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Brief introduction of IEEE AIMDWG

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IEEE Artificial Intelligence Medical Device Working Group

[P2801:Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence]

[P2802: Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology]

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IEEE AIMDWG

- Approved on Dec-05-2018
- Two projects are under development
  - P2801: Recommended Practice for the Quality Management of Datasets for Medical Artificial Intelligence
  - P2802: Standard for the Performance and Safety Evaluation of Artificial Intelligence Based Medical Device: Terminology

General consideration for standardization of AIMD

- Safety and effectiveness

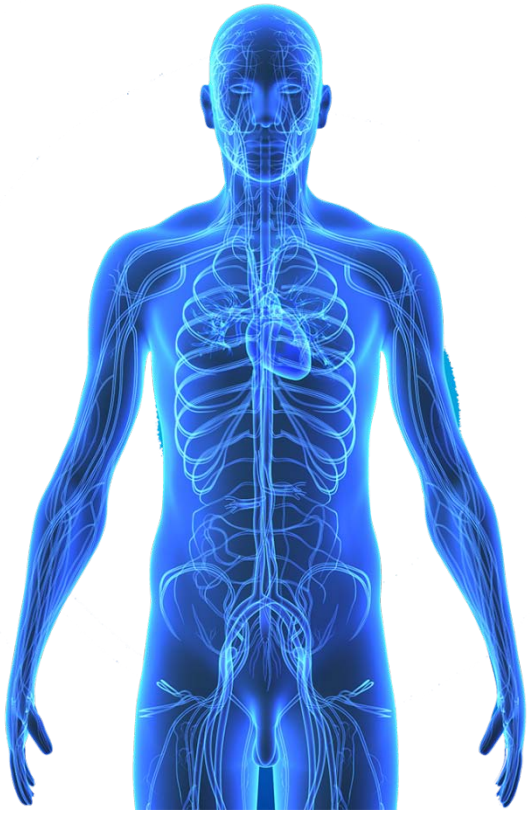
- Quality service

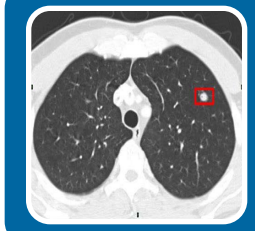
Quality management of datasets for AIMD

P2801

Background

- The development of AIMD is driven by datasets.



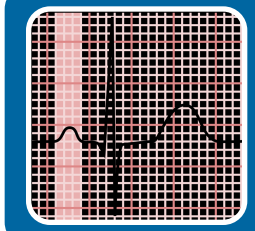


Radiology

- LIDC, Chest X, NCI, etc.
- Bone Age images(RSNA)

