
XA – X-Ray Angiography;
BI – Biomagnetic Imaging;
CD – Color flow Doppler;
ST – Single-Photon Emission Computed Tomography (SPECT);
TG – Thermography;
AU – Audio;

SR – SR Document;
SMR – Stereometric Relationship;
SC – Secondary Capture;
OT – Other.

Normally, medical images are stored in the DICOM format; which, however, does not always allow storing the full amount of diagnostic data (e.g., for spectral images).

After image processing, the data can be converted to other storage formats, such as Neuroimaging Informatics Technology Initiativea (NIFTI), various graphic formats (jpg, png), and others.

2. APPROACHES TO CHOOSING AN OPTION FOR USING ARTIFICIAL INTELLIGENCE IN HEALTHCARE

An ideal AI use case should be specific, measurable, and achievable, and have well-defined users and value [3]. When defining the use case, one can be guided by the adapted SMART-GEM scale [4]. Use cases also help illustrate the existence of standards or the need to develop them [5].

AI algorithms in healthcare create new value for doctors and patients as they help healthcare providers improve patient treatment outcomes and reduce healthcare costs [6]. However, commercially available AI algorithms for medical image analysis require independent evaluation and potential approval by the Food and Drug Administration (FDA) [7]. Datasets for independent validation of AI algorithms should include data elements that provide adequate understanding of limitations, inaccuracy, and even potential ethical concerns caused by the use of a specific AI service [8].

An AI use case in a medical facility should reflect its clinical task, including clinically important outcomes based on the current clinical guidelines and findings easily amenable to independent human evaluation [9]. However, AI can be misused, for example, in case of applying a diagnostic screening algorithm [10] (e.g., intended for tuberculosis screening) in urgent care. This is incorrect as the algorithm is designed to detect signs of infectious diseases in screening of apparently healthy individuals, and its use in emergency settings to detect hemothorax, pneumothorax, hydrothorax, or other urgent conditions may pose a risk for patients' life as such abnormalities are out of the scope of screening studies.

Thus, an AI algorithm for use in a medical facility should demonstrate [11]:

1) clinical utility improving medical care;

2) statistical validity, by training the model on large-scale and diverse datasets to achieve high reliability in a new population;

3) economic utility demonstrated prospectively or retrospectively.

3. APPROACHES TO DATASET CREATION

3.1. Preparation of a technical specifications

Figure 3 shows the main stages of dataset creation to be addressed in these guidelines.

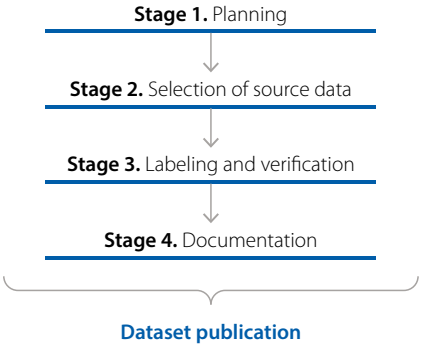

Figure 3 – Stages of dataset creation

An important stage of dataset creation is the choice of its planning, i.e., the formation of requirements for a dataset (technical specifications). This stage is necessary to specify the technical requirements for a dataset in strict correspondence with its clinical and practical tasks.

3.1.1. Setting clinical and practical tasks of dataset creation

A clinical or practical task means the AI use case in medical imaging, differential diagnosis (independent reading), decision support (increasing the range of inputs for decision-making by a healthcare provider), patient routing (triage), technical support (reducing the burden of routine tasks), etc.

The task meets the relevance criteria if:

1) it covers the needs of medical community; in other words, healthcare providers understand the outcomes they will get from the AI services and are interested in them;

2) corresponding AI solutions are marketed both in Russia and abroad; and

3) solution of this task will bring about a significant socioeconomic effect.

To be considered relevant, it is not mandatory for a task to meet all the three criteria. For instance, an automation task may be relevant even if no AI solutions are

available on the market, but the task is strategically important for healthcare.

When setting clinical and practical tasks, it is necessary to define the data access and processing rules and specify:

1) what kind of data may be collected, in what amount, and from which source;

2) how it should be used (with respect to specific tasks);

3) how to protect data when using AI service;

4) to whom it should be disclosed (third-party access policy); and

5) for how long it should be available.

