

Introduction of an Integrated Review and Assessment System for Artificial Intelligence and Digital Innovative Medical Devices in Korea

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OBJECTIVE

- The purpose of the study is to share an effective policy to ensure innovative medical devices (IMD) to be used swiftly at the medical field.

METHOD

- This study focused on the Integrated Review and Assessment System (IRAS) implemented in October 2022 for IMD to be put in place quickly to the medical field.

CONCLUSION

- The IRAS allows IMD to enter the healthcare field as swiftly as possible. It helps **medical device industry** compensated for their innovative value and **the patients** have a wide range of choices and easy access to the innovative diagnostic and therapeutic services.

GLOSSARY

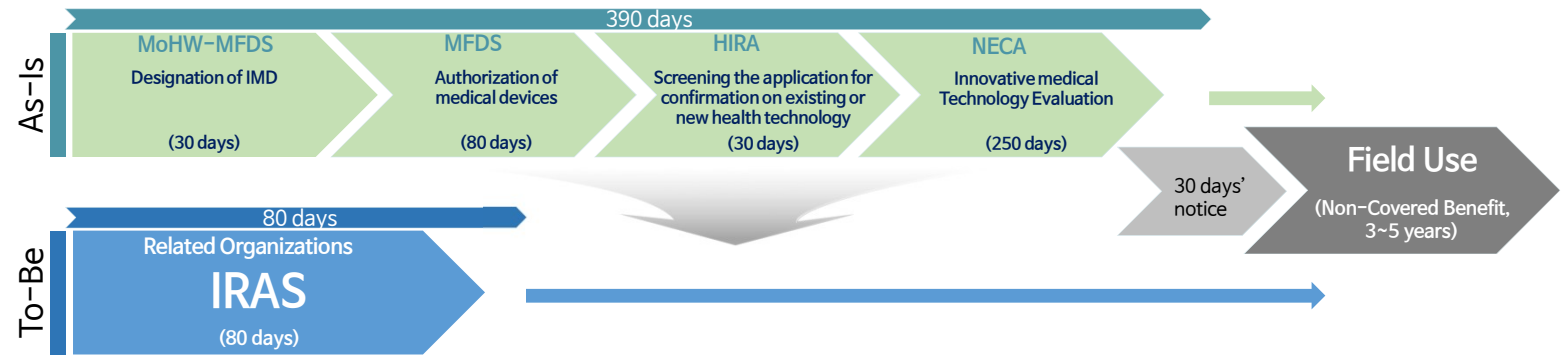
HIRA: Health Insurance Review and Assessment Service
MoHW: Ministry of Health and Welfare
MFDS: Ministry of Food and Drug Safety
NECA: National Evidence-based healthcare Collaborating Agency

RESULTS

✓ Definition of Innovative Medical Devices (IMD)

- IMD are applying advanced technologies that have excellent potential value and high technology intensity that have significantly improved or are expected to significantly improve safety and effectiveness. (AI, VR·AR, Big Data Technology, Digital therapeutics, IoT/Biosensor-based Wearable etc.)

✓ Integrated Review and Assessment System (IRAS) Schematic Diagram



✓ Performance of Health Insurance Review & Assessment Service (HIRA)

- 01 Established the Committee to reflect innovative technology and strengthening the professionalism
- 02 Revised the Guidelines to expand the scope of acknowledgment of innovation

✓ IMD Designation Current Status

	01	02	03	04	05	06
	Cognitive therapy software (Company A)	Cognitive therapy software (Company W)	Neural image, computer aided detection/ diagnosis software (Company J)	Electrocardiograph, analysis software (Company M)	Neural image, computer aided detection/ diagnosis software (Company C)	Neural image, computer aided detection/ diagnosis software (Company D)
Purpose of USE	Improvement of chronic insomnia	Improvement of chronic insomnia	Ischemic stroke detection using MR image	Screening test for left ventricular systolic dysfunction	Intracerebral hemorrhage Diagnosis	Cerebral aneurysm diagnosis using brain MRA image
Designated Date	2022. 12. 15.	2022. 12. 15.	2022. 12. 15.	2023. 2. 16.	2023. 3. 27.	2023. 3. 27.
IRAS Progress	Complete	Complete	Complete	Complete	In Progress	In Progress

- MFDS authorized cognitive therapy software as the first digital therapy device in Korea On February 15, 2023.
- After the authorization of a medical device, it can be used for 3 to 5 years in hospital as a non-covered benefit with minimized administrative procedure.