



**Global Harmonization Working Party**  
GHWP Towards Medical Device Harmonization





# Regulatory Progress of Medical Device Digital Health in CHINA

Center for Medical Device Evaluation, NMPA,  
CHINA  
2023.11





# Topic Agenda

-  **1 General Consideration**
-  **2 Terminology**
-  **3 Guideline System**
-  **4 Regulatory Focus**



## Definition:

- ✓ Cross fusion of information and communication technology (ICT) and medical devices (MD) based on computer technology



## Scope:

- Medical Device Software
- Medical Device Cybersecurity
- Mobile Medical Device
- AI & ML Medical Device
- Digital Therapeutics
- VR & AR



## Regulatory Method:

Total lifecycle regulation based on software safety class



*Minor*

Unlikely to cause harm



*Moderate*

May directly or indirectly cause slight (not serious) harm

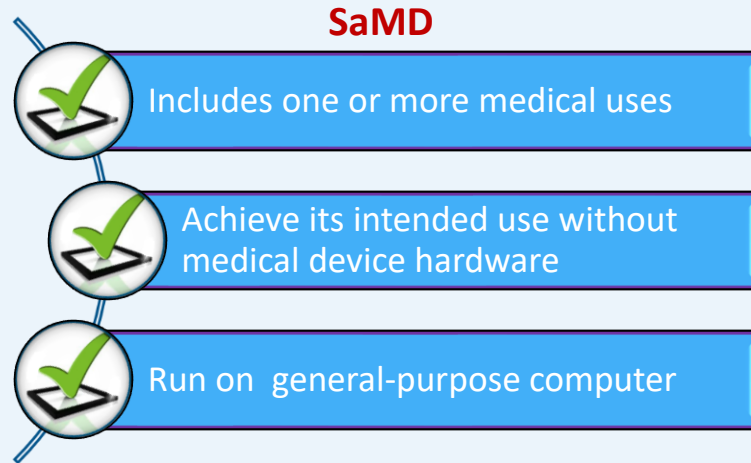


*Major*

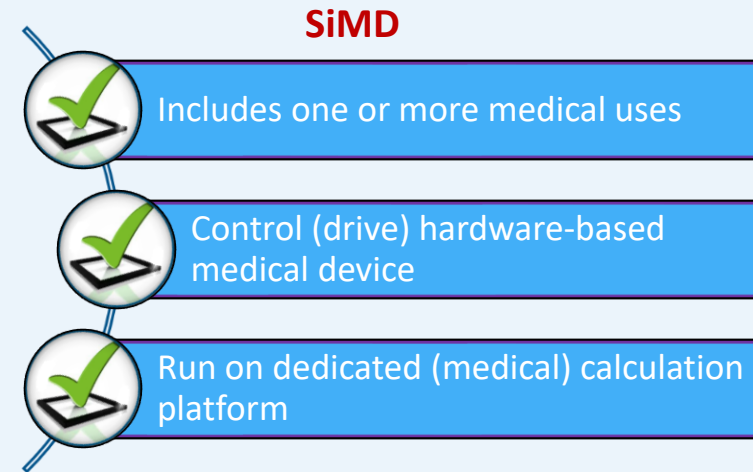
May directly or indirectly cause serious harm or death



## SaMD & SiMD



VS



## Mobile Medical Device

- ◆ Use mobile computing technologies to achieve their intended use, including:
  - ✓ Mobile SaMD
  - ✓ Mobile electrical equipment (SiMD)
  - ✓ Mobile medical accessory



## AI Medical Device

- ◆ Use artificial intelligence technologies to achieve their intended use based on medical device data, including:
  - ✓ AI SaMD
  - ✓ AI electrical equipment (SiMD)

## Administration Guidelines

Qualification and Classification

Product Naming

## Technical Guidelines

Software

Cybersecurity

Mobile

AI & ML

VR & AR

## Product Guidelines

Data-based  
(Imaging, Signal, etc)

Model-based  
(TPS, PK, etc)

