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**Health informatics — Applications  
of machine learning technologies  
in imaging and other medical  
applications**

*Informatique de santé — Applications de technologies  
d'apprentissage automatique en imagerie et autres applications  
médicales*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

Due to the rapid advancement of artificial intelligence, especially machine learning and deep learning, defining categories of use cases in the clinical setting have started to be adopted to enhance healthcare system and patients' outputs. Therefore, it is crucial to define the categories of use cases for artificial intelligence in the clinical setting to focus on application of artificial intelligence in medicine.

This document proposes categories of use cases of machine learning technologies for artificial intelligence in medicine considering the property of artificial intelligence technology including machine learning and deep learning and clinical settings especially requiring repeated detection and/or diagnosis, real-time monitoring, and treatment prediction with images and continuous signals, etc. This document will assist the health IT companies by reviewing the current status of machine learning technologies for artificial intelligence in medicine and then by proposing a gap for a new application. This document can be used to further develop the applications or the necessary standards of machine learning technologies for artificial intelligence in medicine.

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# Health informatics — Applications of machine learning technologies in imaging and other medical applications

## 1 Scope

This document lists examples of and defines categories of use cases for machine learning in medicine for clinical practice.

The developments and applications of machine learning technologies for artificial intelligence consist of 1) data collection and curation, 2) pre-processing, 3) model training and validation, and 4) medicine depending on various kinds of specialty including radiology, pathology, emergency medicine, dermatology, ophthalmology, anaesthesia, surgery, etc., and clinical settings including repeated detection and/or diagnosis, real-time monitoring, and treatment prediction.

This document covers categories applications of medicine in (4). It also defines the clinical usages and necessities of the artificial intelligence in medicine.

(1) to (3) are not the scope of this document

This document also excludes

- basic research and other scientific areas,
- use cases related to artificial intelligence methods other than machine learning (for example, symbolic artificial intelligence, expert systems), and
- non-human results such as veterinary medicine.

## 2 Normative references

There are no normative references in this document.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

### 3.1

#### artificial intelligence

##### AI

branch of computer science devoted to developing data processing systems that perform functions normally associated with human intelligence, such as reasoning, learning, and self-improvement

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.234]

### 3.2

#### **big data**

extensive datasets — primarily in the data characteristics of volume, variety, velocity, and/or variability — that require a scalable technology for efficient storage, manipulation, management, and analysis

Note 1 to entry: Big data is commonly used in many different ways, for example as the name of the scalable technology used to handle big data extensive datasets.

[SOURCE: ISO/IEC 20546:2019, 3.1.2]

### 3.3

#### **electronic medical records**

##### **EMR**

electronic record derived from a computerized system used primarily for delivering patient care in a clinical setting

### 3.4

#### **clinical decision support**

##### **CDS**

type of service that assists healthcare providers in making medical decisions, which typically requires input of patient-specific clinical variables and provide patient-specific recommendations

[SOURCE: ISO/TS 22756:2020, 3.1]

### 3.5

#### **clinical decision support system**

##### **CDSS**

software designed to be a direct aid to clinical decision-making, in which the characteristics of an individual patient are matched to a computerized clinical knowledge base, whereafter patient-specific assessments or recommendations are presented to the clinician or the patient to aid in the process of making evidence based clinical decisions

[SOURCE: ISO/TS 22756:2020, 3.2]

### 3.6

#### **computer aided detection**

##### **CADe**

health information technology system to provide physicians and other health professionals with automated detection in medical records (i.e., images), that is, assistance with clinical diagnosis tasks

### 3.7

#### **computer aided diagnosis**

##### **CADx**

health information technology system to provide physicians and other health professionals with automated diagnosis by using medical records including images, and EMR, that is, assistance with clinical diagnosis tasks

### 3.8

#### **computer aided differential diagnosis**

##### **CADD**

health information technology system to provide physicians and other health professionals with automated differential diagnosis by using medical records including images, and EMR

### 3.9

#### **computed tomography**

##### **CT**

radiographic scanning technique that uses a number of CT projections of an object at different angles in order to allow calculation of a CT image

[SOURCE: ISO 15708-1:2017, 3.7]

### 3.10 deep learning

approach to creating rich hierarchical representations through the training of *neural networks* (3.16) with many hidden layers

Note 1 to entry: Deep learning is also known as deep neural network learning

[SOURCE: ISO/IEC TR 29119-11:2020, 3.1.26, modified — Note 1 has been modified.]

