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| **Abstract:** | This document describes the topics to be addressed in the forthcoming Deliverable 5.3 "Data Annotation Specification". Data annotation would be one of the most dependable factors on model performance, it serves as one important aspect of data quality control on Artificial Intelligence for health. This document is committed to give a general guideline of data annotation specification, including definition, background and goals, framework, standard operating procedure, scenario classifications and corresponding criteria, as well as recommended metadata, etc. A questionnaire is attached to seek input and collaboration with topic groups in FG-AI4H regarding data annotation. Rev.1 resolves the review questions from the secretariat. |

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|  |  |
|  | **FG AI4H Deliverable 5.3Data annotation specification** |
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Summary

This document describes the topics to be addressed in the forthcoming deliverable "DEL05-A03: Data Annotation Specification". Data annotation is one of the most dependable factors on model performance, it serves as an important aspect of data quality control on Artificial Intelligence for health. This document is committed to give a general guideline of data annotation specification, including definition, background and goals, framework, standard operating procedure, scenario classifications and corresponding consistency criteria, as well as recommended metadata, etc. A questionnaire is attached to seek input and collaboration with topic groups in FG-AI4H regarding data annotation.

Keywords

Data Annotation, standard operating procedure, consistency criteria, metadata

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FG AI4H Deliverable 5.3

Data annotation specification

# Scope

This initial draft describes the topics to be addressed in the forthcoming deliverable "DEL05-A03: Data Annotation Specification" and help seed future content. This document is committed to give a framework of data annotation specification for different stakeholders to develop and implement AI-based tools in advancing healthcare.

# Reference

The following ITU-T Recommendations and other references contain provisions, which, through reference in this text, constitute provisions of this Recommendation. At the time of publication, the editions indicated were valid. All Recommendations and other references are subject to revision; users are therefore encouraged to investigate the possibility of applying the most recent edition of the Recommendations and other references listed below. A list of the currently valid ITU-T Recommendations is regularly published.

The reference within this document does not give it, as a stand-alone document, the status of a Recommendation.

[ISO/IEC 2382:2015] ISO/IEC 2382:2015, Information technology — Vocabulary

[IEC 62304] IEC 62304:2006 + A1:2015, "Medical device software – Software life cycle processes"

[IEC 82304] IEC 82304-1 Health software – Part 1: General requirements for product safety

[FDA] FDA's "Proposed Regulatory Framework for Modifications to Artificial Intelligence / Machine Learning (AI/ML) Based Software as Medical Device

[NMPA] Key Points for the Review and Evaluation of Deep Learning Based Software as Medical Device

# Definitions

## Terms defined elsewhere

This document uses the following terms defined elsewhere:

**3.1.1 Artificial intelligence** [ISO/IEC 2382:2015]: 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.

**3.1.2 Machine learning** [ISO/IEC 2382:2015]: automatic learning, process by which a functional unit improves its performance by acquiring new knowledge or skills, or by reorganizing existing knowledge or skills.

**3.1.1 Medical device** [GHTF/SG1/N71:2012]: Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: a) diagnosis, prevention, monitoring, treatment or alleviation of disease, b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury, c) investigation, replacement, modification, or support of the anatomy or of a physiological process, d) supporting or sustaining life, e) control of conception, f) disinfection of medical devices, g) providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

**3.1.4 Software as a medical device** [IMDRF/SaMD WG/N12FINAL:2014]: Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device

## Terms defined in this document

This document defines the following terms:

**3.2.1 Controlled vocabulary:** an organized arrangement of words and phrases used to index content and to retrieve content through browsing or searching.

**3.2.2 Data annotation:** process of labelling data by humans usable for supervised machines learning.

**3.2.3 Metadata:** data that provides information about other data.

**3.2.4 Supervised learning:** the [machine learning](https://en.wikipedia.org/wiki/Machine_learning) task of learning a function that maps an input to an output based on example input-output pairs.

**3.2.5 Unsupervised learning:** a type of machine learning that looks for previously undetected patterns in a data set with no pre-existing labels and with a minimum of human supervision.

# Abbreviations and acronyms

This document uses the following abbreviations and acronyms:

|  |  |
| --- | --- |
| AI | Artificial Intelligence |
| AI4H | Artificial Intelligence for health |
| FG-AI4H | Focus Group on Artificial Intelligence for health  |
| ML | Machine Learning |
| SOP | Standard operating procedure |

# Background and goals

The great potential of digital technologies, especially Machine Learning (ML) and Artificial Intelligence (AI) are recognized to revolutionize the fields of medicine and public health in an unprecedented manner. While holding great promise, this rapidly developing field raises a number of uncertainties, for example if the model is poorly designed or the underlying training data are biased or incorrect, errors or problematic results can occur. AI technology can only be used with complete confidence if it has been quality controlled through a rigorous evaluation in a standardized way. Among all the quality controls, the data annotation would be one of the most dependable factors on model performance. In the case of mislabeled or inaccurate training instances, it is difficult for the supervised model to obtain the expected results.