## QMS Guidelines

GMP - Software Appendix  
Inspection guideline for software GMP

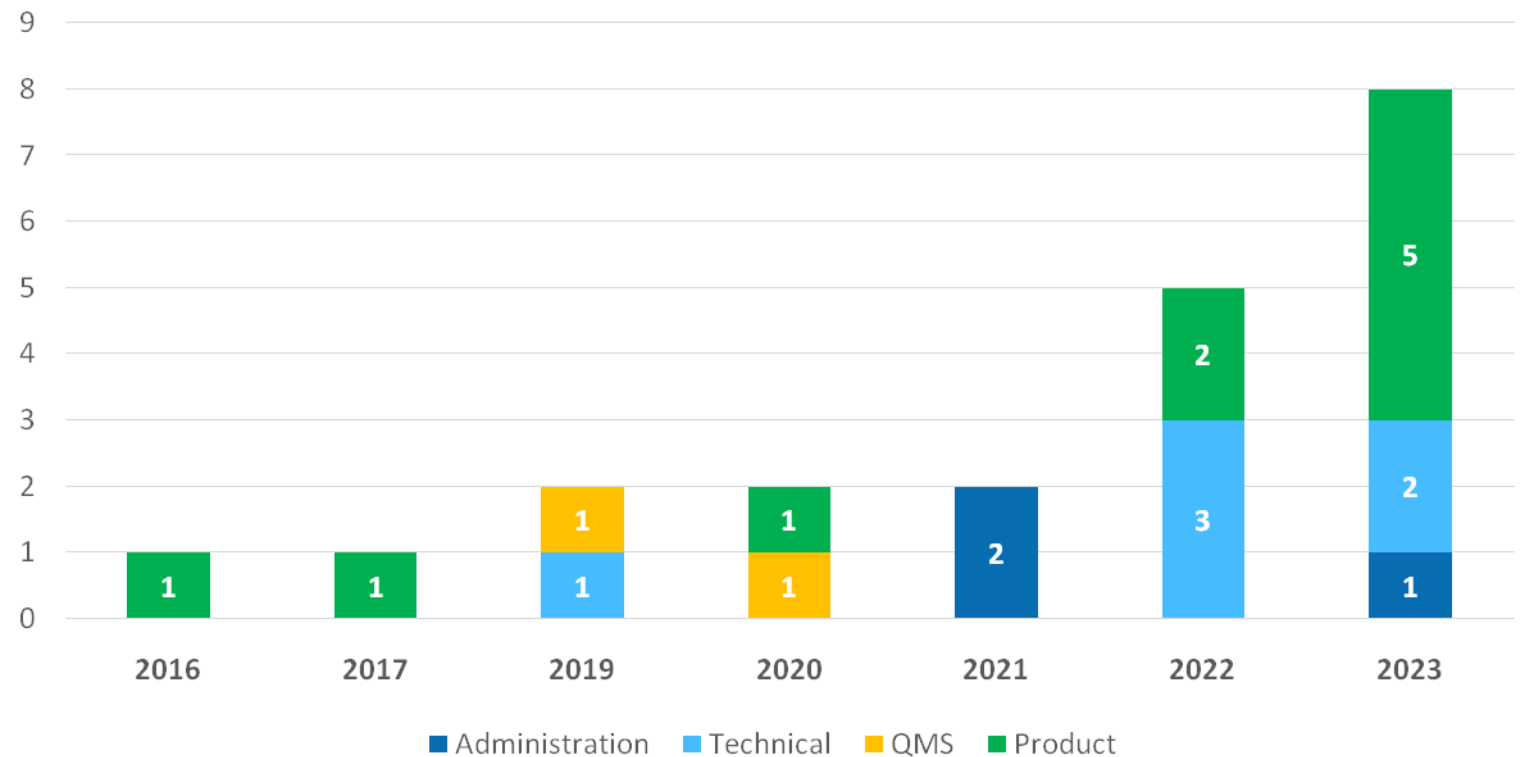


Total of 21 guidelines related with Digital Health have been published or under exposure draft

- **3** Administration
- **6** Technical
- **2** QMS
- **10** Product guidelines

\* **12** of which are relating to AI medical device.