3.1.2. Defining the dataset parameters

It is necessary to define the expected AI service performance results and dataset requirements (including labeling and verification requirements). This process involves researchers, doctors, and biostatisticians.

Paragraphs 3.1.2.1–3.1.2.7 of this section provide the basis for completing the dataset technical specifications. As a result, dataset technical specifications and baseline requirements for AI service performance will be defined.

3.1.2.1. Characteristics of clinical and practical tasks

A clinical task may be dichotomous (division into two classes, such as "signs of target disease present/absent" – in this case, the goal of binary classification is achieved), or it may contain a differential diagnosis (such as the differentiation of one pathology from another, i.e., multiclass classification). The clinical task may also consist in measuring a continuous value (e.g., the percentage of lung parenchymal involvement) or in the detection, search, and display of imaging findings, as well as in choosing patient management strategy, analysis-based prediction of outcomes, etc.

The requirements for the AI outputs may vary depending on the clinical task, namely:

1) for binary classification – a choice of one of the classes or a probability percentage of one of the classes;

2) for multiclass classification – a choice of the most probable class or a probability percentage of each class;

3) for a continuous variable – a prediction of this value with a known error;

4) for imaging findings – coordinates of the finding, heatmap, or contours in the image .

3.1.2.2. Defining the dataset scope of application

Such parameters as class balance (equal number of dataset units for different classes, for example, norms and pathologies for binary classification, see par. 3.1.2.6), target number of studies, etc. may vary depending on the dataset scope of application.

At this stage, the dataset intended use should be determined, in particular:

1) AI service testing for its validation and verification:

– functional testing (checking algorithm performance, visual assessment of outputs, etc.);

– clinical validation (verification of the AI service accuracy metrics considering AI service use cases);

– self-testing (self-verification of the AI service's ability to process heterogeneous input data carried out by the developer);

2) Machine learning:

– transfer learning;

– algorithm training.

In the case of using the dataset for machine learning, it is important to consider the AI application pattern. For instance, to develop an AI service that will be used "before a doctor's review", i.e., screen for "normal" studies without abnormalities, the dataset should contain anatomic variations of the norm. In contrast, a dataset for the development of an AI service that will be used "by a doctor" should be aimed at differential diagnosis, complex cases, etc.

3.1.2.3. Defining clinical parameters of the dataset

To describe each dataset, it is necessary to provide a check list that specifies all clinical parameters of the dataset in relation to a specific healthcare domain.

The proposed version of the check list of clinical parameters is applicable for instrumental diagnostics:

1) type of input data according to generally accepted standards (e.g., for medical images – according to the DICOM standard [12]);

2) anatomical localization (according to the reference book [13]);

3) target nosology (one or several, according to the reference book [14]);

4) population criteria:

– specified upper age limit;

– specified lower age limit;

– gender distribution;

– location and dates of data collection;

– characteristics of a medical facility taking part in data collection:

  • name;

- type;
- type of care (pediatric, adult, mixed);

– epidemiological situation during data collection;
– other patient selection criteria.

3.1.2.4. Defining technical parameters of the dataset

It is necessary to specify the following technical parameters of the dataset:
1) characteristics of diagnostic devices the data was obtained from:
– a list of manufacturers (and models, if necessary);
– technical specifications;
– availability of special imaging modes;
2) technical data requirements (e.g., resolution);
3) requirements for de-identification:
– de-identification of metadata:

- according to generally accepted standards (e.g., the DICOM standard, Section E1, Table E.1–1 [15] – for medical images);
- preserving specific personal information for future comparison with the supporting materials;

– de-identification of pixel images:

- text detection in images;
- removal of facial soft tissues for head, neck, and brain imaging.

3.1.2.5. Defining the labeling criteria

Labeling criteria are a prerequisite for proper labeling. They include the following:
1) dataset inputs:
– name of the input data unit;
– format of the input data unit;
2) dataset outputs:
– name of the output data unit;
– format of the output data unit;
3) labeling classification:
– single-label;
– multi-label;
4) for each label:
– level of labeling (from the list):
– patient;
– study;

- series;
- image;
- level of labeling details:
- study/series/image;
- finding (localization);
- finding (segmentation);
- type of label:
- binary classification;
- multiclass (more than 2 dependent classes);
- continuous variable;
- for each class:
- class inclusion criteria;
- class exclusion criteria;
- Data source for criteria (the study itself (images), metadata, other sources);
- literature reference.