Quality control on data annotation is a factor that is easily overlooked but crucial to the model performance. It is especially critical to models based on large-scale dataset. Therefore, this addresses the following:

* Assist the quality control of data annotation from standard operating procedure
* Reduce model performance problems caused by inconsistent data annotations
* Enable large-scale dataset projects on high diversity of data formats and multi-annotators.
* Act as a training material for non-professional annotators and improve common understandings.

# Framework

Data annotation is one of the most dependable factors on the performance of supervised machine models. If the annotation for machine learning is incorrect, then the decision rules built by the machine are also biased. As a part of the entire AI for Health project, data annotation works as shown in Figure 1.

With the help of annotators and annotation tools, a standard operating procedure of data annotation can convert input dataset into qualified annotations for supervised machine learning. This standard operating procedure will be discussed in clause 7 in details.

The information from the data annotation process and the raw dataset can be used for training dataset for supervised machine learning and optimization, as well as testing dataset for the evaluation process. Therefore, data annotation has a very close relationship to the above core process of AI for health model, as a result, recognized as one of the most dependable factors on the model performance.



Figure 1: Framework of data annotation and external relations

# Standard operating procedure

To establish a unified understanding and quality control mechanism, a standard operating procedure is recommended. Figure 2 illustrates a formulated process of data annotation, with much feasibility through variables and configurable threshold.



Figure 2: Data annotation procedure

## Independent annotation

The data annotation process starts with independent annotation, represented by the left grey box in figure 1. To avoid bias in data distribution, it is suggested that the process is carried out by grouping and crossing, and ensure the effective resolution of inconsistencies. Several annotators (represented as variable n in the figure) are invited to label the raw dataset. Certain qualifications are required on the annotators, for example doctors/ trained annotators in specific case domain.

However, for cost considerations, some projects will also set up one annotator (Set n to 1) in this parallel independent annotation part, and then goes to arbitration if encounter difficulties.

## Arbitration

In the above independent annotation part, if there is an inconsistency that can be acceptable, or difficulties/‌uncertainties in single annotator setting, additional annotator with more experience should be introduced for the arbitration, represented by the upper right grey box in figure 1. Stricter requirements on annotator qualifications, for example, doctor with more than 3 years of experience in the case domain.

## Expert Reviewing

The expert reviewing is represented by the lower right grey box in figure 1. This final review deals with some very tricky cases which cannot reach an agreement on the previous steps. Annotations confirmed by review experts will be marked as a final answer, and cases not approved could be considered to send back to arbitration process and arbitrated by another arbitration expert. Stricter requirements on annotator qualifications, for example, with 5 years of experience or more.

## Decision making box

Represented by the blue boxes in figure 1, the judgment and decision making on labelling consistency cannot be avoided anywhere in the independent annotation, arbitration and expert reviewing. The simple mechanism should be: If the consistency is up to the threshold, the annotation shall be saved with confidence; If the consistency is not up to the threshold, the annotation will be discarded. Therefore, the criteria of consistency and corresponding threshold should be identified, and they are usually designed according to different scenarios, with more details in clause 8.

## Annotators training and assessment

With the continuous popularity of the AI4H model afterwards, we may expect a future with more mature and extensive mechanisms for annotators engagement. In addition to the experienced doctors mentioned above, candidates with no professional qualification but well-trained and quantitative assessed are also possible to be invited in the process of data annotation. This will reduce the cost and barriers of data annotation and provide more employment opportunities to the society.

The training and assessment of annotators may include the following ways:

* Gold standard materials: Data annotation made by review experts or arbitration groups can be seen as gold standards, a unified document with examples can be developed as reference to teach candidates to how to achieve the tasks.
* Training courses: In addition to paper documents, training courses is also an effective way to educate candidates and reach a common understanding on data annotation tasks, especially in large-scale dataset and very many annotators.
* Quantitative assessment: To evaluate the performance of different annotators, examinations and certificates can be conducted. For example, set up a gold standard dataset, and let each candidate labels 20 samples randomly, and calculate the Kappa value compared with the gold standard. Only after the Kappa value reaches a certain threshold, candidate can be assigned to the annotation tasks.

## Variable description

Variables and configurable threshold in this procedure are listed here for your convenience.

* Number of independent annotators
* Number of arbitration experts
* Number of review experts
* Different options on consistency criteria (usually the same in 7.1-7.3)
* Configurable threshold on consistency criteria in the independent annotation
* Configurable threshold on consistency criteria in the arbitration
* Configurable threshold on consistency criteria in the expert reviewing

# Consistency judgement

For decision box in Figure 2, different criteria on consistency is selected according to different application scenarios. Main considerations are from two perspectives: one is input data type, elaborated in clause 8.1; the other is the output requirement for Ai for health models, elaborated in clause 8.2. Under these two different classification dimensions, the options on consistency criteria will be different, elaborated in clause 8.3.

