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Artificial Intelligence Medical Device Registration Data and Algorithm Requirements

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Meet the Speaker

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Statistical programmer at IQVIA.

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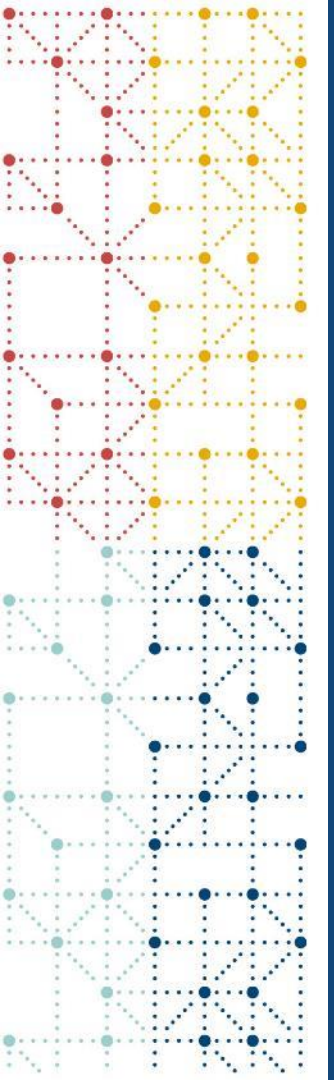
Agenda

1. The concepts and background
2. Current Situation and Development
3. Relevant regulatory guidelines
4. Data and algorithm requirements for registration (China)
5. Summary

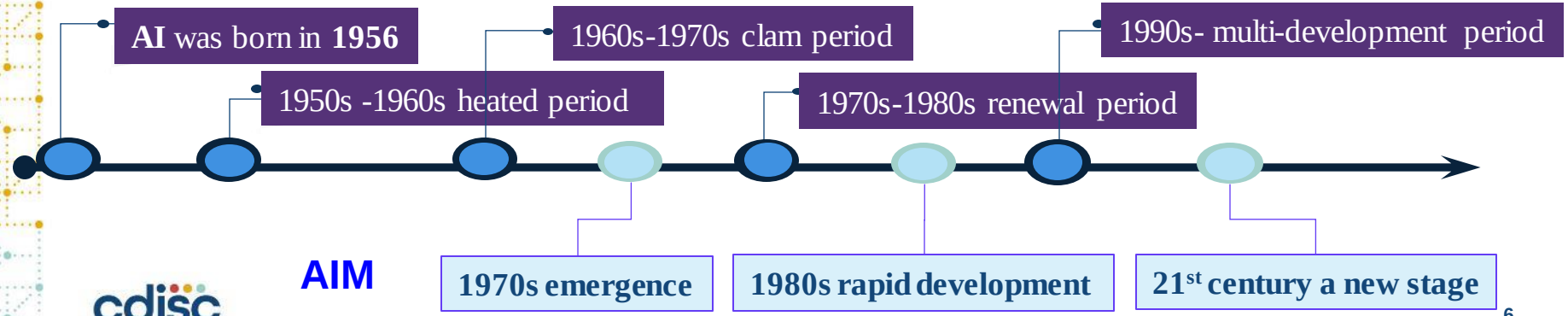


The concepts and background

- The development of AI + medical
- The application of AI in medical fields
- AI medical devices

“Artificial Intelligence in Medicine”

- **Artificial intelligence in medicine (AIM)** is based on the Internet, through the construction of infrastructure and data collection. Health organizations have accumulated vast data sets. AI technologies are well suited to analyze this data and uncover patterns and insights that humans could not find on their own. With deep learning, healthcare organizations can use algorithms to help them make better clinical decisions, improve the service quality and better solve the problem of shortage of medical resources and aging population.



Wu Yazhou, 2022;

