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IMDRF International Medical
Device Regulators Forum

IMDRF /DITTA joint workshop

Artificial Intelligence in Healthcare
Opportunities and Challenges

Monday 16 Sept. 2019, Yekaterinburg

Industry overview on regulatory challenges

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And DITTA SC member and JIRA member



JIRA





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DEVELOPMENT OF GUIDANCE FOR AI IN SOME JURISDICTIONS

CANADA	<p>“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</p>
CHINA	<p>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</p>
KOREA	<p>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.</p>
JAPAN	<p>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.</p>
USA	<p>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</p>





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IN CASE OF NON-MEDICAL DEVICE AUTOMATED DRIVING SYSTEM



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 <i>human driver</i> of all aspects of the <i>dynamic driving task</i> , even when enhanced by warning or intervention systems	Human driver	Human driver	Human driver	n/a
1	Driver Assistance	the <i>driving mode</i> -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 <i>human driver</i> perform all remaining aspects of the <i>dynamic driving task</i>	Human driver and system	Human driver	Human driver	Some driving modes
2	Partial Automation	the <i>driving mode</i> -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 <i>human driver</i> perform all remaining aspects of the <i>dynamic driving task</i>	System	Human driver	Human driver	Some driving modes
Automated driving system ("system") monitors the driving environment						
3	Conditional Automation	the <i>driving mode</i> -specific performance by an <i>automated driving system</i> of all aspects of the dynamic driving task with the expectation that the <i>human driver</i> will respond appropriately to a <i>request to intervene</i>	System	System	Human driver	Some driving modes
4	High Automation	the <i>driving mode</i> -specific performance by an automated driving system of all aspects of the <i>dynamic driving task</i> , even if a <i>human driver</i> does not respond appropriately to a <i>request to intervene</i>	System	System	System	Some driving modes
5	Full Automation	the full-time performance by an <i>automated driving system</i> of all aspects of the <i>dynamic driving task</i> under all roadway and environmental conditions that can be managed by a <i>human driver</i>	System	System	System	All driving modes

Supporting

Automated

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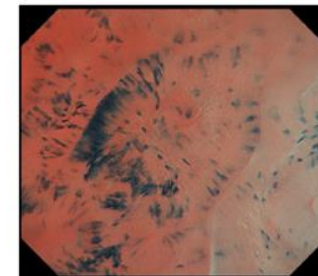
INTENDED USE OF MEDICAL DEVICES WITH AI

Supporting system with AI

- Improve Imaging processing with AI
- Mechanical Movement with AI
- Detection Supporting with AI



Prof. Sankai, University of Tsukuba / CYBERDYNE Inc.





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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 ASSESSEMENT

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 ASSESMENT

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 ASSESSEMENT

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?





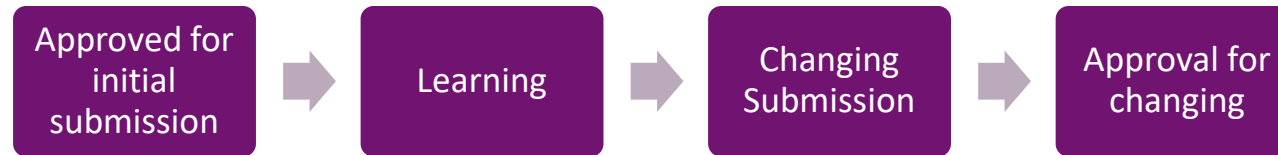
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DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

Pre-Market

Unique characteristics by AI.

