MDREX

National Health Insurance Reimbursement Guidelines for Digital Therapeutics(DTx) in Korea

MDREX is a boutique Korea Medical Device Regulatory, Quality, Compliance, Reimbursement and Clinical Consulting Firm dedicated to providing strategic and operational consulting service to medical device and digital health companies.

MDREX Introduction, Doc Num: 202310-01

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About MDREX

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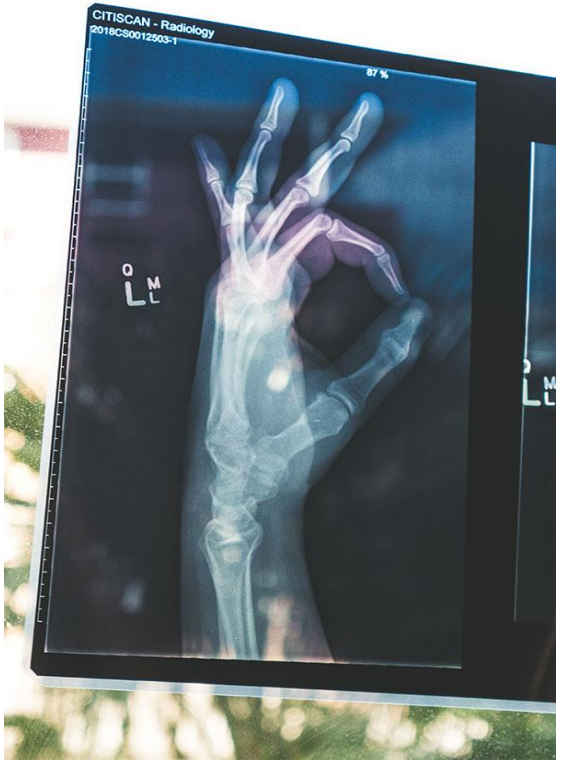
Korean Boutique Medical Device Consulting Firm

- Professional Service Firm that helps digital health and medical device companies with market access and regulatory issues.
- Consulting Service Scope – Medical Device and Digital Health
  - ✓ Market Survey
  - ✓ Product Approval/Certificate/Registration
  - ✓ K-GMP Certificate
  - ✓ K-MAH(Korea Marketing Authorized Holder)
  - ✓ Reimbursement (Including nHTA and Breakthrough Tech)
  - ✓ Clinical Study Consulting (Including IDE and IRB review)
  - ✓ Compliance Check and Investigation Defense



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Korean Boutique Medical Device Consulting Firm (Cont.d)

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- ✓ Law Firms
- ✓ Customs office
- ✓ CROs
- ✓ Distributors specializing in medical devices

National Health Insurance System and Assessment for Innovative Medical Devices & Technology

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Guideline for NHIS Enrollment of DTx

- ✓ Published on August 25, 2023
- ✓ Introduced National Health Insurance (NHI) system registration and enrollment procedure for innovative medical technology (with DTx)

Definitions

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Innovative Medical Device

Medical devices "designated by the Ministry of Food and Drug Safety(MFDS)" that have significantly improved or are expected to improve safety and effectiveness through the application of advanced technologies or improvements in usage in fields with high technology intensity or rapid innovation.

- Types: 10 advanced technology categories (AI·Big Data, Digital·Wearable, etc.), Medical Innovation, Technological Innovation, Public Medicine

Innovative Medical Technology

Medical Technology that is recognized for its safety and potential and can be used in clinical practice if it meets the conditions set by the Ministry of Health and Welfare, including the designated period of use, purpose, target and method of use.

- Technical Properties: 9 innovative · advanced technology types (3D Printing, Robots, AI, DTx, etc.), Potential medical technology recognized by public agencies (through research on newly developed technology, etc.)

Definitions

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Digital Therapeutics (DTx)

A SaMD(Software as a Medical Device) that provides evidence-based medical involvement in order to prevent, monitor, and treat medical disorder or diseases

※ Source: 'Guideline for DTx Approval' (MDFS, 2020.08)

Integrated Review and Assessment for Innovative Medical Device

A system that shortens the time required for innovative medical devices to enter the medical field by expanding the range of innovation recognition and simplifying the government assessment process through integrated review (designation and approval of innovative medical devices, confirmation of eligibility for reimbursement, and evaluation of innovative medical technology) by the relevant ministries.