Benefits of AIM

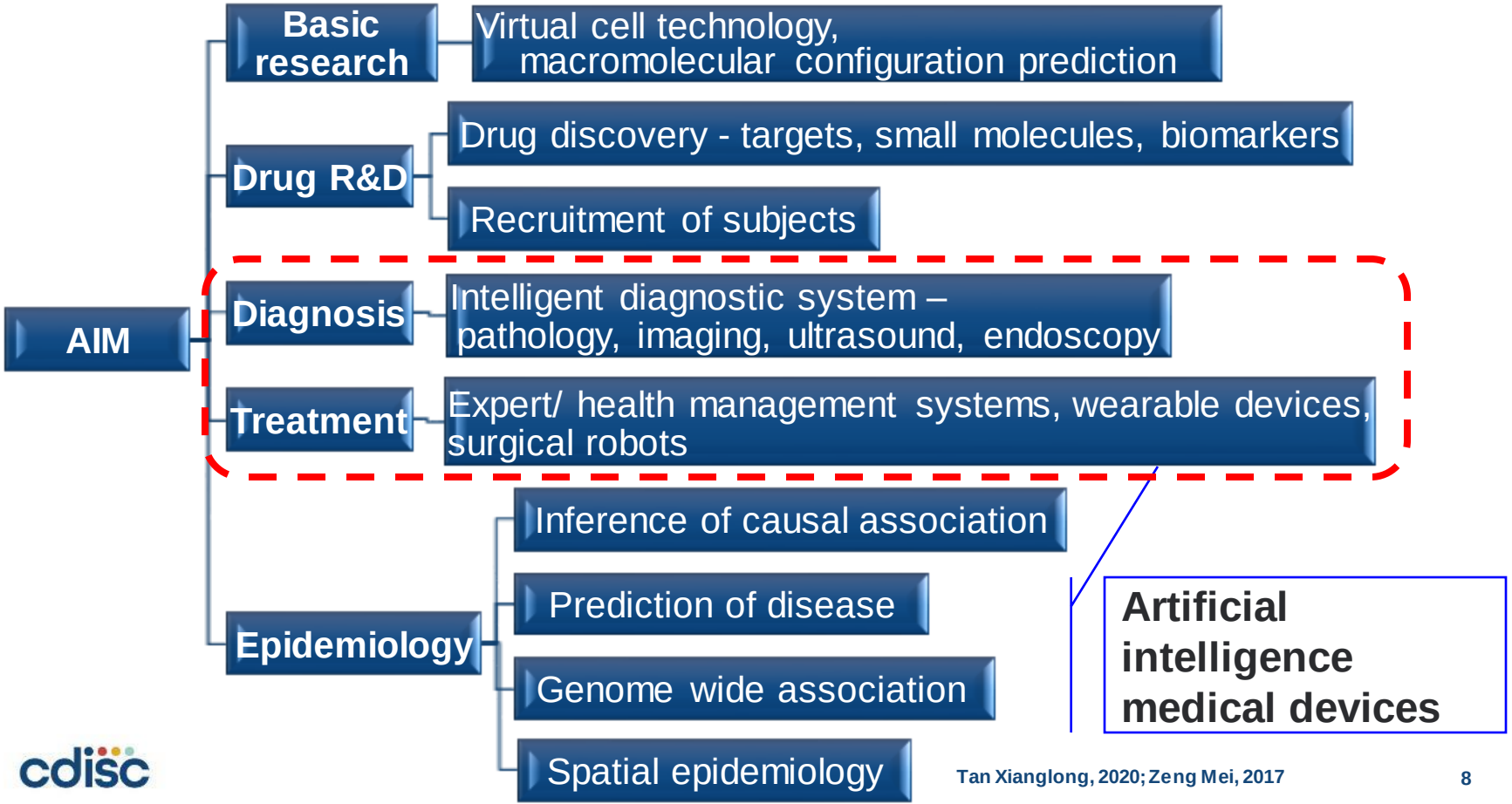
The current health care industry

- Serious imbalance between supply and demand;
- Lack of excellent medical care;
- Imbalance between urban and rural distribution;
- Relatively low medical efficiency.

AIM were created to solve such supply-demand conflicts

- ✓ AI will be a good healthcare providers' assistants;
- ✓ Improve the professional ability of healthcare providers;
- ✓ Improve medical efficiency and standardization of diagnosis and treatment;
- ✓ Enjoy the benefits of technological progress.

Application of AIM



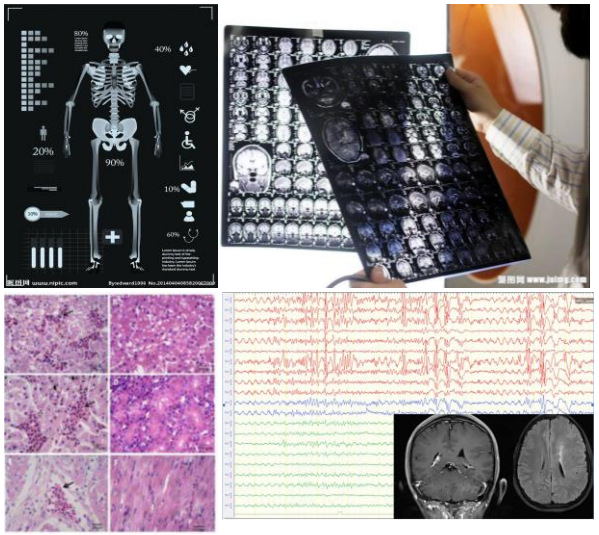
Tan Xianglong, 2020; Zeng Mei, 2017

Key concept

AI medical devices: based on "medical device data" and using artificial intelligence technology to achieve their intended use (i.e., medical use).

Medical device data:

- **Objective data generated by medical device**, such as medical image data (X ray, CT, MRI), physiological parameter data (ECG, EEG), in vitro diagnostic data (pathological images, microscopic images) , etc;
- **Objective data generated by general equipment** (non-regulated objects), such as skin photos taken by digital cameras for skin disease diagnosis, ECG data collected by health electronics for heart disease warning, etc.;
- **Based on medical device data:** including the generation and use of medical device data, Such as patient complaint information, lab examination report, electronic medical record, etc.