3.1.2.6. Defining the class balance and the target number of studies

To define the class balance and the target number of studies, it is necessary to consider the scope of application of a dataset and the degree of labeling complexity (number of labels and classes).

Classes of one label can be:

1) balanced (the number of studies is the same across different classes);

2) imbalanced (the number of studies of one class is prevalent).

Ones of the most common imbalanced datasets are the datasets based on the pre-test probability. In this case, the number of studies with abnormal signs will be comparable to the detected number of such signs in a given population.

To achieve the goals of testing by receiver-operating characteristic analysis (ROC analysis), it should be strived for balanced datasets.

The target number of studies of each class can be calculated statistically based on a required statistical power of the test. To calculate the dataset size, biostatisticians should be involved.

3.1.2.7. Defining the sources of dataset source data

Typically, source data is harvested from medical information systems (e.g., URIS UMIAS in Moscow). However, data can come from other databases and physical carriers as well; supporting documentation can also be downloaded from other sources (such as clinical diagnosis data, etc.).

3.2. Source data collection pursuant to the technical specification

3.2.1. Introduction to digital health data

Rationale for the AI development, data preparation for labeling and testing, as well as prospective AI performance depend on the access to source data, which can be either raw data or pre-processed on medical equipment and are available to the end user (healthcare providers). Raw data mean unprocessed data collected from diagnostic devices, which is often inaccessible both to the user and medical information systems, and represent a complex mathematical dataset that has no value for the doctors. Raw data are valuable for software developers who fine-tune the algorithms for medical signal preprocessing.

3.2.2. Regulatory framework for the collection of source data

Access to source data is restricted by the following regulations:

1. Federal Law No. 323-FZ of November 21, 2011 "On the fundamentals of health protection of the citizens of the Russian Federation" (as amended effective from July 13, 2021): Article 4; Article 13, Parts 2–4; Article 92.
2. Federal Law No. 152-FZ of July 27, 2006 "On personal data". Excerpts related to the collection, processing, and transmission of datasets: Articles 5 and 6.

Under the European General Data Protection Regulation (GDPR) [16], personal data includes all data which are or can be assigned to a person directly or indirectly, which is a broader interpretation compared to the one accepted in the Russian Federation (pursuant to Federal Law No. 152-FZ of July 27, 2006 "On personal data").

De-identification refers to the actions that result in inability to identify a specific data subject without the use of additional information. The main purpose of de-identification is to ensure a confidentiality of personal data.

Regulatory and methodological documentation addressing the issue of removing the connection between personal data and data subject use three common terms to define this process:

1. Anonymization (de-identification) refers to removing the connection between the identifiable data and the data subject. For this purpose, all attributes are deleted from the record or irreversibly altered in such a way that the data subject can no longer be identified (irreversible de-identification).
2. Pseudonymization refers to a particular type of de-identification that removes the direct association with a data subject and adds an association between a particular set of characteristics relating to the data subject and one or more pseudonyms. This process is reversible. As for anonymization, attributes are altered or deleted from the record, but anonymized patient data is associated with a pseudonym.

3. The reverse process, i.e. de-anonymization (reverse personification), refers to the processing of data in such a way that anonymous data can be attributed to a specific data subject, as a result of which anonymous data becomes personal data.

When creating datasets, the terms "anonymization", and "de-identification" are synonymous.

Pursuant to Order No. 996 of the Federal Service for Supervision of Communications, Information Technology, and Mass Communications (Roskomnadzor) of Moscow of September 5, 2013 "On approval of requirements and methods for personal data anonymization", properties of anonymized data include:

1) exhaustive (it has all information about specific subjects or groups of subjects that was available before anonymization);

2) structured (it retains structural links between the de-identified data of a specific subject or a group of subjects matching those links that existed before anonymization);

3) relevance (the ability to process personal data in such a way that the request and responses have the same semantic form);

4) semantic integrity (preservation of the semantics of personal data during their anonymization);

5) applicability (a possibility of achieving personal data processing goals by the operator who de-identifies personal data handled in personal data information systems, including data created and managed in federal target programs (hereinafter, the operator(s)), without prior de-anonymization of the entire volume of subject records);

6) anonymity (impossibility to unambiguously identify data subjects after de-identification without the use of additional information).