Guideline Release Trend



## Administration Guidelines (3)

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- **Guideline for Qualification and Classification of Artificial Intelligence Software, 2021.7**
- Guideline for Qualification and Classification of Digital Therapeutics Rehabilitation software(Draft), 2023.8
- Guideline for Medical Software Product Naming, 2021.7

## Technical Guidelines (6)

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- **Review Criteria of Decision-making Assisted Medical Device Software by Deep Learning, 2019.7**
- Guideline for Premarket Review of Medical Device Software(Ed2), 2022.3
- Guideline for Premarket Review of Medical Device Cybersecurity(Ed2), 2022.3
- **Guideline for Premarket Review of Artificial Intelligence Medical Device, 2022.3**
- **Guideline for Premarket Review of Clinical Evaluation of AI-assisted Detection Medical Device, 2023.11**
- Guideline for Premarket Review of Mobile Medical Device(Ed2 Draft), 2023.11

## QMS Guidelines (2)

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- Medical Device Good Manufacturing Practice - Software Appendix, 2019.7
- Guideline for Inspection of Software Good Manufacturing Practice, 2020.6

## Product Guidelines (10)

- Guideline for Premarket Review of Picture Archiving and Communication Software, 2016.3
- Guideline for Premarket Review of Central Monitoring Software, 2017.12
- **Review Criteria of CT image-assisted Triage and Assessment Software for Pneumonia, 2020.3**
- **Guideline for Premarket Review of CT Image-assisted Detection Software for Pulmonary Nodules, 2022.5**
- **Guideline for Premarket Review of Fundus Image-assisted Diagnostic Software for Diabetic Retinopathy, 2022.6**
- **Review Criteria of Artificial Intelligence Software Functions in Image Ultrasonic Device, 2023.7**
- **Review Criteria of Performance Evaluation on Pathology Image Artificial Intelligence Analysis Software, 2023.7**
- **Review Criteria of Clinical Evaluation on Pathology Image Artificial Intelligence Analysis Software, 2023.7**
- **Review Criteria of Performance Evaluation on Artificial Intelligence Analysis Software for Flow Cytometry of Blood Diseases, 2023.7**
- **Review Criteria of Artificial Intelligence Software Functions in Magnetic Resonance Imaging System, 2023.9**

[More detail about these guidelines can click here :](https://www.cmde.org.cn/flfg/index.html)  
<https://www.cmde.org.cn/flfg/index.html>



## Submission Requirements

- Software basic information, realization process, core function, and conclusion
- Software Report depends on software safety class

## Review Focus

- Algorithm, function, intended use, basic principles of clinical evaluation
- Software change and version control, software lifecycle process and traceability
- Interoperability and software interface, Measurement function and Non-MD function
- Mobile computing, Cloud computing, and Computing platform

## Inspection Focus

- Software lifecycle process and agile development, Software change and version control
- Software requirement, verification and validation, and traceability
- OTS software purchase control and quality control



## Qualification and Classification

- **Qualification depends on**
  - Intended use
  - Core function
  - Type of input data
- **Classification depends on risk that based on**
  - Type of intended use
  - Algorithm maturity
    - ✓ Low algorithm maturity:
      - Class III (assisted decision making)
      - Class II (Non-assisted decision making)
    - ✓ High algorithm maturity:
      - same as the existing category



## Submission Requirements

- **Algorithm Report includes**
  - Basic Information
  - Risk Management,
  - Requirement Specification
  - Data Quality Control,
  - Algorithm Training,
  - Verification and validation,
  - Traceability Analysis,
  - Conclusion



## Review Focus

- **Data quality control**
  - Data Diversity
  - Data Annotation
  - Dataset Construction
- **Algorithm generalization ability**
  - Algorithm Training
  - Algorithm Performance Assessment and Clinical evaluation
  - Real-world Performance Monitoring
- **Risk of clinical use**
  - False Negative
  - False Positive
  - Human Factor/Usability