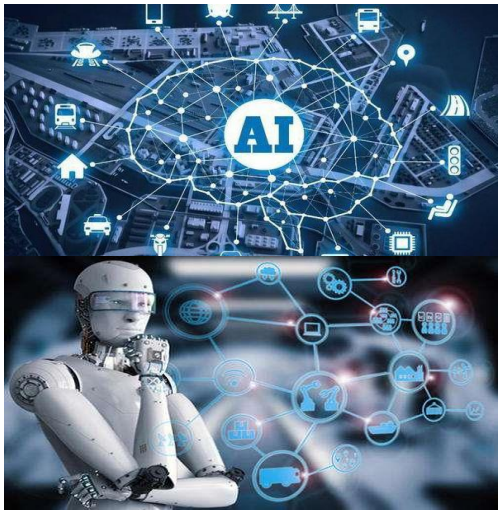


Key concept

AI medical devices: based on "medical device data" and using artificial intelligence technology to achieve their intended use (i.e., medical use).

Artificial intelligence:

- The ability of a machine to exhibit behavior related to human intelligence, is computer software or systems that perform reasonable actions to achieve desired goals by perceiving the situation around them.
- Machine learning refers to AI related to human learning behavior, computer software or systems performance were improved by using existing data and/or capture new data.
- Although machine learning is a subset of artificial intelligence, it is the core field of AI, and the two have the same meaning for medical devices.



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Current Situation and Development