Thus, the collection of source data is highly restricted by the current regulations that should be observed when translating AI into clinical care.

3.2.3. Preparing the infrastructure for source data harvesting

At the initial stage, software solutions are developed to automate the preparation of source data for labeling, to provide labeling itself, and to create datasets. The work at this stage involves a software development team, including a systems architect, database architect, user interface designer, DevOps engineer, programmers, and testers. Obtaining source data from medical information systems may be either single-unit or batch. To prepare datasets intended for AI applications, batch data processing is preferable as, typically, large amounts of studies from different patients are needed. It requires software with appropriate functionality. As shown by the example of digital imaging data from medical facilities of the Moscow Healthcare Department, the software should incorporate the following functionality:

1) search for source data in URIS UMIAS;
2) download text reports using available lists of unique identifiers of studies (study UIDs);
3) select studies by keywords (pre-sorting);
4) select and filter studies by technical parameters;
5) ensure first/second reading by radiologists (annotators and experts);
6) ensure verification;
7) save labeling and verification results in machine-readable form;
8) prepare dataset supporting documentation.

3.2.4. Source data collection

An important feature when planning the source data collection is its availability, which depends on the data source (Table 2).

Table 2 – Data sources

Data source types	Data types
Medical sources	– Images (CT, MRI, surgery videos, etc.) – Text (EHR, medical reports and recommendations, etc.) – Sounds (patient voice recordings, wheezing and coughing sounds, etc.) – Signals (EEG, ECG, data from bedside monitors and wearable devices, etc.) – Genetic data (NGS, DNA microarray, etc.)
Pharmacological sources	– Clinical trials data – Data on medications – Sales data – Pharmacovigilance data
Financial sources	– Cash flow data from the Compulsory Medical Insurance Fund and medical facilities – Cash flow data from insurance companies
Administrative sources	– Data on medical facilities (doctor offices' workload, equipment load, doctor appointment schedule, etc.) – Federal Register of Medical Facilities (FRMO), Federal Register of Healthcare Professionals (FRMR), regulatory references – Data on complaints and feedback on medical facilities – Data on disease prevalence, epidemics, etc.
Insurance data	– Insurance reports – Customer scoring reports – Complaints data

External sources	– Demographic data – Biomedical literature – Data from patient forums – Cancer database (cancer registry) – Database of the Civil Registry Office – Open-access databases

When additional characteristics are added to the designed dataset, the number of subjects who will simultaneously have the entire set of such characteristics decreases; therefore, a planning stage of source data collection should give the understanding of each dataset purpose.

Since 2013, the Ministry of Health of the Russian Federation has regulated the structure of an electronic health record (hereinafter, EHR) [17] to be applied when creating and improving medical information systems (hereinafter, MIS).

The EHR enables a long-term storage of patient data related to all types of medical care, including the results of medical observations, clinical judgments, and treatment plans.

The structure of the EHR includes 15 sections such as "Patient metrics", "Diagnostic tests", "Medical examinations", "Diseases and complications", "Medications", and others.

Sections, in turn, include dozens of parameters (EHR fields). For instance, the "Medical examinations" section should contain the full name and position of a doctor, symptoms and complaints, diagnosis, etc. Structured reporting facilitates more accurate query to collect various datasets.

3.2.5. Stages of dataset creation

Most healthcare systems are not adequately equipped to share large amounts of medical images [18]. Even when ethical, regulatory, and financial prerequisites for AI development/testing/application are fulfilled, rapid proliferation of AI in clinical care is hindered as health data is often stored in separate repositories, what is not optimal for the development of medical AI, which can be widely used in clinical practice. Collecting a large amount of source data from one place prevents them from being used for the appropriate development, testing and/or post-registration monitoring of AI in healthcare. Furthermore, the process of collecting and storing source data lacks sound methodology, which should be elaborated before handling the source data. One of the possible solutions is to delegate the rights and responsibility for the creation, training, and testing in the common digital environment to one medical facility. This is the case in Moscow, where the Center for Diagnostics and Telemedicine took over the responsibility for the methodology and implementation of AI in the

Experiment on the application of innovative computer vision technologies for the analysis of medical images and further use in the Moscow healthcare system [19].