### 3.11 image processing

<computer graphics> process of applying any operation to a pictorial representation of objects or data for a given purpose

Note 1 to entry: Examples of operations include scene analysis, image compression, image restoration, image enhancement, preprocessing, quantizing, spatial filtering, and construction of two- and three-dimensional models of objects.

[SOURCE: ISO/IEC 2382:2015, 2125939, modified — Admitted term and Note 3 to entry deleted.]

### 3.12 machine learning

process using computational techniques to enable systems to learn from data or experience

[SOURCE: ISO/IEC TR 29119-11:2020, 3.1.43]

### 3.13 magnetic resonance imaging MRI

imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ISO 14630:2012, 3.5]

### 3.14 natural language processing NLP

technology used to determine and identify key words and phrases within processing audio data (e.g. call centres) and free-form text (e.g., the body of an email)

Note 1 to entry: This technology is able to reduce words to their base constructs and perform other actions, such as stemming, along with locating similar words or phrases without user intervention. This technology also varies greatly from standard IDR technology due to the ability to automatically update rules as determined by the users without the need for technical intervention. This technology is best suited for unstructured documents.

[SOURCE: ISO/TR 22957:2018, 3.7]

### 3.15 artificial neural network neural network neural net ANN

network of primitive processing elements connected by weighted links with adjustable weights, in which each element produces a value by applying a nonlinear function to its input values, and transmits it to other elements or presents it as an output value

Note 1 to entry: Whereas some neural networks are intended to simulate the functioning of neurons in the nervous system, most neural networks are used in artificial intelligence as realizations of the connectionist model.

Note 2 to entry: Examples of nonlinear functions are a threshold function, a sigmoid function, and a polynomial function.

[SOURCE: ISO/IEC 2382:2015, 2120625, modified — Notes to entry 3 to 5 deleted.]

**3.16  
prediction**

output of an algorithm after it has been trained on a historical dataset and applied to new data when forecasting the likelihood of a particular outcome

**3.17  
robotics**

techniques involved in designing, building, and using robots

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.3554]

**3.18  
speech recognition**

automatic speech recognition  
conversion, by a functional unit, of a speech signal to a representation of the content of the speech

Note 1 to entry: The content to be recognized can be expressed as a proper sequence of words or phonemes.

[SOURCE: ISO/IEC 19794-13:2018, 3.22]

## 4 Abbreviated terms

CBIR	Content-based case retrieval
CNN	Convolutional Neural Net
DB	Database
EMR	Electronic Medical Records
ICU	Intensive Care Unit
IDR	Intelligent Document Recognition
IoT	Internet of Things
OR	Operation Room

## 5 Categories for defining use cases of machine learning in medicine

### 5.1 Categories based on technology

#### 5.1.1 General

AI techniques used in medicine can be summarized as in [Table 1](#).

**Table 1 — Technology based categories of artificial intelligence and their purposes**

Technology	Purpose
Robotics	Providing high quality treatments by increasing the precision and accuracy of the surgical process.
Continuous monitoring	Within golden time, proper treatment could be performed by continuously monitoring of patient condition and alerting nurses.
Machine learning	Predict response by analyzing data affecting treatment outcomes.
Deep learning	Self-learning ability to process large amounts of medical imaging records, reducing uncertainty in medical treatment decisions.
Image processing	Process large-scale medical images and apply them to detect diseases, diagnosis, etc.
Natural language processing	Translate long descriptive character sets such as electric medical records to be interpreted.
Audio recognition	By recognizing voice and language of patient, dictate important information in electric medical records.
Bigdata analysis	Process vast patient health records held by healthcare organizations and provide tailored recommendations to patients and providers.
Prediction modeling	Apply AI models to predict outcomes such as predicting risk disorders.