- Research and approval of artificial intelligence medical devices

Annual trends in AI medical device published articles

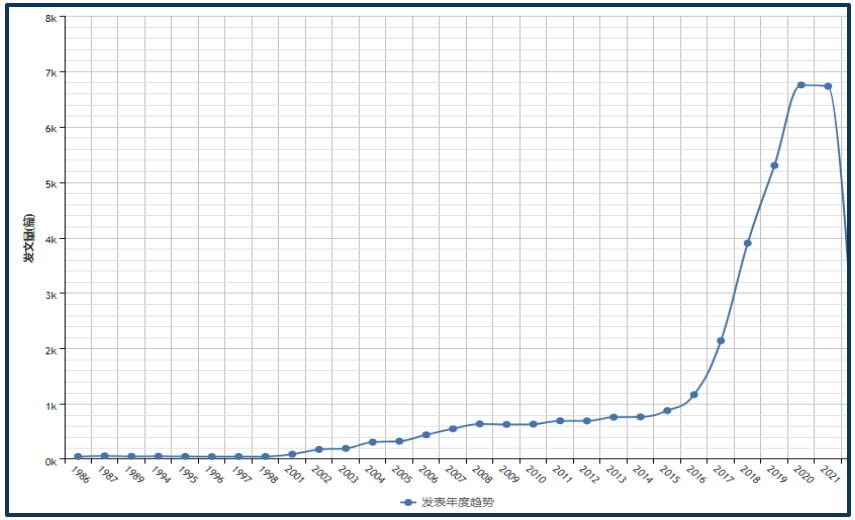


Figure 1. CNKI

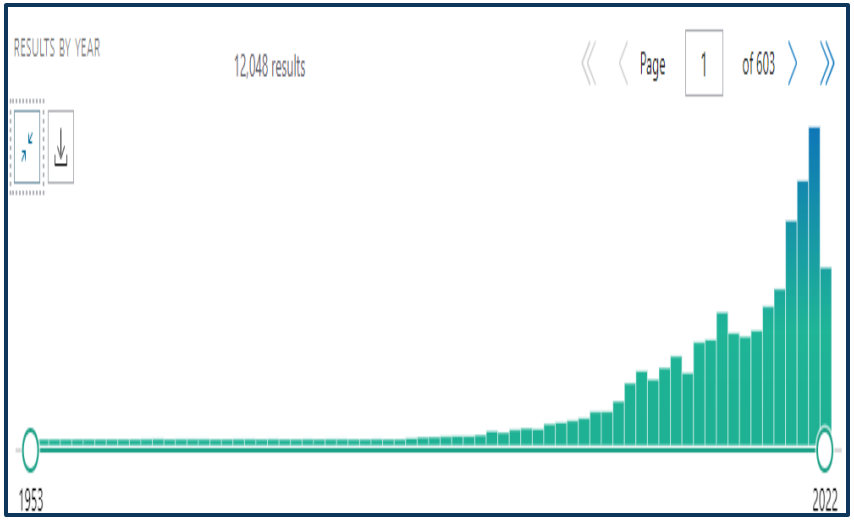


Figure 2. Pubmed

Relevant regulatory guidelines

The guidelines of AI medical device or software

Organizations		
IMDRF	2021.9	Machine Learning-enabled Medical Devices -A subset of Artificial Intelligence-enabled Medical Devices: Key Terms and Definitions
FDA	2017.7	Digital Health Innovation Action Plan
FDA	2019.2	Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback
FDA	2021.1	Artificial Intelligence/Machine Learning (AI/ML)-Based: Software as a Medical Device (SaMD) Action Plan
FDA	2021.9	How is the FDA considering regulation of Artificial Intelligence and machine learning medical devices
FDA	2021.10	Good Machine Learning Practice for Medical Device Development: Guiding Principles
AAMI/BSI	2019	Artificial Intelligence and Machine Learning - the Emergence of Artificial Intelligence and Machine Learning Algorithmsin Healthcare: Recommendations to Support Governance and Regulation
AAMI/BSI	2020	Machine Learning AI in Medical Devices: Adapting Regulatory Frameworks and Standards to Ensure Safety and Performance
NHFPC	2017.2	人工智能辅助诊断技术管理规范（国卫办医发〔2017〕7号） 人工智能辅助诊断技术临床应用质量控制指标（国卫办医发〔2017〕7号） 人工智能辅助治疗技术管理规范（国卫办医发〔2017〕7号） 人工智能辅助治疗技术临床应用质量控制指标（国卫办医发〔2017〕7号）
CMDE	2019.7	《深度学习辅助决策医疗器械软件审评要点》（2019年第7号通告）
CMDE	2020.3	《肺炎CT影像辅助分诊与评估软件审评要点（试行）》（2020年第8号）
CMDE	2021.7	《人工智能医用软件产品分类界定指导原则》（2021年第47号文）
CMDE	2022.3	《人工智能医疗器械注册审查指导原则》（2022年底8号）
AIMDICP	2021.11	《基于眼底彩照的糖尿病视网膜病变辅助决策产品性能指标和测试方法》 《基于胸部CT的肺结节影像辅助决策产品性能指标和测试方法》
NMPA YY/T	2022.7	人工智能医疗器械质量要求和评价第1部分：术语 人工智能医疗器械质量要求和评价第2部分：数据集通用要求
NMPA YY/T	2021.8	人工智能医疗器械质量要求和评价第3部分：数据标注通用要求（征求意见稿） 人工智能医疗器械肺部影响辅助分析软件算法性能测试方法（征求意见稿）

Data and algorithm requirements for registration (China)

- Guideline
- AI classification of medical devices
- Lifecycle of AI medical devices
- Algorithm research report

Published guideline

Guide the applicants to establish the lifecycle of AI medical devices and prepare the application documents for registration. Meanwhile, standardize the technical evaluation requirements and provide inspection reference of AI medical devices.

