

[MDREX Newsletter] SaMD products that identify type of cerebral stroke utilizing MR images designated as "innovative medical technology"

The Ministry of Health and Welfare ("MOHW") in Korea designates "innovative medical technology" ("IMT") for new medical technologies that have shown sufficient safety during "new health technology assessment" ("nHTA"), despite the lack of sufficient data on efficacy, acknowledging the potential of such technology. If a IMT designation is made, the MOHW permits clinical trials to be conducted in Korea for 3-5 years without qualifying for National Healthcare Pricing(e.g., RV - Relative value) in the Korea market. Therefore, if a IMT designation is made, the company with the IMT can submit a clinical protocol to NECA and IRB(institutional review boards) for approval and once the approval is obtained, the company can raise revenue from patients using the IMT (= non- reimbursement), while also securing its case report form as well as clinical evaluation report for the IMT.

The AI technology that has been designated as IMT this time (April 2023) is summarized as follows:

- Technology: Artificial Intelligence based Ischemic Stroke Detection using MR image
- Purpose: Identify type of cerebral stroke/infarction and assist in diagnostics
- Target patients: Patients with cerebral stroke/ infarction
- Use method: the AI technology analyzes patients' MR image and clinical information of brain to identify cerebral stroke type (see 4 types below):
 - ✓ LAA, large artery atherosclerosis
 - ✓ SVO, small-vessel occlusion
 - ✓ CE, cardio embolism
 - ✓ Other

The IMT term has been designated from March 1, 2023 to February 28, 2026. Please contact MDREX at pro@mdrex.co.kr if you or your company has any questions on the IMT designation system.

Kind regards,