DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

IMDRF /DITTA joint workshop

Artificial Intelligence in Healthcare

Opportunities and Challenges

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Industry overview on regulatory challenges

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And DITTA SC member and JIRA member

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DEVELOPMENT OF GUIDANCE FOR AI IN SOME JURISDICTIONS

CANADA	"An Overview of Clinical Applications of Artificial Intelligence" was issued by CADTH https://www.cadth.ca/sites/default/files/pdf/eh0070_overview_clinical_applications_of_AI.pdf
CHINA	Reviewing Criteria for Medical Decision Support Software with deep learning (CMDE notification 2019-7th Dated:2019/7/3) https://www.cmde.org.cn/CL0004/19360.html
KOREA	The following guidance were issued by MFDS. However, they were described in Korean. Therefore, we are not sure of the contents yet. "Guideline on Review & Approval for Big Data & AI-applied Medical Devices" was issued by MFDS in Nov. 2017. "Guideline on Clinical Evaluation of Validity for Artificial Intelligence(AI) Medical Devices" was issued by MFDS in Dec. 2017.
JAPAN	In May 23th, MHLW was issued ""Guidance on medical imaging systems for assisting diagnosis using artificial intelligence" as reviewing criteria in PMDA. MHLW just now are translating into English.
USA	Discussion Paper and Request for Feedback "Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) " https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

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IN CASE OF NON-MEDICAL DEVICE AUTOMATED DRIVING SYSTEM

Supporting

Automated

SAE level	Name	Narrative Definition	Execution of Steering and Acceleration/ Deceleration	*Monitoring* of Driving Environment	Fallback Performance of *Dynamic Driving Task*	System Capability *(Driving Modes)*
***Human driver* monitors the driving environment**						
0	**No Automation**	the full-time performance by the *human driver* of all aspects of the *dynamic driving task*, even when enhanced by warning or intervention systems	Human driver	Human driver	Human driver	n/a
1	**Driver Assistance**	the *driving mode*-specific execution by a driver assistance system of either steering or acceleration/deceleration using information about the driving environment and with the expectation that the *human driver* perform all remaining aspects of the *dynamic driving task*	Human driver and system	Human driver	Human driver	Some driving modes
2	**Partial Automation**	the *driving mode*-specific execution by one or more driver assistance systems of both steering and acceleration/ deceleration using information about the driving environment and with the expectation that the *human driver* perform all remaining aspects of the *dynamic driving task*	**System**	Human driver	Human driver	Some driving modes
***Automated driving system* ("system") monitors the driving environment**						
3	**Conditional Automation**	the *driving mode*-specific performance by an *automated driving system* of all aspects of the dynamic driving task with the expectation that the *human driver* will respond appropriately to a *request to intervene*	System	**System**	Human driver	Some driving modes
4	**High Automation**	the *driving mode*-specific performance by an automated driving system of all aspects of the *dynamic driving task*, even if a *human driver* does not respond appropriately to a *request to intervene*	System	System	**System**	Some driving modes
5	**Full Automation**	the full-time performance by an *automated driving system* of all aspects of the *dynamic driving task* under all roadway and environmental conditions that can be managed by a *human driver*	System	System	System	**All driving modes**

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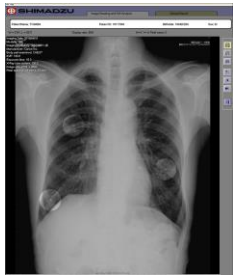
INTENDED USE OF MEDICAL DEVICES WITH AI

Supporting system with AI

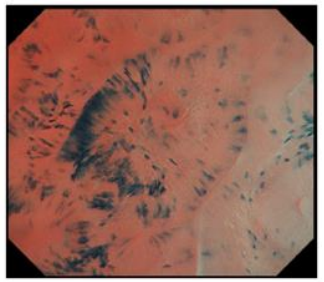
- Improve Imaging processing with AI



- Mechanical Movement with AI

Prof. Sankai, University of Tsukuba / CYBERDYNE Inc.