To prepare source data, the following steps need to be taken:

1. Planning the goals of dataset application. This important step is often neglected. However, it is important to define the number of patients/studies, dataset scope of application; inclusion/exclusion criteria; availability of ground-truth labels in the dataset; the need (or possibility) to update (or expand) the dataset to extend the scope of application of available data, including limitations of dataset use.
2. Approval from the ethical committee to use the source data for a specific purpose. The informed consent is required to use source data.
3. Getting access to the desired source data using a relevant query.
4. Data anonymization and secure storage of de-anonymization (de-identification) keys.
5. Data quality control. The quality and amount of images vary depending on the target task and domain. If the data is intended for open-source research, then additional human inspection of each image is standard practice because some images contain free-form annotations that cannot be removed reliably with automated methods.
6. Data structuring in homogenized and machine-readable formats [20] (e.g., DICOM or NIFTI).
7. Linking ground-truth information to the studies, which can be one or multiple labels, segmentations, or a third-party study with a higher degree of evidence (e.g., biopsy or laboratory results).
8. Registration of the dataset as an independent intellectual property.

3.2.6. Recommendations for data collection

The data used for training, transfer learning, testing, validation, or scientific analysis can be collected for datasets in the following ways:

1) retrospective/prospective data collection (should follow the above steps);

2) conducting research;

3) using publicly available databases with appropriate authorization, which is the easiest way that has its limitations, namely:

- some open-source datasets may be used for research only but not for the commercial AI development;
- inability to control a dataset quality;
- a limited size of dataset.

The search for ground-truth information to confirm the target pathology in medical images is a challenging and topical issue. In addition to the image labeling, which can be very time-intensive, each study should be interpreted in line with the

corresponding reporting guidelines. The use of these protocols can either result in self-labeling or contribute to reducing the number of images that will require labeling in the future. There are approaches to perform retrospective labeling, ranging from simple manual labeling [21] by radiologists to automated approaches that can extract structured information from the radiology report and/or electronic health record.

There is a trend toward interactive reporting where the radiologist's report contains hypertext directly connected to image annotations [22]. Such annotations can be used for labeling of open-source datasets [23]. However, this approach cannot be considered reliable as 2–20% of radiology reports contain errors [24].

When it comes to image annotation, priority should be given to specialists with sufficient experience, keeping in mind that an expert radiologist should validate such labeling as an auditor. Such crowd-sourced labeling should be performed after a preliminary discussion with experts since the number of annotators and the need for an auditor may vary depending on the task. Thus, complex tasks require a substantial number of annotators; for instance, the recommended number of experts to label lung lesions is 4 labelers and 1 expert validator for each CT scan [25].

When planning data collection, it is advisable to design the dataset in such a way that the ratio of training, testing, and validation in the dataset is 80:10:10 or 70:15:15. To ensure generalizability of the AI algorithm, bias of the training dataset should be limited. If the AI algorithm is trained on images from a Moscow facility and the algorithm is used in the Asian population, its performance may be affected by population bias or prevalence bias. Similarly, if all the imaging training data was acquired by using one type of scanner, it may not work as well on machines from other manufacturers. It is thus advised to use images from multiple diverse sources, or at least images representing the target population or health system in which the algorithm is to be deployed. To ensure generalizability, large training datasets are often essential. For specific targeted applications or populations, relatively small datasets (hundreds of cases) may be sufficient. Large sample sizes are especially required in populations with substantial heterogeneity or when differences between imaging phenotypes are subtle [26].

The sample size calculation for test datasets should use traditional power calculation methods to estimate the sample size. In general, the development of generalizable AI algorithms in medical imaging requires statistically powered datasets in the order of hundreds of thousands, which is problematic for many researchers and developers. A partial solution for this problem may be semi-supervised learning. Fully annotated datasets are needed for supervised learning, whereas semi-supervised learning [27] uses a combination of annotated and unannotated images to train the algorithm.

Special attention should be given to federated learning. A number of companies [28, 29] enabled multi-institutional collaborations in order to train AI

models using in-house computing capabilities without sharing data between institutions. As the trained models are exchanged between medical facilities, they are fine-tuned and boast higher diagnostic accuracy. Training, testing, and prospective research are carried out inside the institution without the need to transfer datasets (studies) outside of the facility. Despite the potential benefits of this technique, there are important issues listed below need to be solved before federated learning can be widely applied in practice.