- Locked Algorithm – Discontinuous Learning

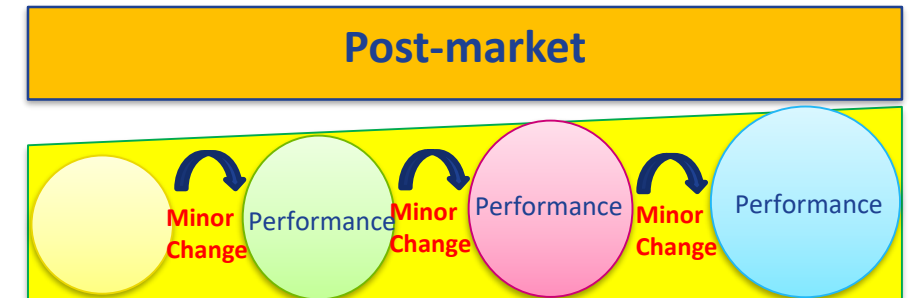


- Unlocked Algorithms – Continuous Learning/On site Learning

➤ 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



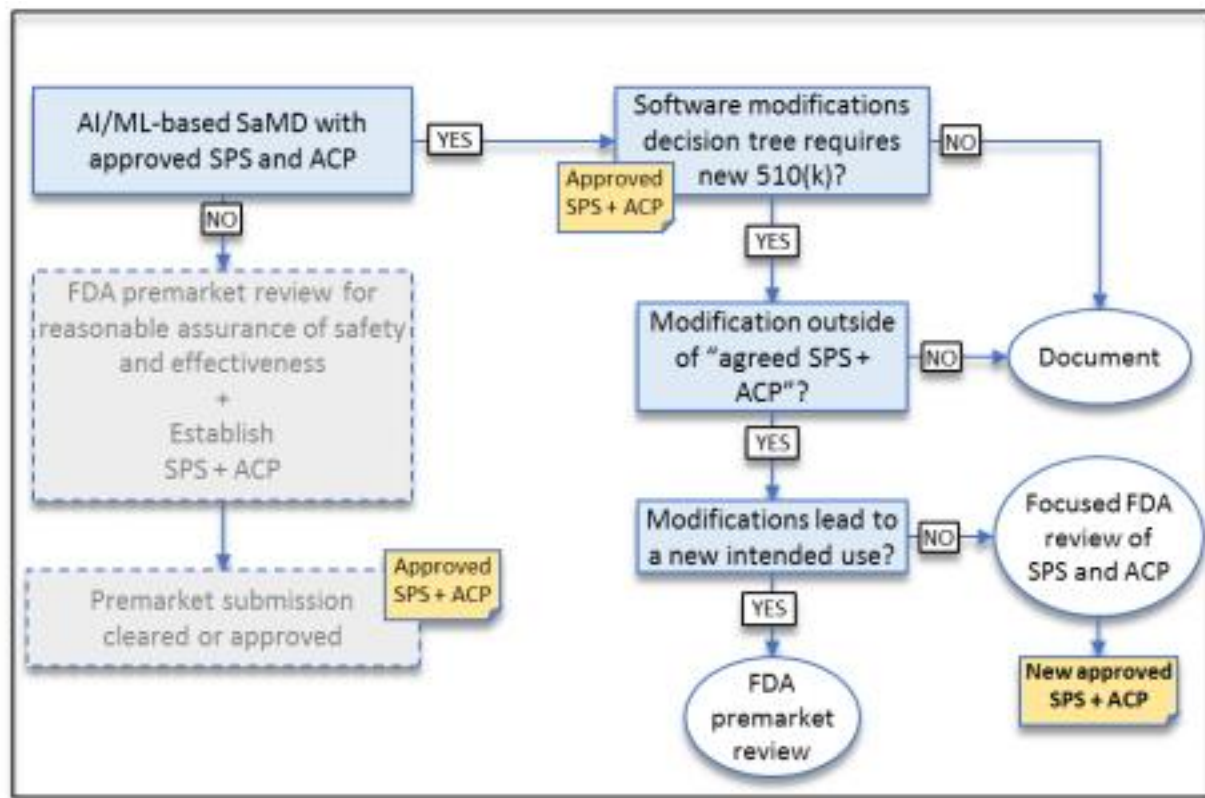


DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

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

Legend

Proposed regulatory pathway for new AI/ML-based SaMD

Proposed regulatory pathway for modifications for AI/ML-based SaMD