### 5.1.2 Robotics

In robotics, AI can provide high quality treatments by increasing the precision and accuracy of the surgical process. For example, it can control the trajectory, depth, and speed of the robot movements with high precision and can go where traditional tools cannot. It can also reduce the burdens of the surgeons during surgery by providing the same, repetitive movements without fatigue.

### 5.1.3 Continuous monitoring

Proper treatment within golden time could be performed by continuously monitoring of patient condition and alerting nurses by AI. AI model with continuous monitoring data also can alert the clinicians before onset.

### 5.1.4 Machine learning

By using traditional machine learning methods, AI can be used to predict response by analysing data affecting treatment outcomes.

### 5.1.5 Deep learning

By using deep learning, self-learning ability to process large amounts of imaging and audios records in medicine, reducing uncertainty in medical treatment decisions including computer aided detection, computer aided diagnosis, computer aided differential diagnosis, and clinical decision support system. Deep learning can handle multiple different types of clinical data such as images, texts, and signals at the same time.

### 5.1.6 Image processing

In image processing, AI can be used to process large-scale medical images and apply them to detect diseases, diagnosis, etc. AI for clinical image handling has demonstrated its performance in clinical settings.

### 5.1.7 Natural language processing

In NLP, AI can be used to translate long descriptive character sets such as electric medical records to be interpreted, i.e. extracting the information from unstructured electronic medical records.

**5.1.8 Audio recognition**

In audio recognition, by recognizing voice and language of patient, AI can automatically dictate important information in electronic medical records.

**5.1.9 Bigdata analysis**

In bigdata analysis, AI can be used to process vast patient health records held by healthcare organizations and provide tailored recommendations to patients and providers.

**5.1.10 Prediction modeling**

In prediction modeling, AI models can be applied to predict outcomes such as predicting risk disorders.

**5.2 Categories based on medical specialty**

**5.2.1 General**

The applications of AI in medicine can be categorized by medical specialty as in [Table 2](#).

**Table 2 — Typical use cases of artificial intelligence in medicine in each medical specialty**

Specialty	Use Cases
Radiology	Quantification, computer aided detection, diagnosis, and differential diagnosis on radiologic images; Automated dictation system.
Pathology	Quantification, computer aided detection, diagnosis, and differential diagnosis on pathologic images; Automated dictation system.
Dermatology	Skin cancer detection and classification.
Ophthalmology	Eye disease detection and classification in retina image and OCT.
Internal Medicine	Complication/outcome prediction; clinical decision support system.
Cardiology	Quantification, computer aided detection, diagnosis, and differential diagnosis on cardiologic images; Complication/outcome prediction; clinical decision support system.
Neurology, Urology, Surgery	Complication/outcome prediction; clinical decision support system.
Anaesthesiologist, Intensive Care Unit (ICU)	Continuous monitoring system; Complication/outcome prediction.
Emergency	Triage system; Continuous monitoring system; Complication/outcome prediction.

**5.2.2 Radiology and Pathology**

In Radiology and Pathology, AI can be used for fully automated quantification, computer aided detection, diagnosis, and differential diagnosis on radiologic or pathologic images and automated dictation system.

**5.2.3 Dermatology**

In Dermatology, skin cancer detection and classification could be one of typical use cases.

**5.2.4 Ophthalmology**

In Ophthalmology, AI can be used for eye disease detection and classification in retina image and OCT.

### 5.2.5 Internal Medicine

In Internal Medicine, complication and outcome prediction, and clinical decision support system could be one of important use cases.