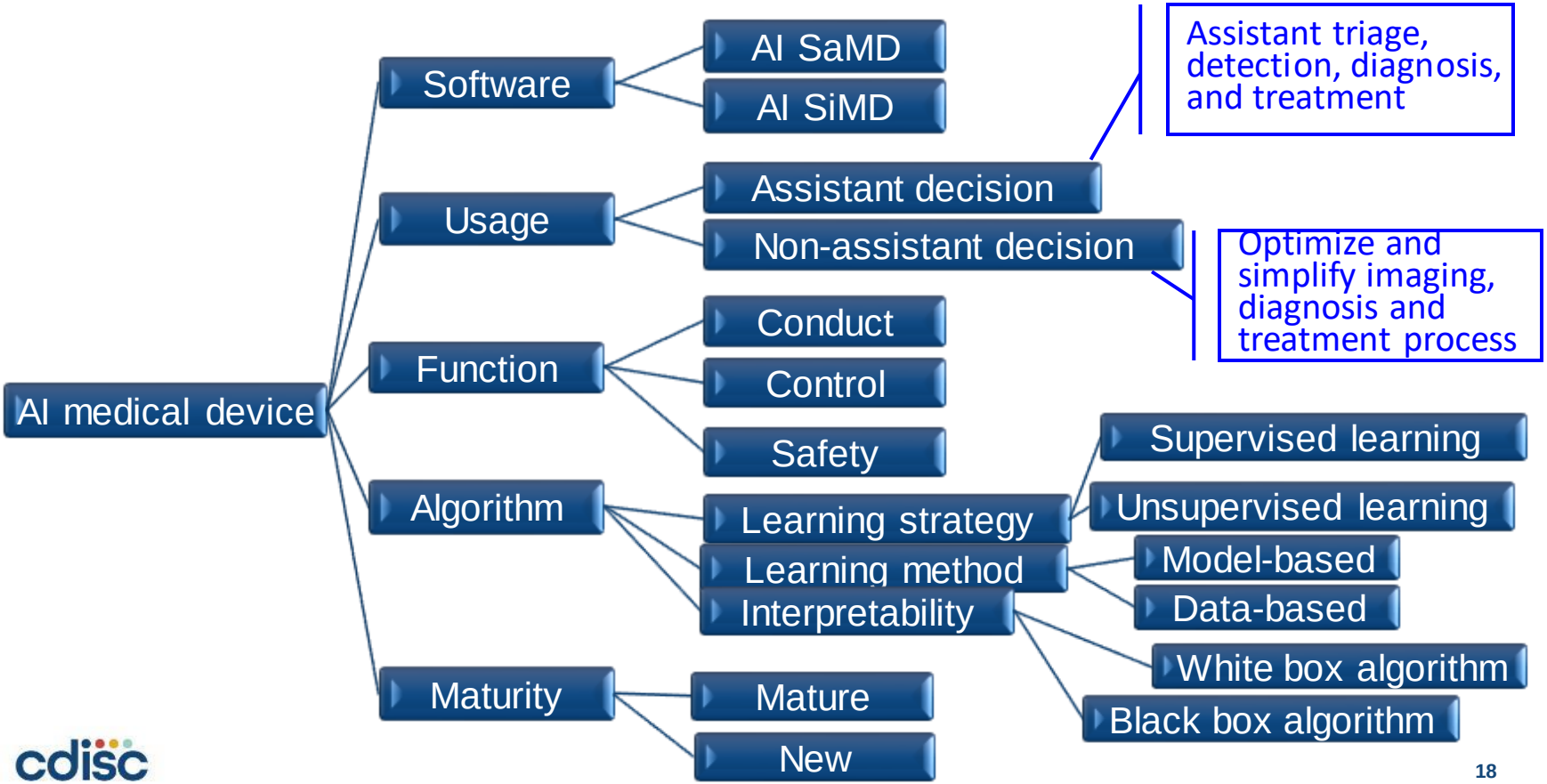
Applicable conditions

Application for registration of AI medical devices, including category II and III AI Software As a Medical Device (SaMD) and AI Software in a Medical Device (SiMD) (including in vitro diagnostic medical devices);

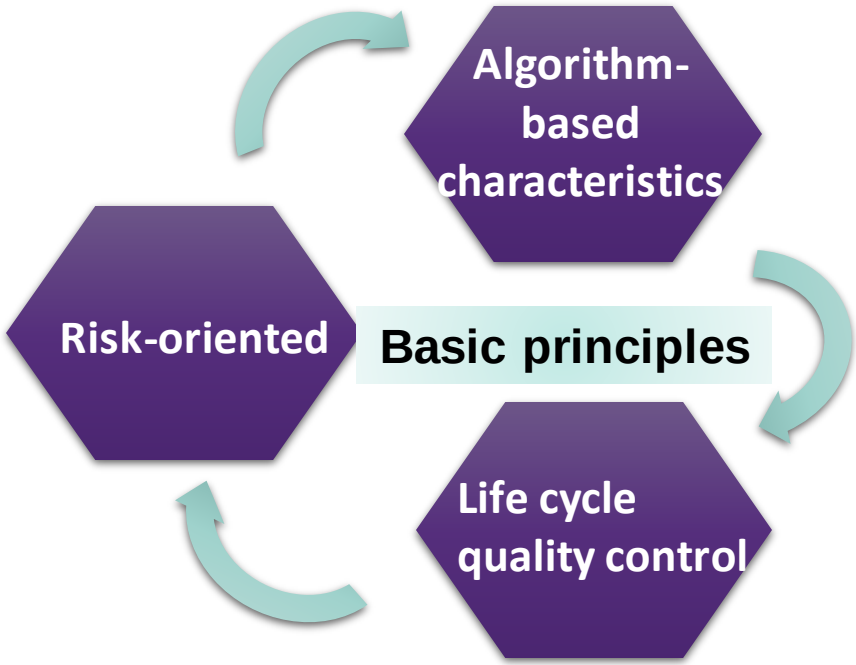
It is applicable to the registration of self-developed software, and software components, not applicable to the external software environment;

It can also be used as reference for inspection of AI medical devices. Quality management software that uses AI may also refer to this guidelines.

Classification of AI medical device

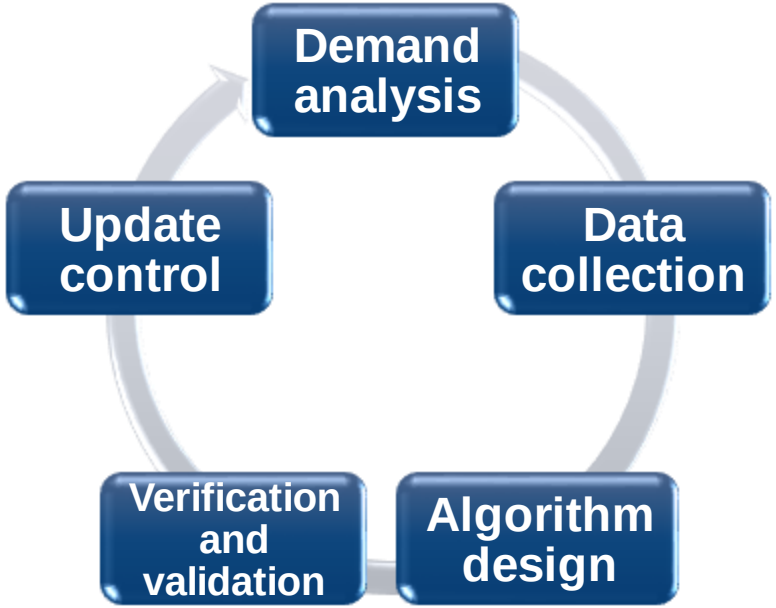


Basic principles of AI medical devices registration



Lifecycle of AI medical devices

Taking supervised deep learning as an example, the quality control requirements for the life-cycle process of AI medical devices includes the following five stages :