- Detection Supporting with AI



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INTENDED USE OF MEDICAL DEVICES WITH AI

Autonomous AI with Medical Device

including Screening/Triage or replacement of Physician

- Autonomous diagnostic first Decision

- Screening/Triage or the other system might be developed so soon.
- Replacement of Physicians……..

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DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSENT

Pre-Market

Performance Evaluation

- Explainability: User cannot understand reason of Decisions.
  - ✓ How to clarify/identify the algorithm of AI in the submission documents?
- Plasticity:Continous Learning or Learning after installation might worsen the performance of AI Product.
  - ✓ How to ensure to keep the performance?

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DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSENT

Pre-Market

Performance evaluation – no large difference between AI and Non-AI

- AI performance test = SOUP(Software of Unknown Provenance)

  defined in IEC62304

  = black box test?

- The manufacturer could evaluate the performance by sensitivity and specificity, or ROC.

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DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSENT

Pre-Market

Clinical Data – no large difference between AI and Non-AI

- Personal information protection is required for clinical data.
- IDE, GCP or the other process will be required.
- How to use big data or Real World Data?

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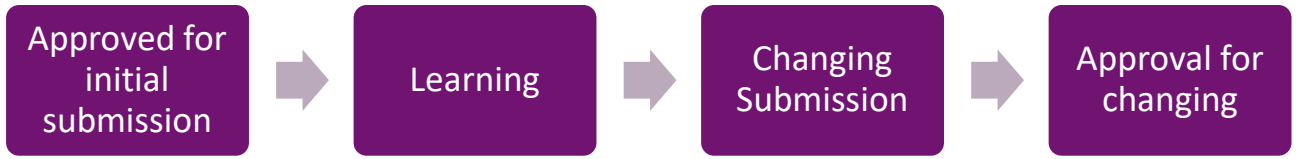
DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

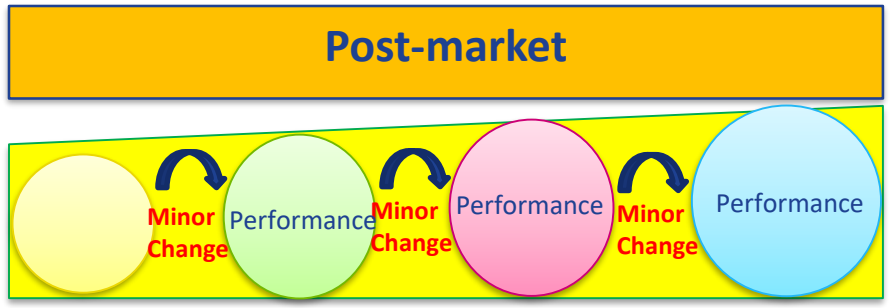
Pre-Market

Unique characteristics by AI.

- Locked Algorithm – Discontinuous Learning



- Unlocked Algorithms – Continuous Learning/On site Learning
  - How to manage for change control
    Which one is best pathway for MD Manufacturer?
    - ✓ The minimum guaranteed specification is specified in the submission of the approval.
    - ✓ Change plan should be included in the submission for the approval.
    - ✓ Pre-certification system for Manufacturer