Ophthalmology

- EyePACS, Messidor, etc.
- Google



Electrophysiology

- MIT-BIH
- P300 interface dataset

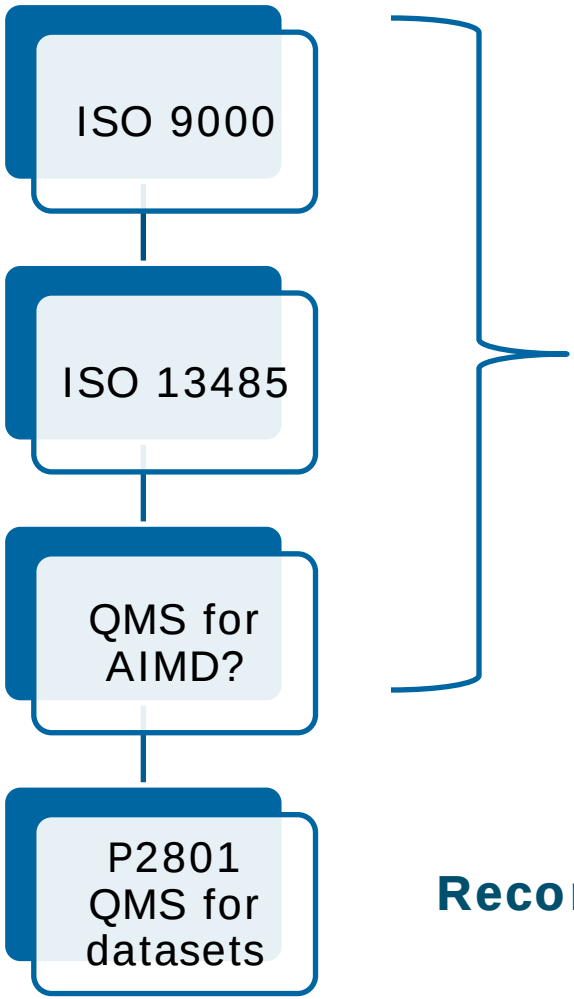
Background

- Third-party sequestered data sets are used to test AI performance
- There is increasing need to build datasets
- The “dataset industry” is the upstream of AIMD industry.
  - The quality of dataset may have significant impact on the quality of AIMD

Background

- QMS of dataset is an important component of AIMD QMS
  - Although “dataset” is not medical device, the QMS of dataset for AIMD should follow MD regulation trend.
  - The technical features of AIMD should be reflected
- Purpose of P2801
  - Describe elements that may impact data quality
  - Provide methods to evaluate datasets
- Major question: what is a good dataset?
  - Solid process
  - Good result

Relation to general QMS standards



Standards to certify organizations

Recommended practice to “certify” datasets

Consideration: documentation

- Most existing MD standards have clear requirement for documentation
  - Example: hardware - IEC 60601 series
  - Example: software - IEC 62304 series
- Question: how to describe a dataset properly

Description

Context

The diagnosis of blood-based diseases often involves identifying and characterizing patient blood samples. Automated methods to detect and classify blood cell subtypes have important medical applications.

Content

This dataset contains 12,500 augmented images of blood cells (JPEG) with accompanying cell type labels (CSV). There are approximately 3,000 images for each of 4 different cell types grouped into 4 different folders (according to cell type). The cell types are Eosinophil, Lymphocyte, Monocyte, and Neutrophil. This dataset is accompanied by an additional dataset containing the original 410 images (pre-augmentation) as well as two additional subtype labels (WBC vs WBC) and also bounding boxes for each cell in each of these 410 images (JPEG + XML metadata). More specifically, the folder 'dataset-master' contains 410 images of blood cells with subtype labels and bounding boxes (JPEG + XML), while the folder 'dataset2-master' contains 2,500 augmented images as well as 4 additional subtype labels (JPEG + CSV). There are approximately 3,000 augmented images for each class of the 4 classes as compared to 88, 33, 21, and 207 images of each in folder 'dataset-master'.

Acknowledgements

https://github.com/Shenggan/BCCD_Dataset MIT License

VS

The Lung Image Database Consortium (LIDC) and Image Database Resource Initiative (IDRI): A Completed Reference Database of Lung Nodules on CT Scans

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Two paragraphs

17 page paper

Consideration: QMS requirement

- How to highlight features of AI?

Personnel
- Responsibility
- Role

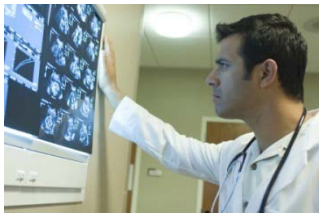
Infrastructure
- Equipment
- Environment