### 5.2.6 Cardiology

In Cardiology, quantification, computer aided detection, diagnosis, and differential diagnosis on cardiologic images, complication and outcome prediction, and clinical decision support system could be one of use cases.

### 5.2.7 Neurology, Urology, Surgery

In Neurology, Urology, Surgery, AI can be used for complication and outcome prediction, and clinical decision support system.

### 5.2.8 Anaesthesiologist, Intensive Care Unit

In Anaesthesiologist, Intensive Care Unit (ICU), continuous monitoring system and complication and outcome prediction could be one of important applications.

### 5.2.9 Emergency

In Emergency, automated triages system, continuous monitoring system, complication and outcome prediction could be one of important applications.

## 5.3 Categories based on medical usage

### 5.3.1 General

The examples of AI in medicine can be categorized by their medical usages including clinical trials, clinical assistance, data-based precision medicine, diagnostic imaging, logistics in ORs and wards, robot surgery, and drug development in medicine (see [Table 3](#) and [Figure 1](#)).

**Table 3 — Categories of use cases of medical usages**

Usage	Sub-usage	Purpose
Clinical trials	Case selection	AI-based search techniques help find the right disease and patient, reduce the time to prepare for clinical trials, and improve objectivity.
Clinical Assistance	Assistant service and wellness with IoT	Convergence of IoT technology, voice recognition technology and artificial intelligence technology, efficient reservation, diagnosis and medical treatment process, business information update and customized curation.
	Automated dictation	Speech recognition and document generation technology that can automate diagnosis and recording of readings, and read and structure medical terminology.
Data based precision medicine	Genome and genetics	Prediction, diagnosis and treatment by analysing and modeling associations of big data based on genome, multimodal medical imaging and clinical pathology for personalized medicine.
	Prediction of complication and mixed drug	Assist physicians in making final decisions by notifying them of case-based risks or complications in treatment and drug use.
	Recommendation of exam	Recommend additional diagnostic testing processes to increase accuracy and lower risk, utilizing artificial intelligence and big data for precise diagnosis and treatment.

Table 3 (continued)

Usage	Sub-usage	Purpose
Medical Imaging and Diagnostic	Normal selection	Early diagnose medical images in advance to reduce clinical burden by differentiating the true normal cases.
	Content based case retrieval	Helps diagnose by searching and visualizing similar cases from numerous cases in DB.
	Generating reading reports	Artificial intelligence-based medical image analysis and natural language processing technology are integrated to generate readings that can assist the reading of image specialists.
	Computer aided diagnosis	Application of AI techniques to diagnostic image big data, pathogenesis analysis, prognostic prediction.
Hospital Management	-	Efficient operation of logistics, operating room, and ward between single hospitals and clusters of hospitals based on artificial intelligence technology.
Robot surgery	-	Use artificial intelligence to plan medical robot surgery, predict risks and minimize invasive areas.
Drug development	-	Apply artificial intelligence techniques to develop new drugs, explore drug combinations and drug repositions that are more effective in treating diseases, and optimize drug candidates and clinical patients.

### 5.3.2 Clinical trials

In clinical trials, automated case selection could be one of important use cases by using AI-based search techniques to help find the right disease and patient, reduce the time to prepare for clinical trials, and improve objectivity.

### 5.3.3 Clinical assistance

In clinical assistance, there are two sub-categories including assistant service and wellness with IoT and automated dictation. In assistant service and wellness with IoT, convergence of IoT technology, voice recognition technology and artificial intelligence technology, efficient reservation, diagnosis and medical treatment process, business information update and customized curation could be one of important use cases. In automated dictation, speech recognition and document generation technology can automate diagnosis and recording of readings and read and structure medical terminology.