## Input data type classification

AI for health models often have a diversified input according to the application scenarios, the input data can be medical image, video, audio/ signal, text, single number, etc. Description and examples are given in Table 1.

Table 1: Input data types

| Data | Description | Examples |
| --- | --- | --- |
| Image | Two-dimensional medical imaging | * Fundus photos
 |
| 3D images | Three-dimensional spatial imaging  | * Sets of CT slices
 |
| 4D | 3D space imaging changes over time | * Heart film imaging
 |
| Video  | Camera or monitor recording | * Falls among the elderly
 |
| Audio/ signal | Sound or transmitted in signal form. | * Heart sound /ECG
 |
| Text | Structured/ unstructured description in words | * Case history, diagnosis extraction
 |
| Single number | Single measurement data | * Blood pressure or respiratory rate
 |
| <TBD> | <TBD> | <TBD> |

## Output requirement classification

When the final output requirements of models are different, even if it is the same input data format, data annotations will be different. Different output requirements include classification, detection, segmentation, prediction/ regression, etc. Corresponding description and examples are given in Table 2.

Table 2: Output requirements

| Task | Description | Examples |
| --- | --- | --- |
| * Classification
 | * the problem of classifying instances into two or more classes.
 | * Identify abnormal tissue
* Diabetic retinopathy grade
 |
| * Detection
 | * identify an object, usually marked with rectangle for further processing.
 | * Detect the position of a coronary plaque for further processing.
 |
| * Segmentation
 | * separate certain lesions, and draw the specific outline of the lesion
 | * Tumour segmentation
 |
| <TBD> | <TBD> | <TBD> |

## Criteria option matrix

With the above two dimensions, a matrix can be developed according to different data input format and model output requirements. This matrix can act as a reference for the selecting criteria options. Details are shown in Table 3, and other scenarios are to be added to cover all possible use cases in the FG and the Ai for health industry.

Table 3 Criteria options in different scenarios

|  TaskData type | Classification | Detection | Segmentation |
| --- | --- | --- | --- |
| * Image
 | Type 1: Classification | Type 2: Detection and segmentation for images |
| * 3D images
 | <TBD> | <TBD> |
| * 4D
 | <TBD> | <TBD> |
| * Video
 | <TBD> | <TBD> |
| * Audio/ signal
 |  |  |
| * Text
 |  |  |
| * Single number
 |  |  |
| <to be added> |  |  |  |

Type 1: Classification

For this type, criteria like Cohen's kappa, Weighted kappa, Fleiss' kappa and Krippendorff's alpha are recommended to use for classification tasks. The detailed calculation methods are shown in Table 4.

* Cohen's kappa: Cohen's kappa coefficient (κ) is a statistic that is used to measure inter-rater reliability for qualitative items. It is generally thought to be a more robust measure than simple percent agreement calculation, as κ takes into account the possibility of the agreement occurring by chance.
* Weighted kappa: allows disagreements to be weighted differently, and is especially useful when codes are ordered. Three matrices are involved, the matrix of observed scores, the matrix of expected scores based on chance agreement, and the weight matrix.
* Fleiss' kappa: Fleiss' kappa is a statistical measure for assessing the reliability of agreement between a fixed number of raters when assigning categorical ratings to a number of items or classifying items. This contrasts with other kappas such as Cohen's kappa, which only work when assessing the agreement between not more than two raters or the interrater reliability for one appraiser versus themself.
* <TBD>

Type 2: Detection and segmentation for images

For this type, criteria like Jaccard index and Dice's coefficient are recommended to use for detection and segmentation for images. Detailed calculation methods are shown in Table 5.

* The Jaccard index: also known as Intersection over Union (IoU) and the Jaccard similarity coefficient, is a statistic used for gauging the similarity and diversity of sample sets.
* Dice's coefficient: is the quotient of similarity and ranges between 0 and 1.This coefficient is not very different in form from the [Jaccard index](https://en.wikipedia.org/wiki/Jaccard_index), and they have a connection as J=D/(2-D)，D=2J/(1+J)