Lifecycle of AI medical devices

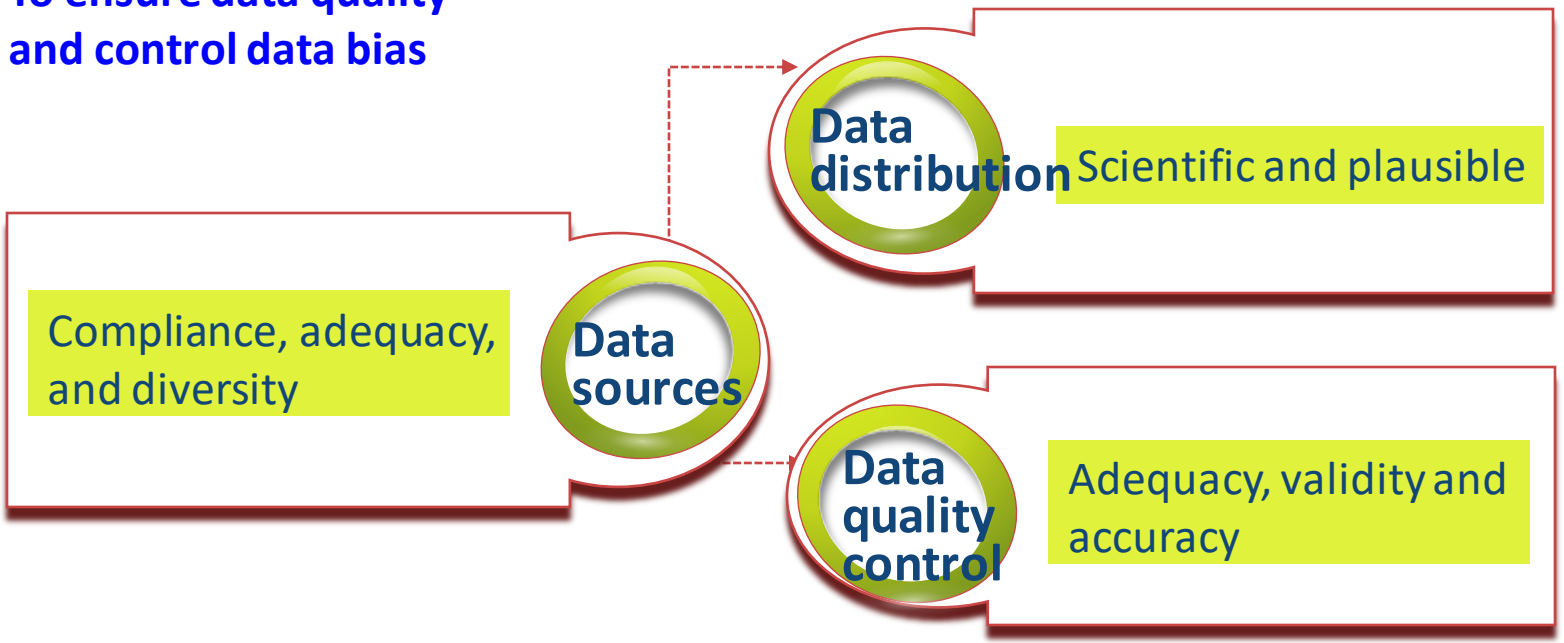
1. Demand analysis:

Based on user requirements, risks and in combination with the intended use, usage scenarios, and core functions of the product, regulations, standards, users, products, data, functions, performance, interfaces, network security, and warnings are comprehensively considered, focusing on data collection, algorithm performance, and usage restrictions.

Lifecycle of AI medical devices

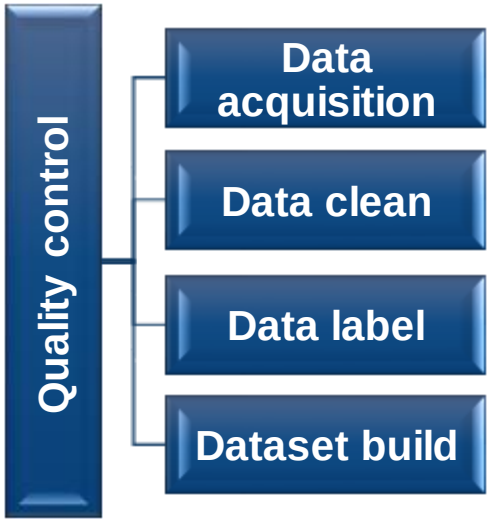
2. Data collection:

To ensure data quality and control data bias



Lifecycle of AI medical devices

2. Data collection:

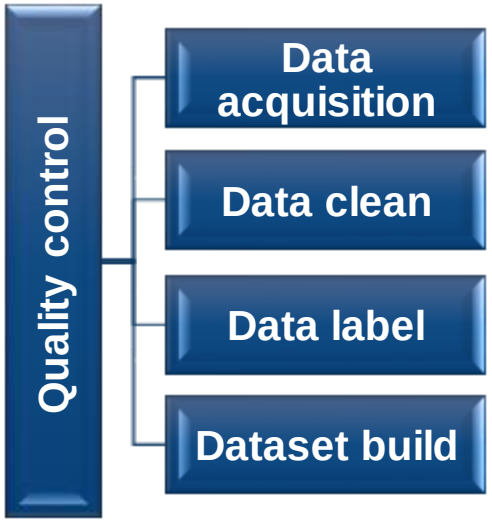


Quality control requirements such as acquisition equipment, acquisition process and data desensitization should be considered, and SOP should be established.

- **Collection device** includes compatibility (name, model, manufacturer, and performance) and collection features (method, protocol, parameters, and accuracy).
- **Collection process** includes personnel management (selection, training and assessment of collectors and auditors), collection process (responsibilities, steps, results review), collection quality (evaluation personnel, methods, indicators, criteria, and recording evaluation results).
- **Desensitization** should be conducted to protect patient privacy (types, rules, methods and the determination basis).

Lifecycle of AI medical devices

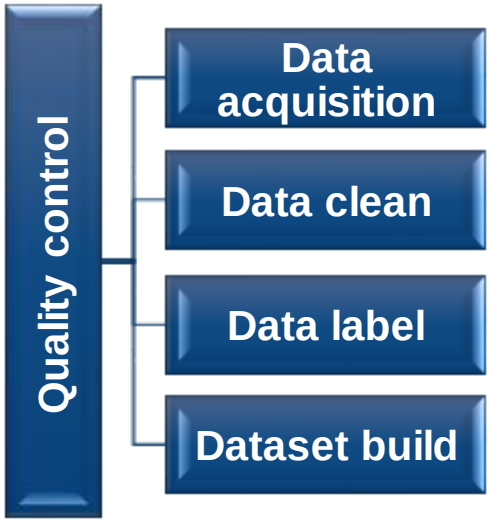
2. Data collection:



- **Raw dataset:** considering data cleaning (rules, methods, results), data preprocessing (methods, results), software tools (name, model specifications, full version, manufacturer, operating environment)
- **Basic dataset:** sample type, total sample size and its reference, sample distribution etc.

Lifecycle of AI medical devices

2. Data collection:



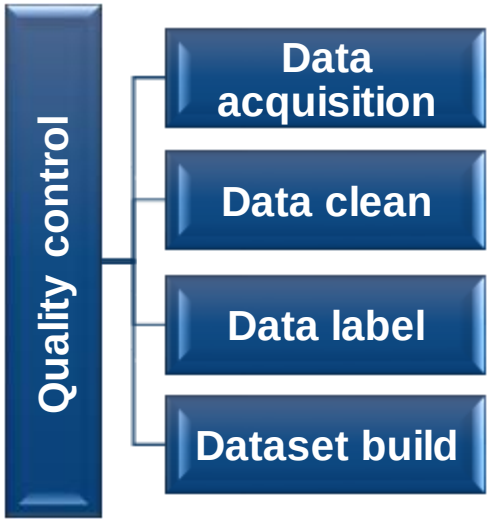
Data label SOP is the key point of supervised learning data quality control

- **Labeling resource management** includes personnel management (selection, training and assessment of label personnel, reviewers and arbitrators) and infrastructure management (site, environmental conditions and software).
- **Labeling process** includes personnel responsibilities, labeling rules, procedures, disagreement handling, traceability.
- **Labeling quality evaluation** includes evaluation personnel, methods, indicators, guidelines, and record the results.

The requirements and risk considerations of the labeled dataset are the same as those of the raw and basic dataset.

Lifecycle of AI medical devices

2. Data collection:



- Training set (algorithm training), tuning set (algorithm hyperparameter tuning) and test set (performance evaluation) will be constructed based on labeled dataset, clarifying allocation method, basis and ratio.
- **Sample distribution:** balanced distribution of training set, and actual distribution of test set and tuning set; these set should have no intersection.
  - training set and tuning set √
  - test set X
- The object, range, method, and multiple of amplification should be clearly defined, and the risk of data bias should be considered.
- **Comparing the differences** between the amplification dataset and the labeled dataset in sample size and distribution (indicate the amplification multiple) to confirm the adequacy and rationality of the amplification dataset.

Lifecycle of AI medical devices

3. Algorithm design

- **Algorithm selection:** the name, type, structure, input and output data types, flow charts, algorithm programming framework, operating environment and other basic information of the algorithm used, and the basic principles of algorithm selection.
- **Algorithm training:** evaluation indicator, method, objective, tuning method, training data and evaluation index curve should be considered.
- **Algorithm performance evaluation:** an important part of software validation. Evaluating the result of the algorithm based on the test set, considering false negative/positive, repeatability and reproducibility, robustness etc.