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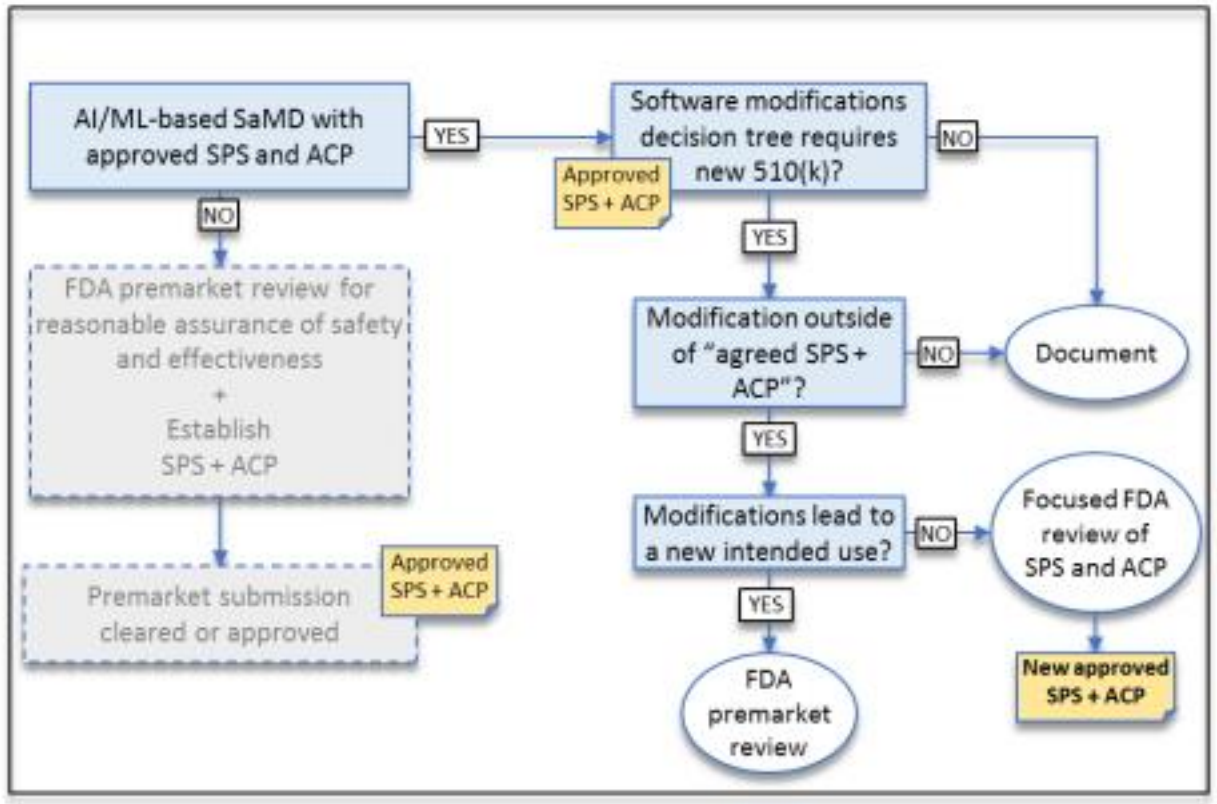
DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

Pre-Market

Unique characteristics by AI.

- Change management (e.g. in the case of the discussion paper by US-FDA)



Change management based on pre-certification program

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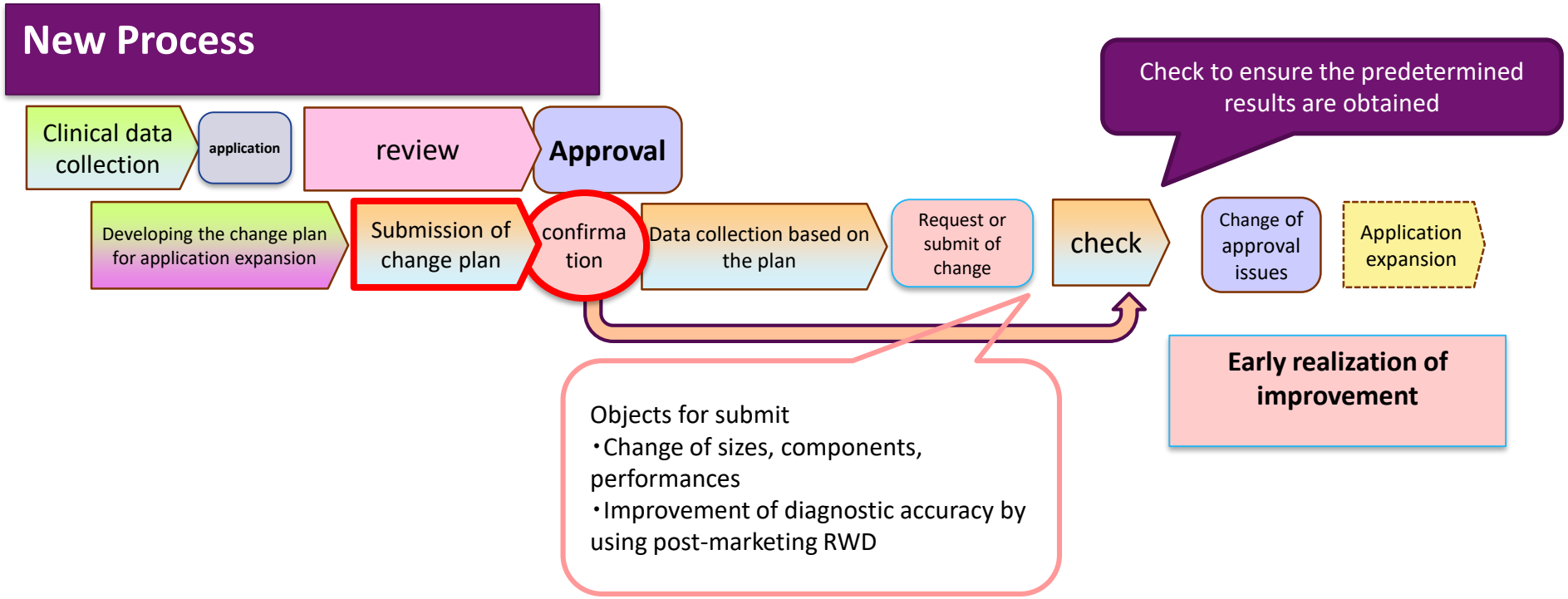
DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