## Algorithm Evaluation Methods

- Stress testing
- Adversarial testing
- **3rd-party testing database**

## Change Control

- Algorithm-driven change and data-driven change
- Version naming rule

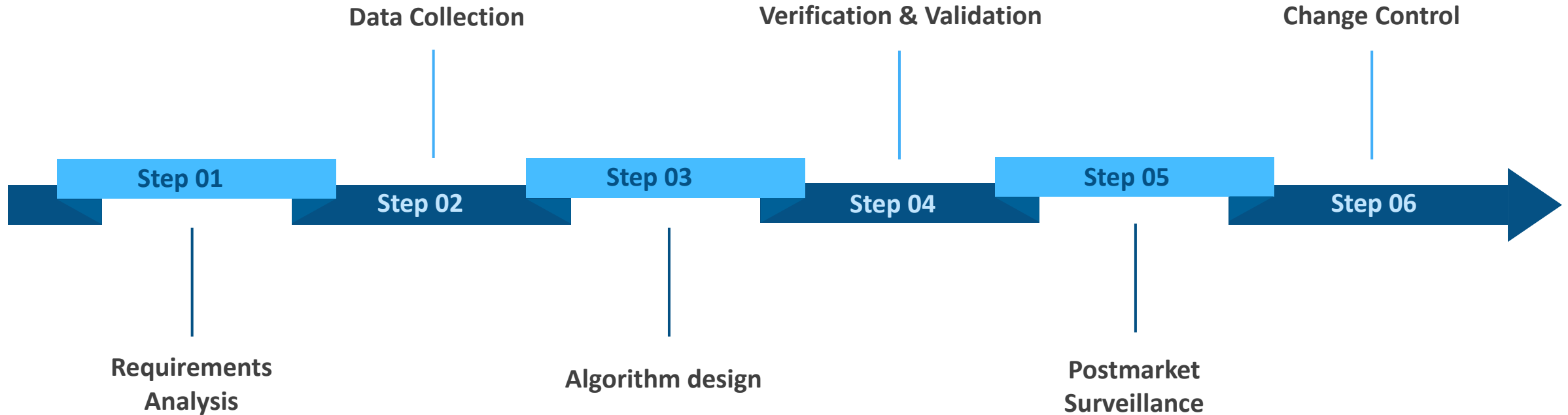
## Information Transparency

- Labelling information disclosure
- User training
- Algorithm stability analysis

## New AI Technologies Evaluation

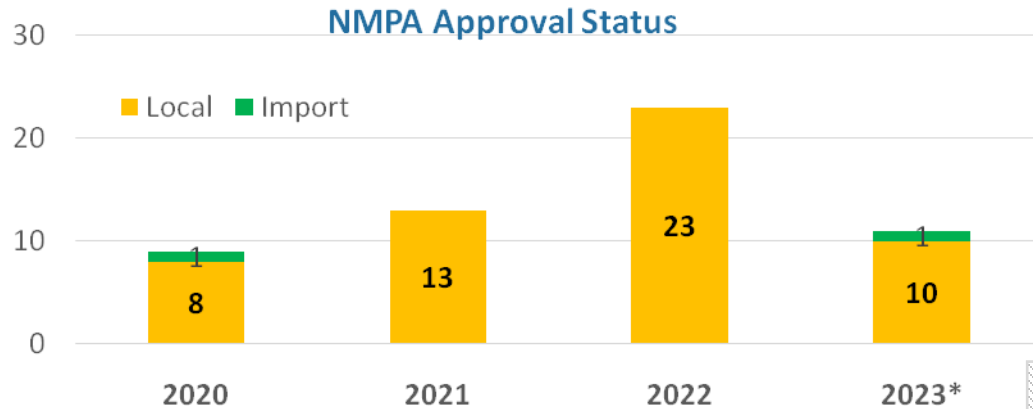
- Transfer learning, ensemble learning, reinforcement learning, federated learning
- Generative adversarial network, **continuous learning/adaptive learning**