Measurement & Monitoring
- Methodology
- Records

Process control and records
- Annotation
- Maintenance
- Auditing

Quality control
- Testing plan
- Research report
- Auditing report

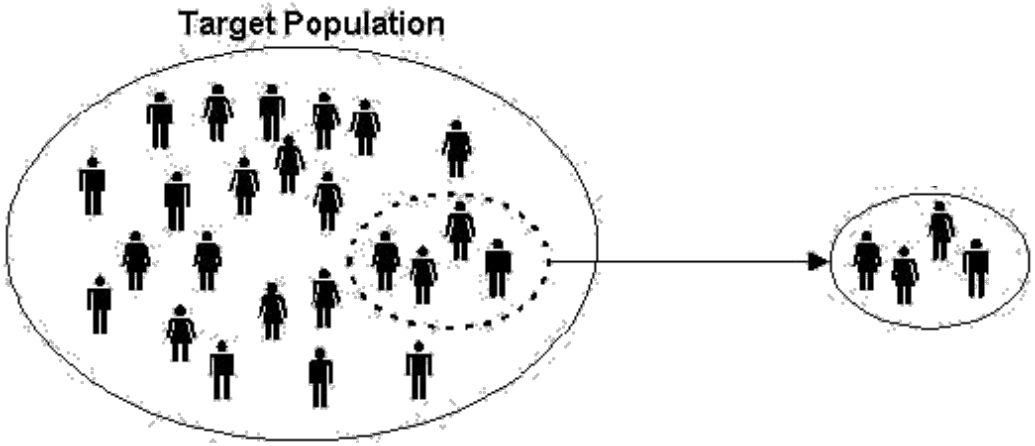
Example: personnel requirement in radiology datasets



- Personnel
  - Medical physicist
    - Professional certification
    - Operation skills
  - Grader
    - Professional certification
    - Training
    - Testing
    - Monitoring

Consideration: quality evaluation

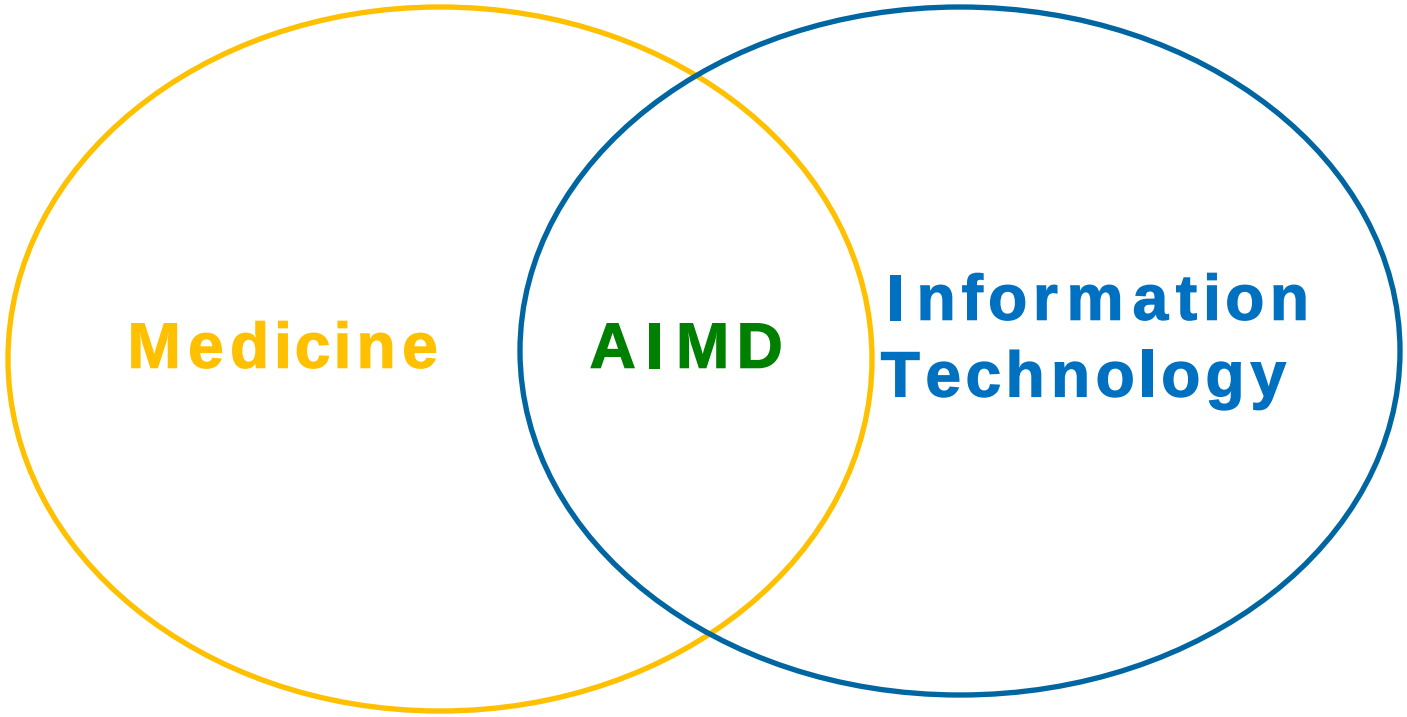
- Inspection methods
- Overall evaluation
- Special consideration