1. It is necessary to standardize the interpretation and labeling of medical data in those facilities where the medical AI algorithm is to be deployed.
2. Depending on the AI algorithm complexity, substantial computing resources may be required in each facility for federated learning.
3. Preprocessing and organizing the data for ingestion by the algorithm are complex tasks, because data visibility for the developers is limited.
4. Data heterogeneity across different facilities in terms of patient populations, pathology distribution, data volume, data format, etc.

One of the most important limitations of training AI algorithms based on data from a single facility or from multiple ones in a small geographic area is sampling bias. If an AI algorithm trained this way is applied to a different geographic area, then results of the algorithm may be unreliable due to differences between the sample population and target population [30].

Consequently, there are various recommendations for data collection and labeling for AI. Doctors, data scientists, and decision-makers who provide access to data or authorize new AI model deployment should be aware of the source for training data and potential biases, which may affect generalizability of AI algorithms. New approaches such as federated learning, interactive and synoptic reporting may help to address the issue of data availability in the future. However, curating and annotating data, as well as computational requirements, are substantial barriers.

3.3. Dataset classification by the type of labeling

The type of image labeling varies depending on the task to be performed by the AI algorithm [31].

There are three types of datasets depending on the type of labeling (Fig. 4, 5) [18]:

1) Retrospective dataset;
2) Prospective dataset;
3) Verified dataset.

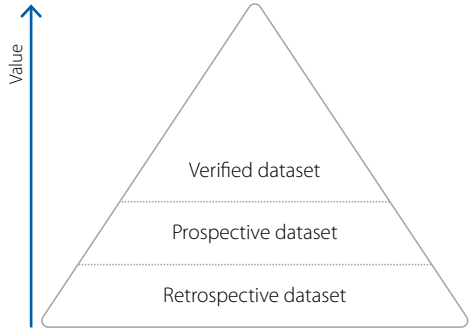

Figure 4 – Value-based classification of image labeling

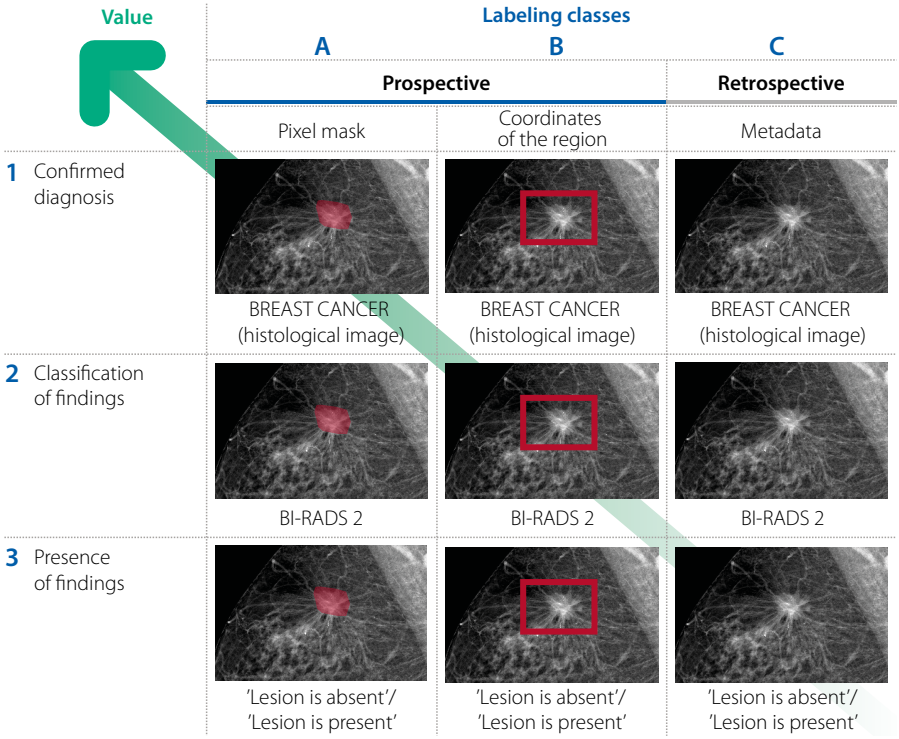

Figure 5 – Classification of labeling in diagnostic radiology

Figure 5 above shows the classification of labeling types [32]. For retrospective labeling (1C, 2C, 3C), data from supporting documentation (e.g., radiology reports), medical information systems, electronic health records, etc. can be used. An example of retrospective labeling is metadata generated automatically during the examination, which is stored in the source data. The obvious advantage of retrospective labeling is saving time of medical professionals as most of the preparations is done by the data scientist.