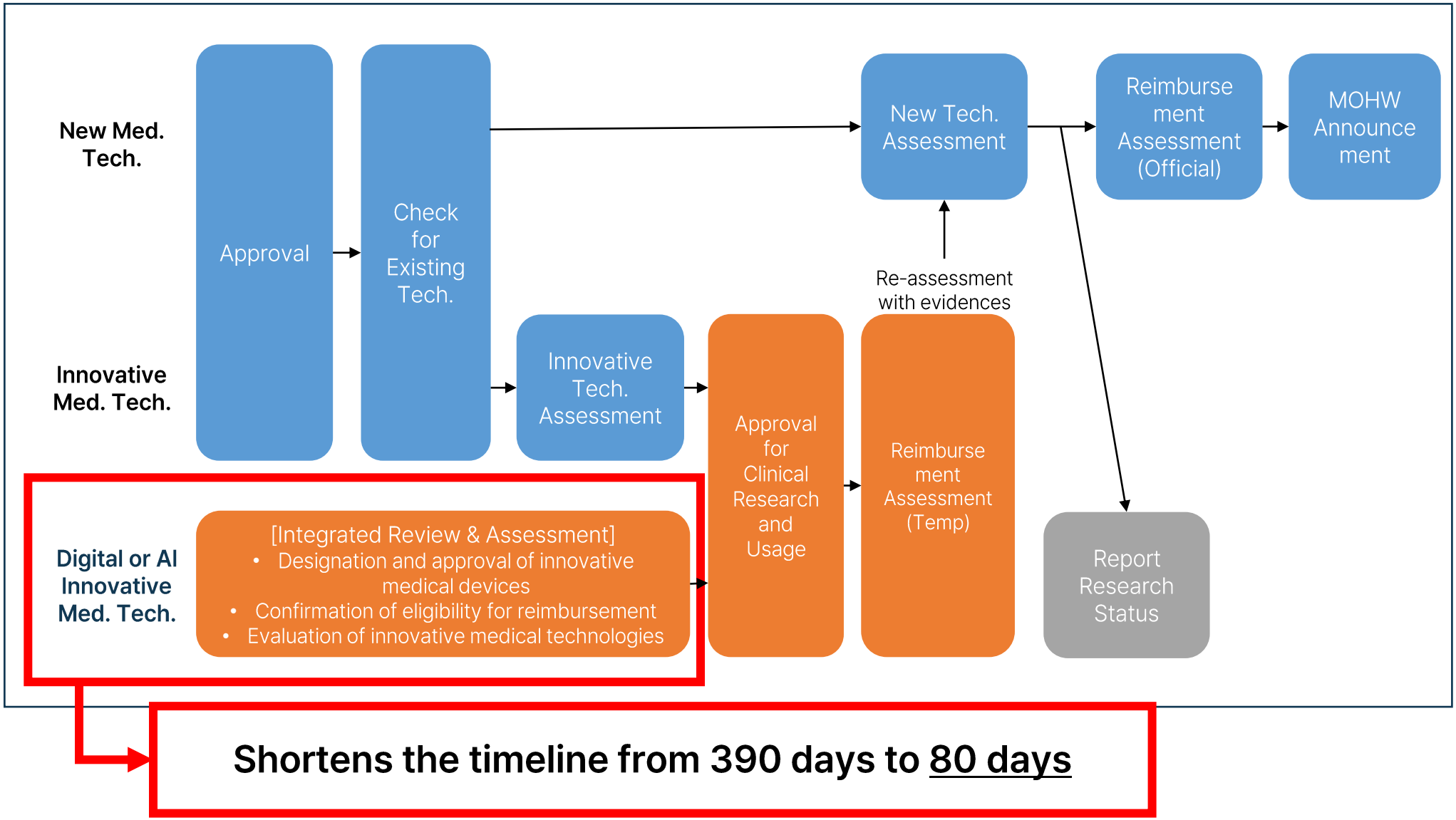
General Enrollment Procedure for New/Innovative Medical Technology

Medical Device Act	National Health Insurance Act	Medical Service Act	National Health Insurance Act
MFDS	HIRA	NECA	HIRA
Safety and Efficacy Assessment of Product (80 days, Designation of Breakthrough Device : 30 days)	Determine whether existing tech or new tech (30 days)	If new tech, determine safety and efficacy (= nHTA, 250 days)	Assess feasibility for reimbursement (30 days, Actual 1~2 years)

Medical Device Approval/license/reg.	Existing Tech?	Assessment delay	Reimbursement Qual.
		New Med. Tech.	Non-reimbursement
KGMP Certification	New Tech?	Developing Tech.	Selective reimbursement
		Innovative Med. Tech.	

