

Considerations on the premarket review of AI medical devices

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- Understanding of AI medical device
- Considerations of premarket review
- Challenges of AI medical device regulation

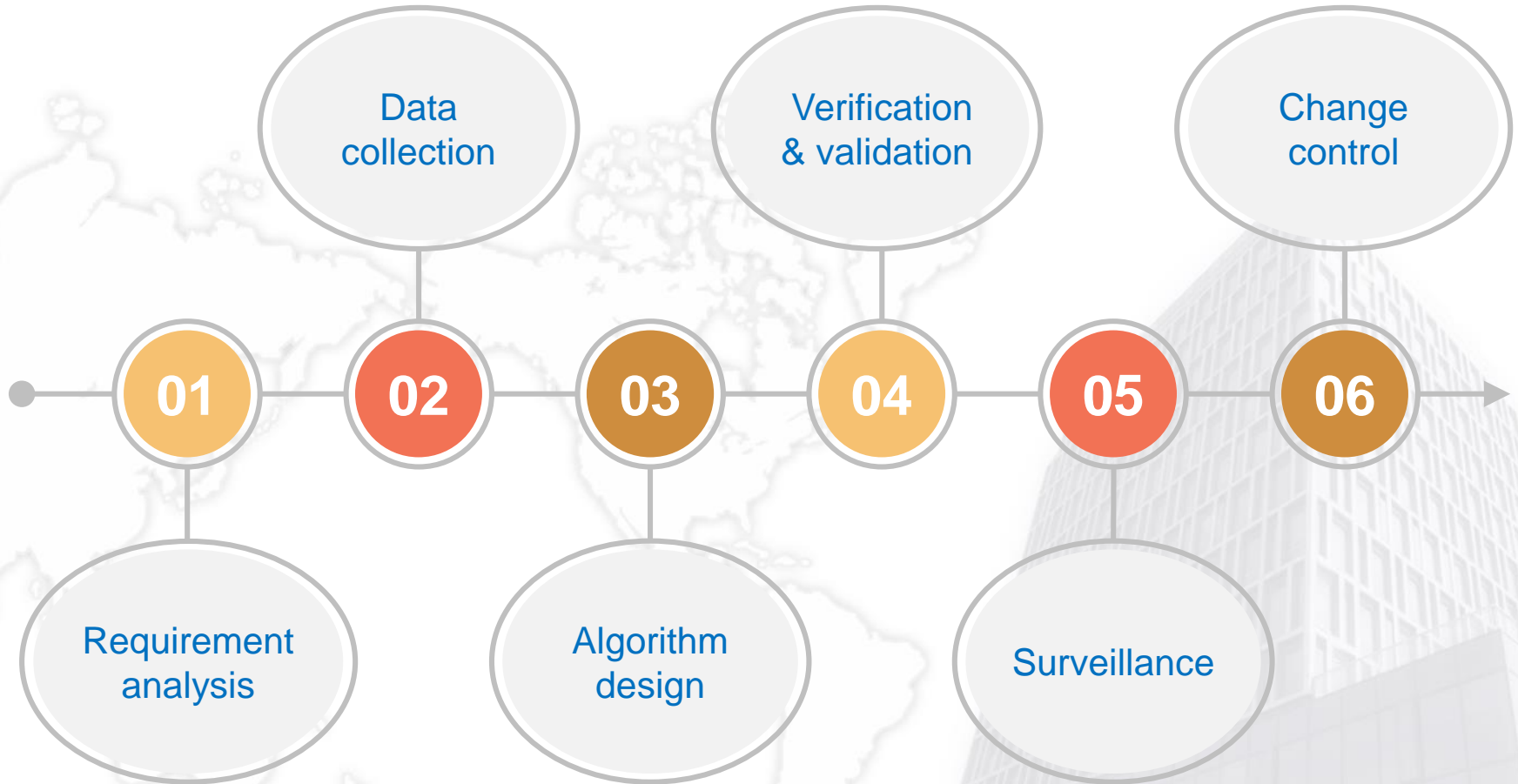
- AI means an algorithm based on data/knowledge and computing capability in nature
 - Deep learning is the end-to-end blackbox algorithm based on big data and high computing capability
- AI medical device is the medical device using AI technologies, that can be:
 - AI-SaMD: smart standalone software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

- Assisted decision-making
 - Assisted screening
 - Assisted detection
 - Assisted diagnosis
 - Assisted therapy
- Non assisted decision-making
 - Process optimization
 - Pre-processing: imaging improvement
 - Post-processing: image segmentation

- 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

- Risk level of AI-MD
 - Minor, Moderate, Major
 - The higher the risk, the tougher the requirements
- Special risk of imported AI-MD
 - Differences of race, epidemiologic features, clinical conditions and guidelines

Total lifecycle management



- Data quality control
 - Data diversity, data annotation, dataset construction
- Algorithm generalization ability
 - Algorithm training, algorithm performance assessment
- Risk of clinical use
 - False negative / false positive, human factor / usability
 - Clinical evaluation: clinical needs and use limitations

- Third-party database
 - Test database: used for software validation
 - Open database: not used for software validation
- Cybersecurity and data security
 - Cybersecurity capabilities
 - Data anonymization, data backup and recovery
 - Data interface and interoperability

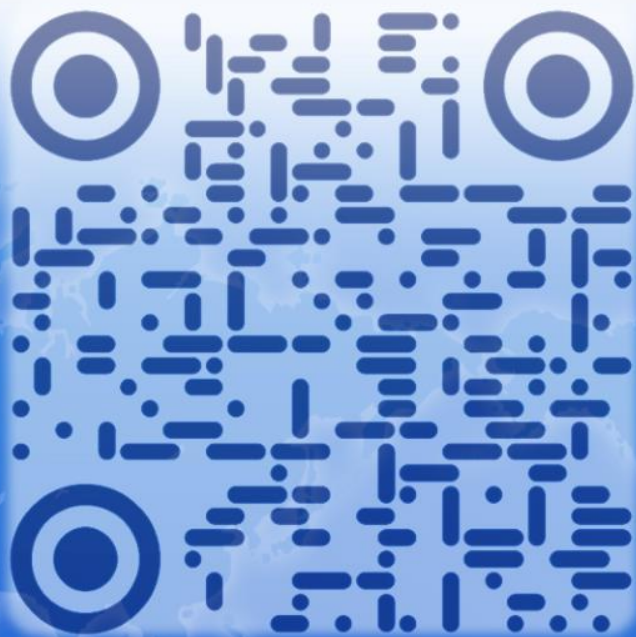
- Regulation scope
 - Medical service Vs. Medical product
- Clinical ethics
 - Assisted tool Vs. Virtual doctor
- Patient rights
 - Data sharing Vs. Privacy protection
- Self learning
 - User Vs. Manufacturer

- 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



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*Thank you for
attention !*

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