A dataset is considered most reliable (line 1) when a confirmed diagnosis is available for elements in the dataset, e.g., the results of histological tests, laboratory data, or follow-up studies (if applicable).

Prospective labeling (1A, 1B) requires the active involvement of doctors in the process of incorporating information into the dataset, what, for example, allows the efficient classification of dataset elements. In diagnostic radiology, labeling is most often understood as the classification of studies by classes (i.e., depending on the presence or absence of radiological signs of a specific disease), as well as designating the region of interest in the form of a graphical notation [18], corresponding to the pathological signs (e.g., demyelinating lesions in multiple sclerosis on brain MRI images). The doctor involvement can be more or less time-intensive: in the first case, experts are to contour the region of interest, i.e., create a pixel mask at the level of the region of interest (Column A); in the second case, they are to designate its coordinates with a simple geometric figure (Column B).

3.3.1. Retrospective labeling

Retrospective labeling enables the collection of elements corresponding to metadata selected in line with the set task. Such labeling is not labor-intensive: it consists in uploading data from medical information system, which can be done by an engineer (analyst) without a doctor involvement. For this purpose, each element (image, signal data, etc.) of the dataset is linked to medical information (diagnosis, laboratory results, etc.).

3.3.2. Prospective labeling

Similar to retrospective labeling, prospective labeling enables the collection of elements in accordance with the set task, but here additional manipulations with elements are mandatory (e.g., providing annotations for event start/end, designating signs of abnormalities, etc.). This type of labeling involves healthcare professionals (normally, a doctor subspecialized in the domain of the labeled dataset) who perform manual annotation of data content in full or parts thereof.

3.3.3. Verified dataset

The verified dataset is collected by supplementing the dataset prepared during prospective labeling by doctors with data from medical records, including the final (clinical) and/or pathological diagnosis. The golden standard of dataset verification for the target pathology is getting the ground truth from follow-up examinations, histopathologic, immunologic, and other tests, treatment responses, etc. [18, 20, 31, 33].

There is one more verification technique where the dataset is evaluated by medical experts using blind analysis with the given level of consistency. When multiple expert readers are involved in the dataset verification, it is necessary to describe the process by which their interpretations are combined to make an overall reference standard determination and how the process accounts for any inconsistencies between radiologists participating in the ground truthing (variability of truth) [34]. The difference from prospective labeling is that data is reviewed by a panel of experts who provide a consensus decision.

The dataset is considered verified if:

1) it contains real-practice data (gathering of synthesized data, e.g., from an ECG waveform generator, is prohibited);

2) dataset structure is consistent with the dataset purpose (training, analytical and clinical validations, validation, etc.);

3) the number of observations (studies) ensures the statistical significance of the result;

4) labeling is done by the group of experts;

5) a thesaurus (i.e., a coded library of words and phrases adopted by the clinical societies' guidelines) is used for labeling.

3.3.4. Requirements for dataset annotators

As per GOST ISO 13485, personnel (doctors, engineers) preparing the dataset should be competent on the basis of appropriate education, training, skills, and experience. Details on the required qualification, experience, and skills of personnel should be specified in their job descriptions.

Annotators should be selected according to the criteria listed below.

1. They should be competent with respect to specific data types: images, text or signal data (ECG, EEG, etc.), quantitative data (heart rate, blood pressure, spirometry parameters, etc.), and binary data (e.g., yes/no response).

2. Depending on the complexity of the required labeling and/or annotation, it may include primary labeling (segmentation) or expert labeling; providing details at the level of classes or subclasses, establishing links with metadata, or predicting possible outcomes (forecasting).