Lifecycle of AI medical devices

4. Verification & validation

- **Software verification:** Confirming that the output of software meets the input requirements, including software verification test and review to ensure the safety and effectiveness of software is the basis for software validation.
- **Software validation:** Confirming that the software meets user needs and expected purposes by providing objective evidence, including software validation test, clinical evaluation, review etc.
- In principle, non-auxiliary decision-making and auxiliary decision-making medical devices with new functions, algorithms and uses need to be **clinically tested.**

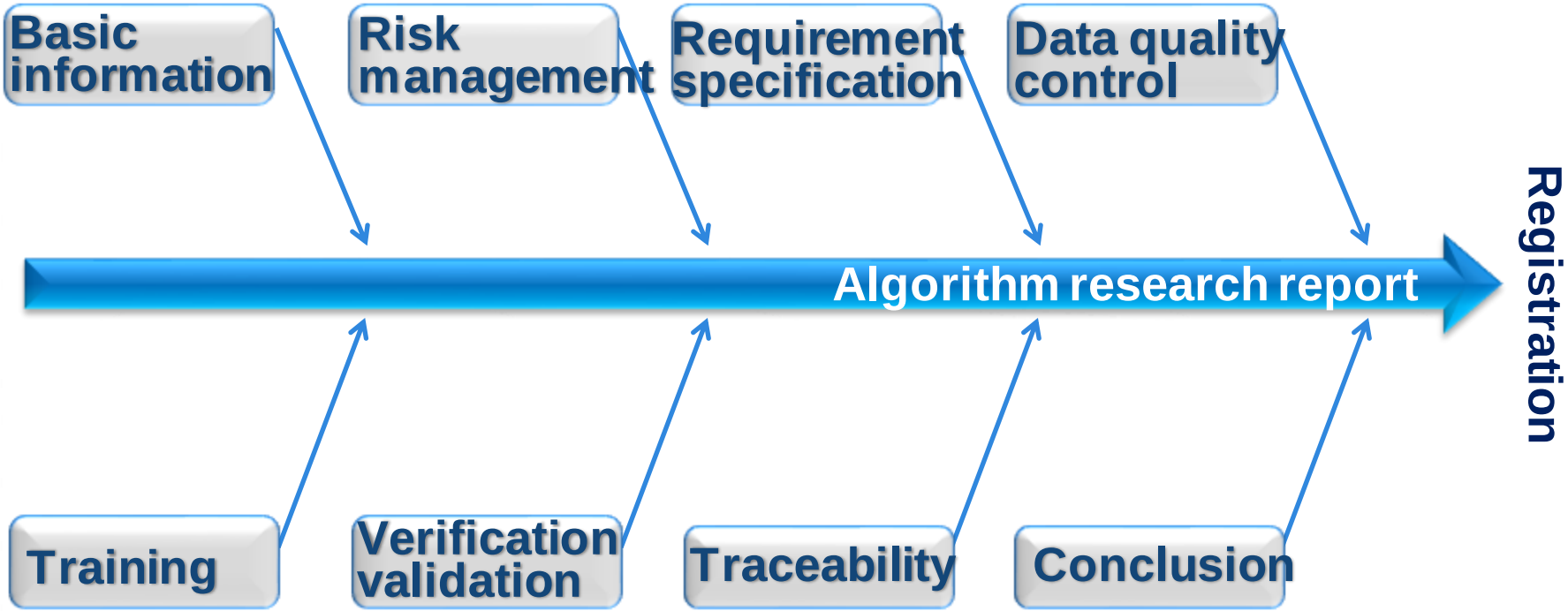
Lifecycle of AI medical devices

5. Update control

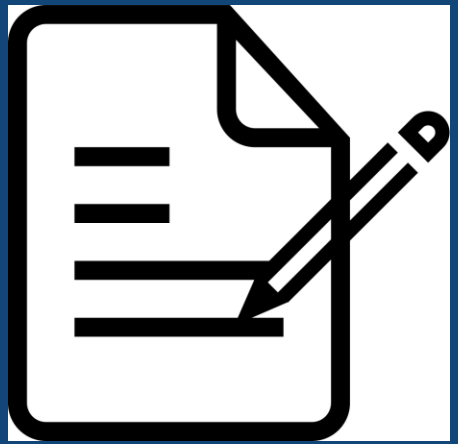
In case of algorithm and software updates,

- ✓ Verification and validation should be carried out in accordance with the requirements of the quality management system.
- ✓ Risk management and traceable analysis should be carried out throughout the whole update process to form records for system verification.

Algorithm research report



Summary



Summary

- The development of AIM is soaring, as well as that of AI medical devices;
- Paying attention to relevant guidelines can improve R&D efficiency;
- The registration review focuses on the characteristics of AI;
- Algorithm is the core of AI;
- Clinical trial content is slightly less, concentrating on verification and validation.

Thank You!