Type 3: <TBD>

Table 4: Criteria calculation for classification

| Criteria | Situation | Calculation method | Parameter explanation |
| --- | --- | --- | --- |
| Cohen's kappa | Assessing the agreement between not more than two raters or the interrater reliability for one appraiser versus themself | If the raters are in complete agreement then kappa =1; If there is no agreement among the raters other than what would be expected by chance kappa =0. It is possible for the statistic to be negative which implies that there is no effective agreement between the two raters or the agreement is worse than random. | where po is the relative observed agreement among raters (identical to accuracy), and pe is the hypothetical probability of chance agreement, using the observed data to calculate the probabilities of each observer randomly seeing each category |
| Weighted kappa | Allows disagreements to be weighted differently, and is especially useful when codes are ordered. |  | where k is the number of codes and , , and are elements in the weight, observed, and expected matrices, respectively. The weights in the diagonal cells are all 1 (i.e., , for all i), and the weights in the off-diagonal cells range from 0 to <1 (i.e., , for all ). |
| Fleiss' kappa | Assessing the reliability of agreement between a fixed number of raters when assigning categorical ratings to a number of items or classifying items. | If the raters are in complete agreement, then Fleiss' kappa =1. If there is no agreement among the raters (other than what would be expected by chance) then Fleiss' kappa <0. | The factor gives the degree of agreement that is attainable above chance, and gives the degree of agreement actually achieved above chance.  |
| <TBC> | <TBC> | <TBC> | <TBC> |

Table 5: Criteria calculation for Image detection and segmentation

| Criteria | Calculation method | Graphical representation |
| --- | --- | --- |
| Jaccard index | Numerator represents the area of overlap between two annotations; Denominator represents the area encompassed by two annotations. Dividing the area of overlap by the area of union yields our final score. | J=D/(2-D)，D=2J/(1+J) |
| Dice's coefficient | Numerator represents the double area of overlap between two annotations; Denominator represents the sum of two annotation area. Dividing the area of overlap by the sum area yields our final score. |
| <TBD> | <TBD> |  |

## Post-processing of the annotations

After the criteria calculation and consistency judgment, different post-processing methods on annotations that are acceptable as consistent will also cause different result. For example, calculate the average value of the marked results (x, y, w, h) or a maximum area with a consistency above threshold in an image is to be discussed later.

<TBD>

# Recommended metadata

Metadata is considered to be the output of the data annotation process, all necessary information for the annotation process should be included in the metadata. A metadata format is to be given as below, more details will be discussed and added in the future.

Table 6 Recommended metadata

| Type | Content |
| --- | --- |
| **General information**  | 1. Institution and responsible or corresponding PI;
2. Construction dates of annotation dataset;
3. Regulatory aspects (e.g. Data privacy)
4. <TBD>
 |
| **Procedure information** | 1. Details on data annotation process (annotator number, experts group setting, tools, etc.)
2. Achieved consistency criteria and threshold configuration
3. Post- processing method on annotations comfited to be consistent
4. <TBD>
 |
| **Sample information** | 1. Sample identification code
2. collection device model
3. collection frame rate/ Sampling rate
4. hospital, patient information (age, gender, race)
5. <TBD>
 |
| Label information |  TaskData type | Classification | Detection | Segmentation |
| * Image
 | <TBD> | <TBD> | <TBD> |
| * 3D images
 | <TBD> | <TBD> |
| * 4D
 | <TBD> | <TBD> |
| * Video
 | <TBD> | <TBD> |
| * Audio/ signal
 |  |  |
| * Text
 |  |  |
| * Single number
 |  |  |
| <to be added> |  |  |  |

Annex A
Questionnaire on data annotation

**By Google Form:** [**https://forms.gle/3fYrm3SZSrNQu3eeA**](https://forms.gle/3fYrm3SZSrNQu3eeA)

The aim of this questionnaire is to gather insights into the current practices, the specific requirements of data annotation in the FG-AI4H topic groups and AI4H products.

Your input and suggestion will be of great value for us in forming a data annotation specification together, as one of the deliverables with the FG-AI4H. We would appreciate it if you could take the time to complete the questionnaire, or if you have further ideas, please feel free to contact us. (xushan@caict.ac.cn; sebastian.bosse@hhi.fraunhofer.de)

1．To which topic group are you contributing?

2. Which signal or data modalities are relevant for your project with the topic group? (image, video, audio/ signal, text, single number, etc.）

3. Which annotation task category is relevant for your project within the topic group? (classification, detection, segmentation, prediction/ regression, etc.)

4.What is the nature of the annotation? (point, line, number, area, class label, etc.)

5. Which additional information do you need to encode the actual meaning of the annotation?

5. What kind of annotation procedure are you using? Which tool do you use?

6. What annotation quality criterions are currently used in your topic group? (Cohen's kappa, Weighted kappa, Fleiss' kappa, Krippendorff's alpha, Jaccard index and Dice's coefficient, etc.)

7. What annotation quality criterions do you consider promising and worth to be investigated for your topic group?

8. How do you train and select annotators?

9. How do you ensure annotation quality during the annotation process?

10. What kind of metadata do you consider relevant for your project? (options in Table 6)

11.What type of ontology are you using? (If any)

Annex B
Data Annotation tools

**Provide some data annotation tools for reference**

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