Introduction to review points for decision-making medical device software using deep learning technology

PENG Liang, PhD, Deputy Division Director
Center for Medical Device Evaluation, NMPA, CHINA
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Outlines

• Understanding of AI medical device
• Introduction to the review points
• Next work
AI medical device

- AI means an algorithm based on data/knowledge and computing capability in nature
  - Deep learning, a subset of AI, is the end-to-end blackbox algorithm based on big data and high computing capability
- AI medical device is the medical device using AI technologies, that can be:
  - AI-SaMD: smart standalone software
  - AI-SiMD: smart device
Intended purpose of AI-MD

• Decision-making
  – Assisted screening
  – Assisted detection
  – Assisted diagnosis
  – Assisted therapy

• Non decision-making
  – Process optimization
  – Pre-processing: imaging improvement, etc
  – Post-processing: image segmentation, etc
Review considerations

• General considerations
  - AI Vs. Digital health
  - Technical characteristics Vs. Product features
  - Tradition AI Vs. New generation AI

• Basic principles
  - Focus on the assisted decision-making software using deep learning
  - Risk-based method
  - Total lifecycle management
Total lifecycle management

01. Requirements analysis
02. Algorithm design
03. Data collection
04. Verification & validation
05. Postmarket surveillance
06. Change control
Total lifecycle management

- **Requirements analysis**
  - Clinical needs and use risk oriented
  - Data diversity, algorithm performance metrics, clinical use limitation

- **Data collection**
  - Data acquisition, data preparation, data Annotation, dataset construction

- **Algorithm design**
  - Algorithm selection, algorithm training, cybersecurity capabilities, algorithm performance assessment
Total lifecycle management

- Verification and validation
  - Unit test, integration test and system test
  - Clinical evaluation, including clinical trial
- Postmarket surveillance
  - Performance, adverse event, etc
- Change control
  - Major change: change registration
  - Minor change: controlled by QMS without registration
Core concerns

- **Data quality control**
  - Data diversity, data annotation, dataset construction

- **Algorithm generalization ability**
  - Algorithm training, algorithm performance assessment, clinical evaluation

- **Risk of clinical use**
  - False negative, false positive, human factor/usability
  - Differences of race, epidemiologic features, clinical conditions and guidelines
Other considerations

- **Application extension**
  - Non decision-making software
  - Tradition AI software
- **Third-party database**
  - Test database: used for software validation
  - Open database: not used for software validation
- **Data security**
  - Data anonymization, data backup and recovery, data interface and interoperability
Next work

- **Product level**
  - Multimodality medical device data
  - Medical device data + non medical device data

- **Technology level**
  - Reinforcement learning
  - Self learning/Unsupervised learning

- **Data level**
  - Small sample data
  - Weak labelling data
  - Unstructured data
System of AI-MD guidelines

- AI diabetic retina guideline
- AI pathological image guideline
- AI pulmonary nodule guideline
- AI ECG guideline
- General guideline for AI-MD
  - Review points for decision-making software
- Software guideline
- Cybersecurity guideline
- Mobile apps guideline
- Human factor guideline
Thank you for attention!