Pre-Market

Unique characteristics by AI.

- Change management (e.g. in the case of Japanese Draft Legal Amendment)



DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

QMS

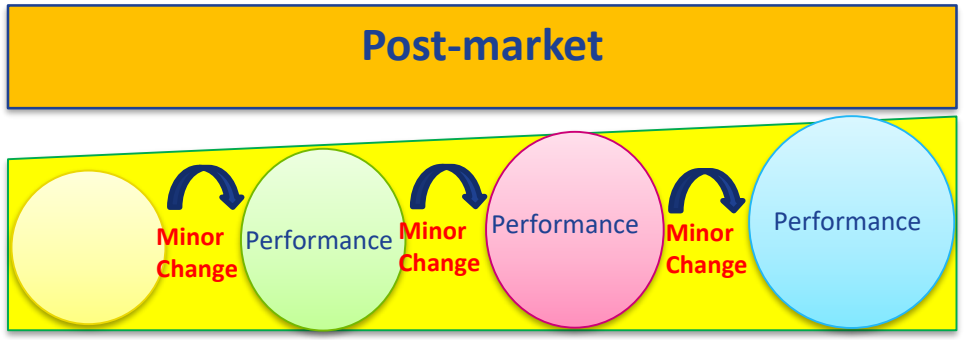
For SaMD

- Manufacturer is required QMS based on ISO13485 and the other national requirements.
- Manufacturer might be required IEC62304 or IEC82304.

Unique characteristics by AI.

- Unlocked Algorithms – Continuous Learning/On site Learning
  - ➢ Who manages the continuous learning?
    - ✓ IF User Facility manage them, they might be required QMS for specification and data management.
    - ✓ Manufacturer might be required to prepare the requirements for data set.

=> **Equally valid for post-market activities**



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ROLES AND RESPONSIBILITIES FOR AI AND PHYSICIANS

Clarification of Roles and Responsibility between AI and Physicians

- Supporting Systems → Clinical Decision will depend on Physicians.
- Autonomous Systems → Clinical Decision will be charged to Manufacturer.

Manufacturers expect development of common sense of responsibilities for AI product with all stakeholders

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REMARKS FOR REGULATORY SYSTEM FROM INDUSTRY PERSPECTIVE

- Basically, if there is no change in performance (locked algorithms and non continuous learning) on user facility, the same regulations as for non-AI products should apply.
- Performance changes should be allowed, as long as they remain within specifications/ approved intended use.
- In Japan, however, the spread of AI diagnostic imaging support systems is expected to prevent overlooking in emergency medical care as a part of the recommendations for preventing the recurrence of medical accidents. More flexible regulatory requirements are expected for such intended use as just supporting.
- Manufacturers will need a harmonized legal amendment for AI applications with the responsibility/role of the user.

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Thank you!
Спасибо!

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