At that point, the signs of common nosologies (such as pneumonia or tubular bone fractures) do not deserve the attention of a highly-qualified radiologist who, however, should be engaged in the annotation of complex cases and differential diagnosis (e.g., annotation of images with the signs of demyelinating disorders).

3.4. Dataset quality control

Dataset creation process is subject to planning, monitoring, and management to ensure quality compliance.

The working group may be led by a responsible employee who is not engaged in the labeling/annotation process, but will manage the project goals depending on their urgency, priority, and workload of experts. It is responsibility of this employee to form a working group to ensure the fairness and reliability of outcomes.

Dataset quality assurance should be applied to ensure that:

1) checking for missing elements in the dataset;

2) checking for the absence of incorrect elements for solving the tasks;

3) verification of compliance of the quality of the dataset elements with the recommended criteria of the professional medical community.

To develop and apply the verified dataset, a quality management system (QMS) is implemented, which is expressed as the organizational structure, functions, procedures, processes, and resources needed to manage and maintain a quality.

The prepared datasets can be structured by highlighting features in accordance with the set task. In the process of structuring, the dimensionality of the dataset is reduced, leaving a sufficient list of attributes for an accurate and complete description of the dataset elements, which will facilitate the subsequent generalization of steps and high-quality labeling (annotation) of data.

Dataset filtering reduces the annotation costs by excluding data that falls short of the specified parameters. The quality control procedure includes finding, preventing, and eliminating problems related to the quality of datasets. Filtering and quality control of datasets can be done by visual control, special tools (e.g., DICOM validators), or an artificial intelligence system (e.g., for automatic image quality assessment).

3.5. Making changes to datasets

After creating and registering a dataset, it may be necessary to make corrections (to correct errors or add new data) [35]. When making any changes, a version change of the dataset (including change in the version number) should be documented in order to be able to evaluate changes over time. Such documentation should be enclosed to the dataset. When changing the dataset version, three-

digit values are used in the A.B.C format, where A is the major version, B is the minor version, and C is the patch version [32]:

1. The major version increases if there are changes in the meaningful parameters of the dataset related to the clinical task, purpose, principles of data labeling and verification.
2. The minor version increases if data units (images, text, or signal data, etc.) are replaced, added, or deleted without changing the meaningful parameters of the dataset (the minor version is set to 0 when a new major version is released).
3. The patch version increases if changes are made to supporting documentation or typos and errors are corrected in the labeling and verification files, however, neither a quantity nor a quality of the input data units of the dataset changes (the patch version is set to 0 when a new minor or major version is released).

When a new minor or patch version is released, AI services can use the dataset without changing the code that ingests dataset elements that provide inputs. When a new patch version of the dataset is released, the amount and quality of dataset elements providing inputs to the AI service should be the same, but the performance results may be different (because labeling and verification files may be affected). When an additional series of data units is added, the major version of the dataset is changing since meaningful changes are introduced to the clinical task and overall purpose of the dataset creation, which, however, do not change it completely. A new dataset is created if the intended use, purpose, and clinical tasks of the dataset creation are changed completely.

CONCLUSION

These guidelines describe practical approaches to planning and creating datasets intended for testing and applying artificial intelligence technology in healthcare. Incorporation of these recommendations into routine practice will standardize the development of medical datasets to ensure their value for artificial intelligence systems in healthcare. As the development and validation of useful, reliable, and secure artificial intelligence systems is preconditioned by the availability of high-quality datasets, it is the process of their creation that requires a transparent and reproducible methodology.

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Best Practices in Medical Imaging

Issue 103

Authors:

Sergey Morozov
Anton Vladzymyrskyy
Anna Andreychenko
Ekaterina Akhmad
Ivan Blokhin
Victor Gombolevsky
Victoria Zinchenko
Nicholas Kulberg
Vladimir Novik
Nikolay Pavlov

REGULATIONS ON DATASET PREPARATION AND APPROACHES TO REPRESENTATIVE DATA SAMPLING

Part 1

Guidelines

Research Coordination Department, Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies of the Moscow Health Care Department

Technical editing by A.I. Ovcharova
Desktop publishing by E.D. Bugaenko

Research and Practical Clinical Center for Diagnostics and Telemedicine Technologies,
Moscow Healthcare Department
24 Petrovka St., Moscow 127051, Russia