国家药品监督管理局医疗器械技术审评中心
CENTER FOR MEDICAL DEVICE EVALUATION , NMPA

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

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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

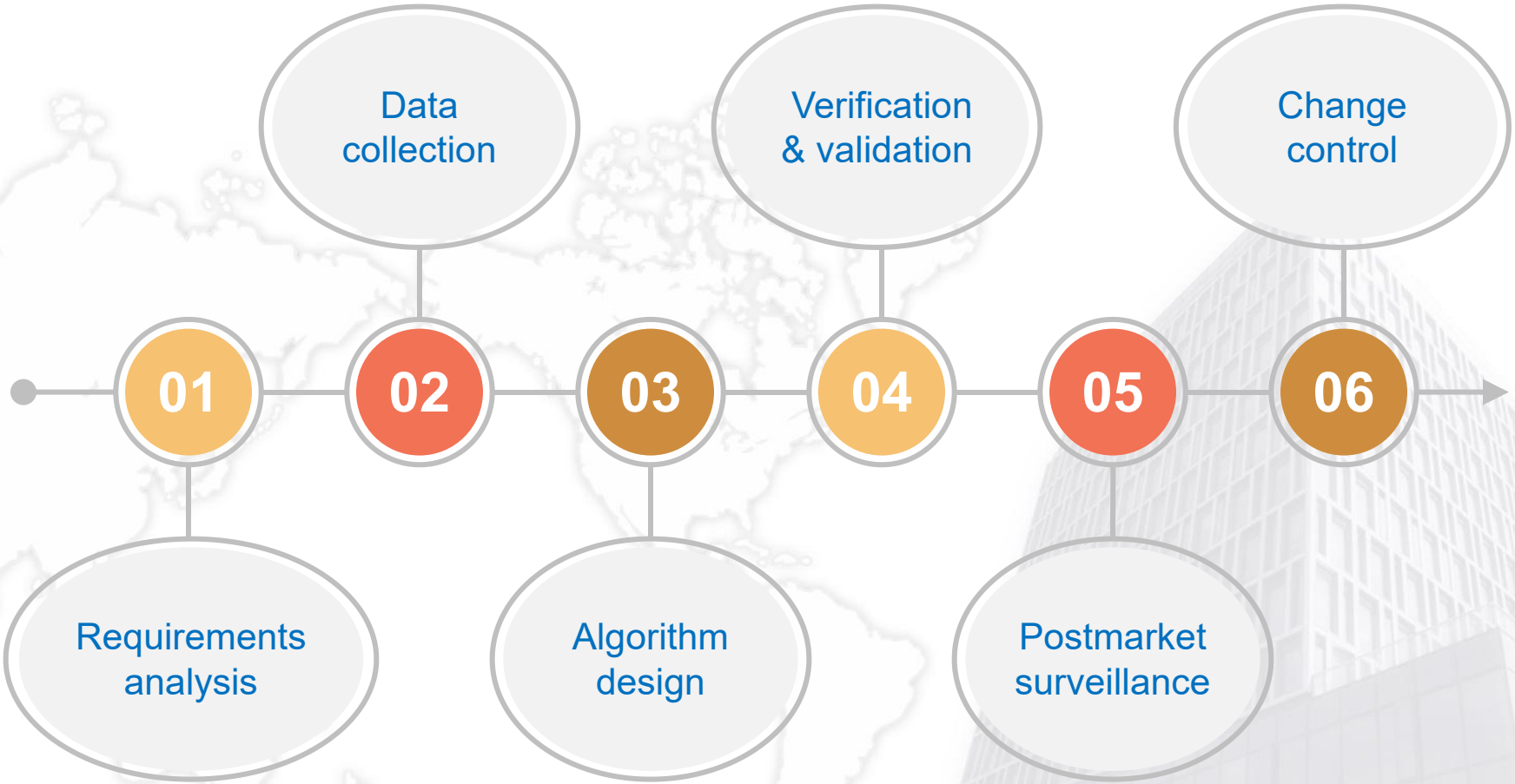
Intended purpose of AI-MD

- 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



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
  - Cilnical 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