### 5.3.4 Data-based precision medicine

In data-based precision medicine, there are three sub-categories including genome and genetics, prediction of complication and mixed drug. In case of genome and genetics, prediction, diagnosis and treatment by analysing and modeling associations of big data based on genome, multimodal medical imaging and clinical pathology could be important use cases for personalized medicine. In prediction of complication and mixed drug, AI can assist physicians in making final decisions by notifying them of case-based risks or complications in treatment and drug use. In recommendation of examination, AI can be used to recommend additional diagnostic testing processes to increase accuracy and lower risk, utilizing artificial intelligence and big data for precise diagnosis and treatment.

### 5.3.5 Medical Imaging and Diagnostic

In diagnostic imaging, there are four sub-categories including normal selection, content-based case retrieval, generating reading reports, and computer aided diagnosis. In case of normal selection, AI can early diagnose medical images in advance to reduce clinical burden by differentiating the true normal cases. In content-based case retrieval, AI can help physicians diagnose by searching and visualizing similar cases from numerous cases in database. In generating reading reports, AI-based reading medical images and NLP technology could automatically generate radiologic reports that can assist the reading of image specialists. In computer aided diagnosis, AI can be used for application to diagnostic image big data, pathogenesis analysis, prognostic prediction.

### 5.3.6 Hospital Management

AI can be used to enhance the operations of logistics in operating rooms and wards between single hospitals and clusters of hospitals based on artificial intelligence technology.

### 5.3.7 Robot surgery

In robot surgery, a robot can use AI to plan medical robot surgery, predict risks and minimize invasive areas.

### 5.3.8 Drug development

In drug development, AI techniques can be used to develop new drugs, explore drug combinations and drug repositions that are more effective in treating diseases, and optimize drug candidates and clinical patients.

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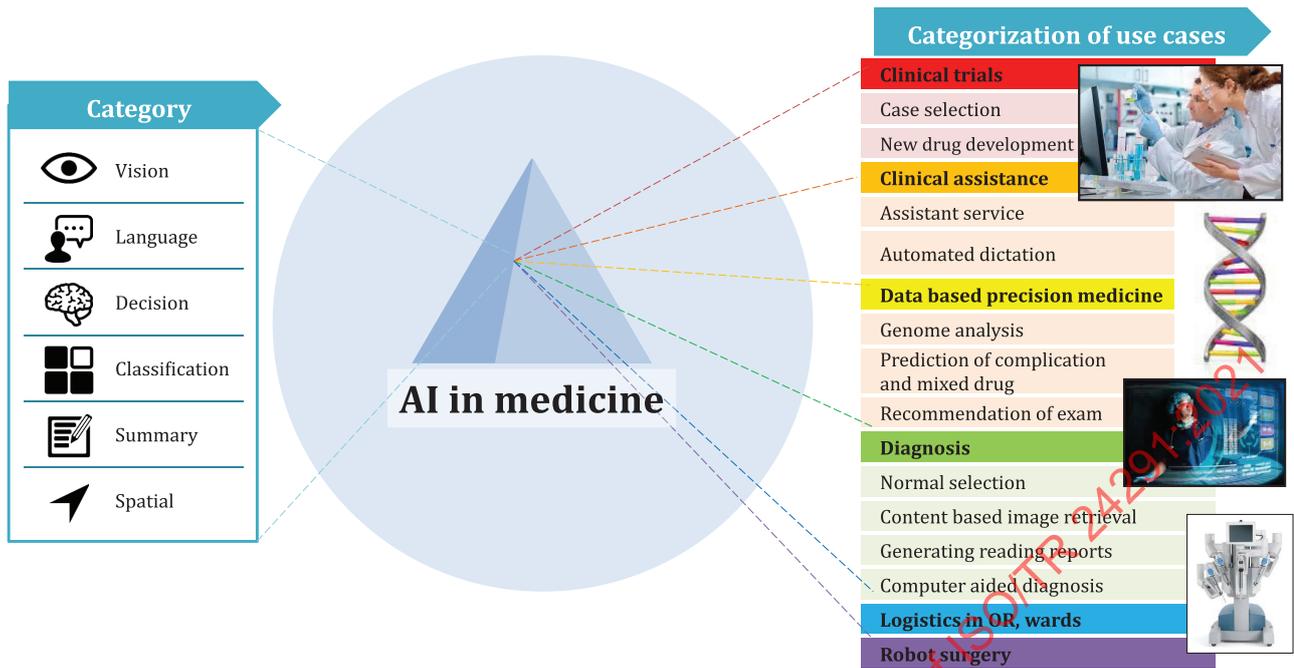