Terminology for evaluation of safety and effectiveness

P2802

Status of terminology for medical AI



Intention to develop AIMD terminology

- New terms are needed to categorize the new intended use of AIMD
- Different parties may be confused with technical terms of AIMD
  - Example: “verification”

In quality management:

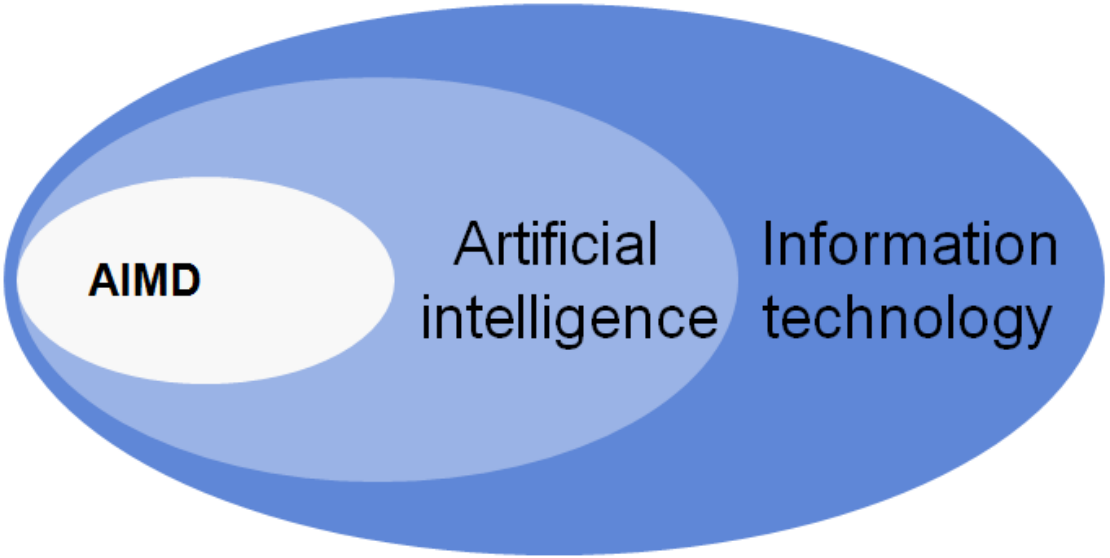
- confirmation, through the provision of objective evidence, that specified requirements have been fulfilled -ISO 9000-2015

In data annotation:

- the confirmation that annotation agrees with gold standard?

Related terminology standards

- ISO/IEC WD 22989 Artificial intelligence -- Concepts and terminology [Under development] （ISO/IEC JTC 1/SC 42）
- ISO/IEC 2382:2015 Information technology – Vocabulary
- Other terminology standards, e.g. IMDRF N41



Consideration: product classification

- General definition
- Intended use
- Technical path

Consideration: dataset related

- Classification of datasets
- Description of process
- Evaluation of datasets

Consideration: product evaluation

- Technical characteristics
- Methodology
- Metrics

Collaboration approaches

Industry

Regulation

Academia

Medicine

Thank you for your attention

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National Institutes for Food and Drug Control