Endpoint for AI/ML modification

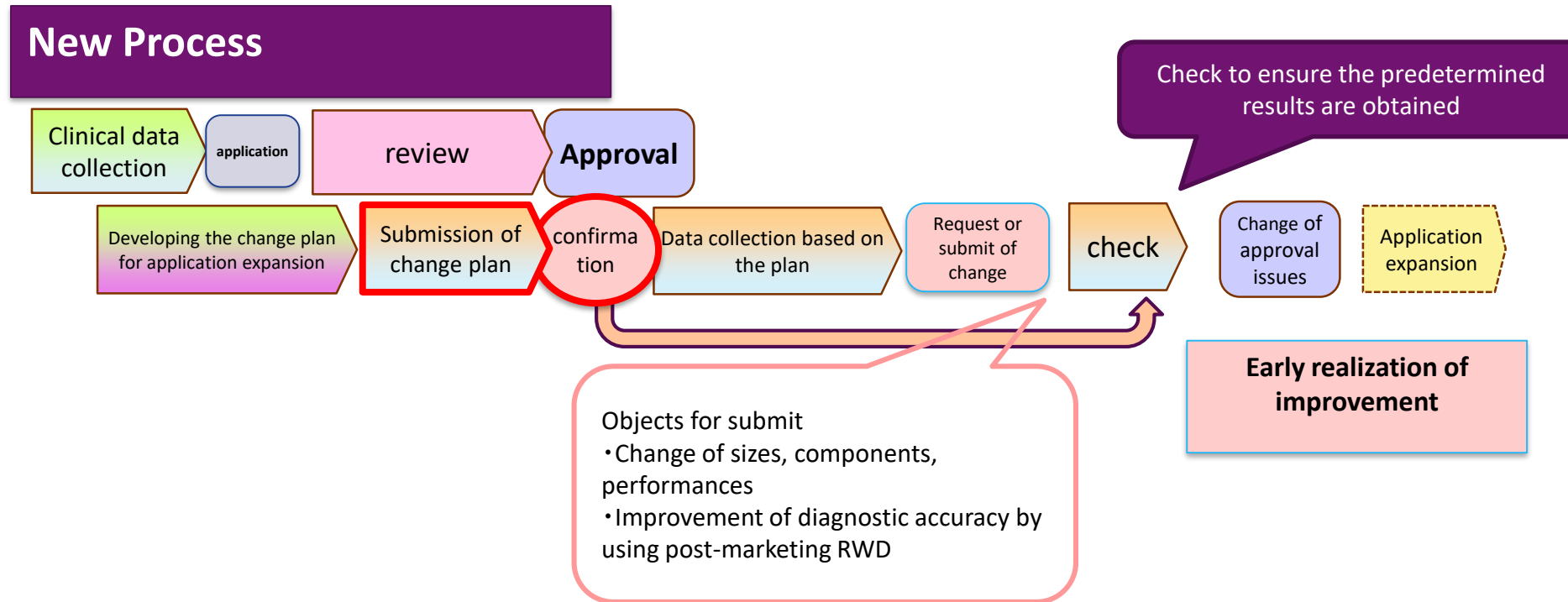


DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

Pre-Market

Unique characteristics by AI.

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





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DIFFERENCE BETWEEN AI AND NON-AI IN CONFORMITY ASSESSMENT

QMS

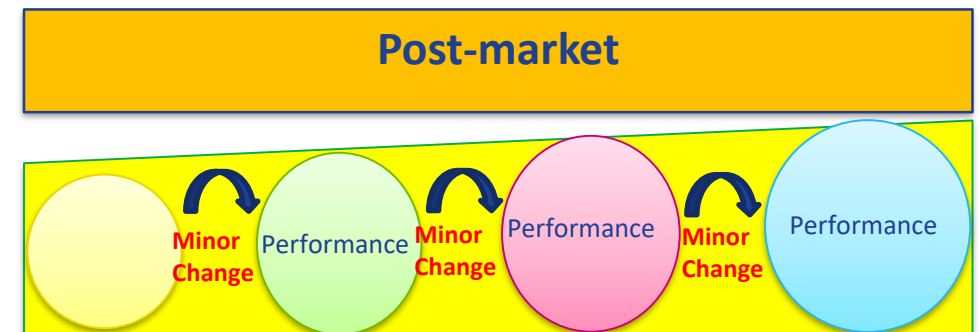
For SaMD

- 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!
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