Figure 1 — Diagram on the categorization of use cases of artificial intelligence in medicine

## 6 Use cases of artificial intelligence in medicine

### 6.1 General

This clause lists typical examples of use cases of AI in medicine.

NOTE See Reference [4] and Table 2 of Reference [3] for a list of FDA-cleared AI applications in medicine.

### 6.2 AI Platform for Lung Cancer Screening and Reporting

Use case name: AI Platform for Lung Cancer Screening and Reporting

Model: On-premise service

Scope: Detecting and analyzing lung nodules and generating automatic screening report

Objective(s): To facilitate early diagnosis of lung cancer using artificial intelligence

Short description: VUNO Med-LungCT AI accurately detects and quantifies pulmonary nodules. It automatically provides size, volume, nodule type, location, calcification and speculation. An automatic report based on the calculated Lung-RADS category is produced to assist in managing pulmonary nodules. VUNO Med-LungCT AI's follow-up registration and nodule matching improve the efficiency of comparing serial CT scans. Operation settings can be customized between sensitivity-oriented for high-risk patients and specificity-oriented for efficient screening.

Stakeholders: Healthcare authorities, Diagnostic radiology physicians, Medical check-up centres

Key Performance Indicators (KPIs): Sensitivity at specified number of false positive detection of lung nodule per CT scan.

Accuracy: 88,2 % sensitivity at 1.0FP/scan

Speed: From 15 seconds to 30 seconds

Challenges: Variation of performance according to the CT image characteristics and imaging protocols.

### 6.3 AI based text to speech services with personal voices for speech impaired people

Use case name: AI based text to speech services with personal voices for speech impaired people

Model: On-premise systems

Scope: All people who have some sort of speech impairments including but not limited to three basic types: articulation disorders, fluency disorders, and voice disorders.

Objective(s): People with speech impairments will be fully integrated into social processes without communication restrictions.

Short description: Communication with other people can be difficult for those who have speech disorders. This seriously complicates communication with the surrounding domestic processes and the involvement of a person in society. A personal wearable device is capable of online synthesizing voice over text or correcting distorted speech. The voice can be fully synthesized with individually selected tone, timbre and pronunciation style settings.

Stakeholders: People with speech impairments

Key Performance Indicators (KPIs)

Mean opinion score: Score from stakeholders whom use new services\hardware

Scale of use: Percentage of stakeholders using the service\hardware to the total number of stakeholders.

### 6.4 AI Platform for Chest CT-Scan Analysis

Use case name: AI Platform for Chest CT-Scan Analysis

Model: Cloud services

Scope: Detecting malignant neoplasms (lungs) on chest CT-scans

Objective(s): To facilitate early stage oncology chest CT-scans through the application of the Botkin.AI platform based on artificial intelligence.

Short description: "Botkin.AI" is a software platform for the diagnosis and assessment of pathology risks using artificial intelligence technologies. The product supports radiologists and oncologists, facilitating the analysis and recognition of diagnostic images of CT-scans, digital X-rays and mammography. The project aims to reduce costs and improve diagnostic accuracy, while detecting pathologies at early stages.

Stakeholders: Healthcare authorities

Key Performance Indicators (KPIs)

Accuracy: 93 % detection rate of malignant neoplasm on chest CT-scans (AUC)

Speed: From 4-10 min

Challenges: Achieving a higher confirmed level than accredited radiologists in the detection of lung cancer

### 6.5 Support system for optimization and personification of drug therapy

Use case name: Support system for optimization and personification of drug therapy

Model: On premise system