## Total lifecycle quality control for AI Medical device



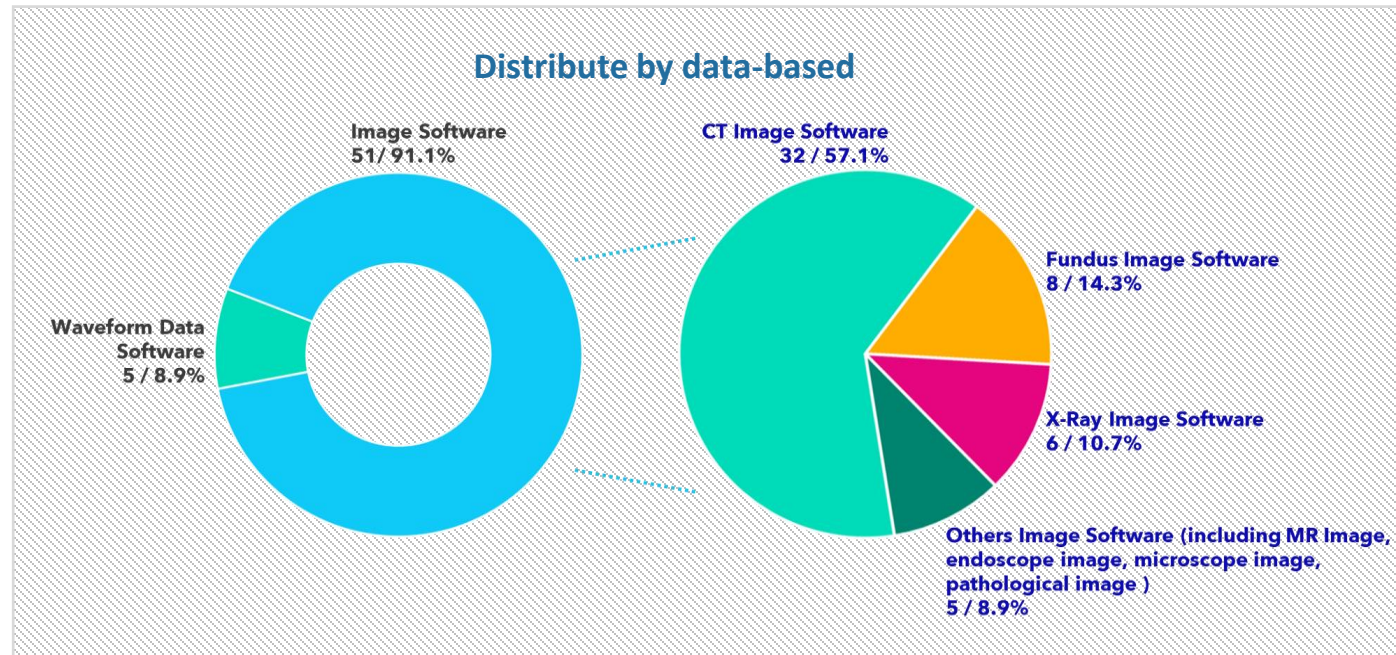
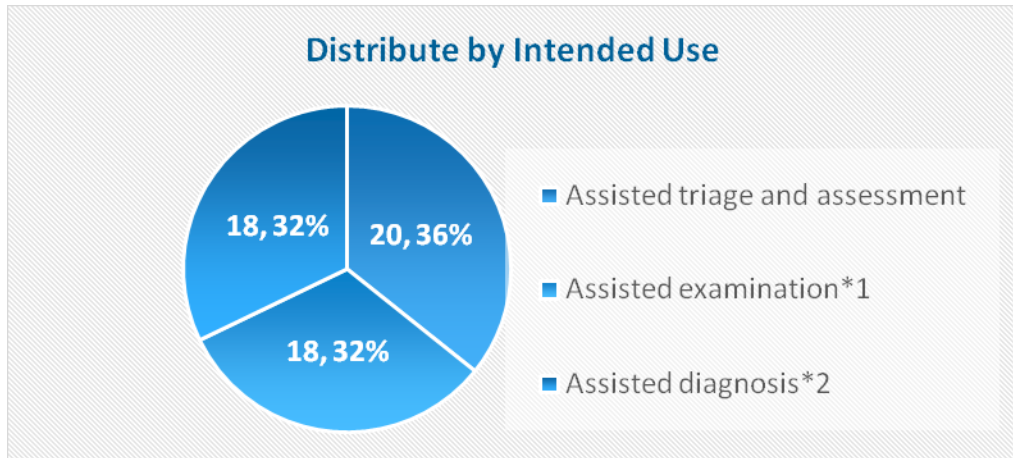


## NMPA Approval Status on SaMD as class III with deep learning- assisted decision-making



From Jan.2020 to May.2023, total 56 were approved:

- ◆ 54 local and 2 import.
- ◆ From intended use: Assisted triage and assessment (20,36%), Assisted examination(18,32%), Assisted diagnosis(18,32%)
- ◆ From Data-based: Image software, occupied(51, 91%), Wave-data software(5,9%)



\*1: Including blood cell image recognition

\*2: Including calculation of blood flow reserve fraction, ECG analysis, pathological image analysis

## Cybersecurity

A state where information and systems are protected from unauthorized activities that the related risks to **confidentiality**, **integrity**, and **availability** are maintained at an acceptable level throughout the lifecycle

## Scope

- **Applied to:**
  - SaMD/AI-SaMD
  - SiMD/AI-SiMD, including OTS software

## Focus of review and inspection

- **Cybersecurity capabilities**
- **incident response**
- **vulnerability assessment**
- **Data management**
  - Cybersecurity Change
  - Data Cross Border
  - Remote Service, etc

## Submission requirements

- **Four parts:**
  - Basic information
  - Realization process
  - Vulnerability Assessment and Conclusion.
- **Detail level of Cybersecurity Report also depends on software safety class**



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***Thank You for Your Attention !***