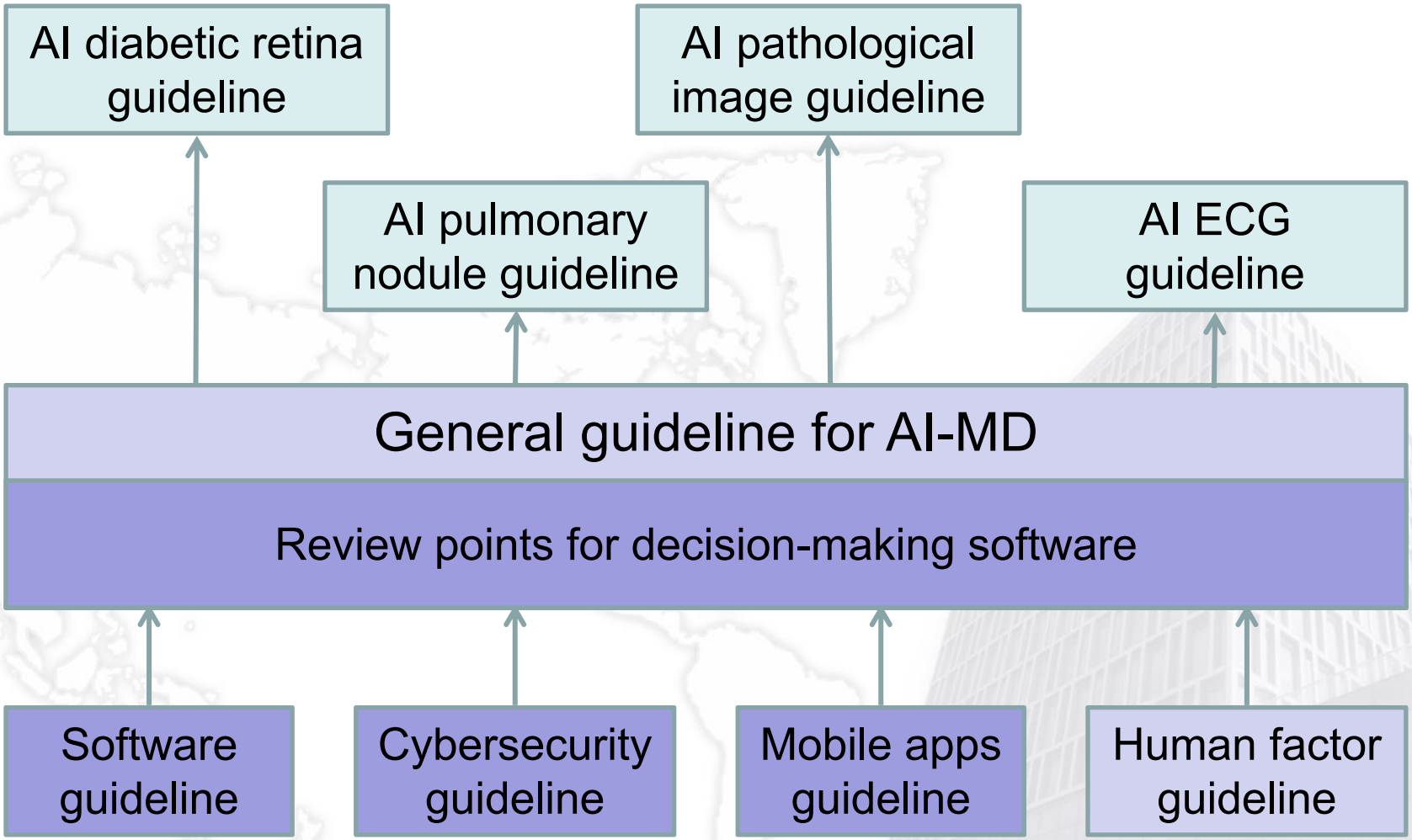
Other considerations

- 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



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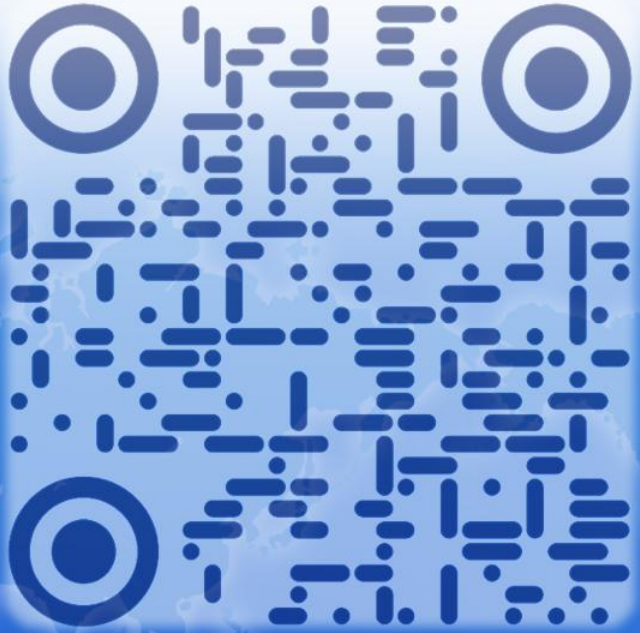

Thank you for attention !

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