MFDS: Ministry of Food and Drug Safety, HIRA: Health Review and Assessment Service, NECA: National Evidence-based Healthcare Collaborating Agency,

Integrated Enrollment Procedure for Innovative Medical Technology with Digital Technology



Shortens the timeline from 390 days to 80 days

Integrated Review & Assessment

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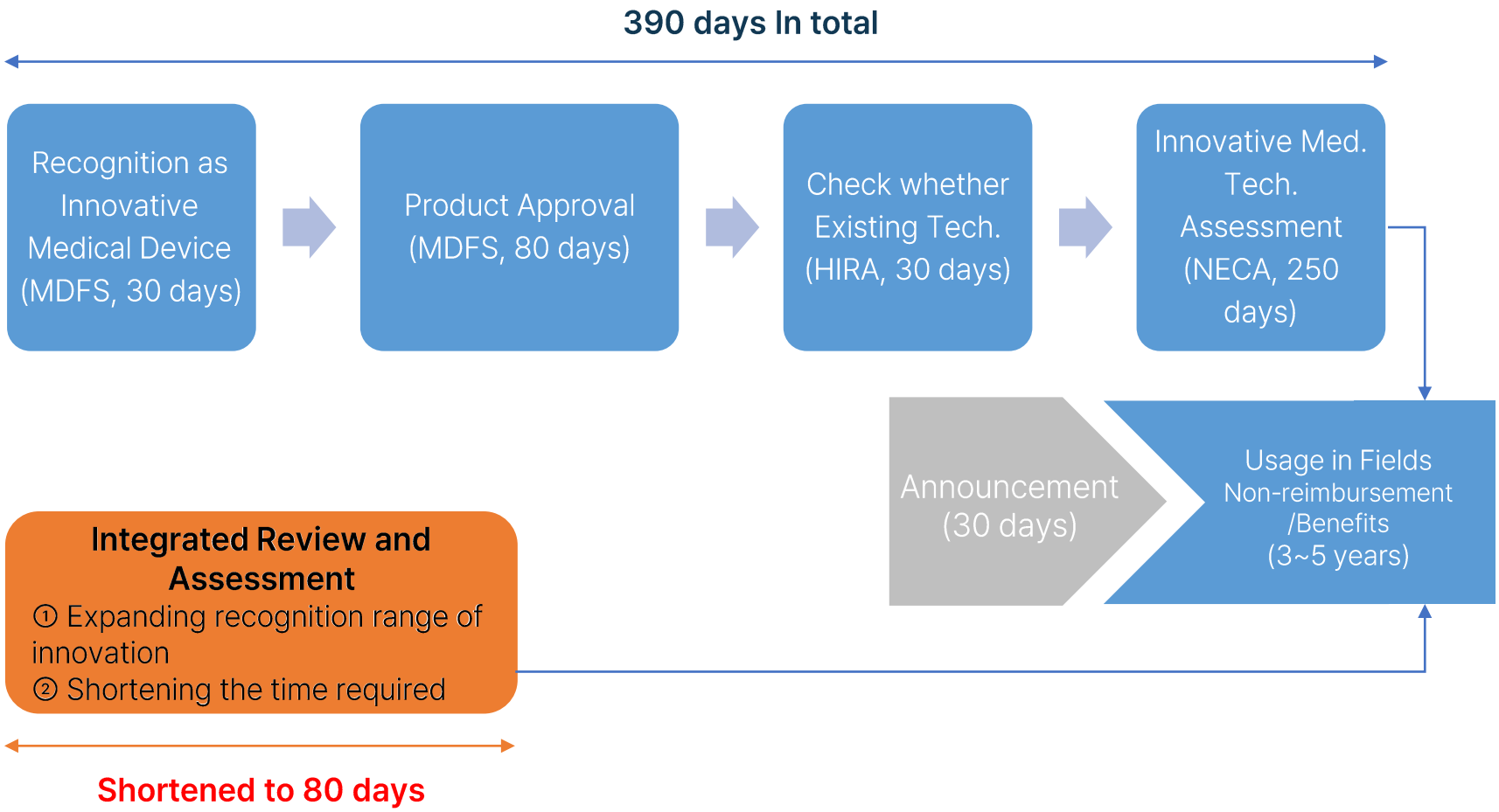
*Target: Digital · Wearable or AI · Big Data Technology



Introduction to Temporary Reimbursement Registration of DTx Products

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Introducing "Temporary Reimbursement Registration" System of DTx Products

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Target: Innovative Medical Technology assessed through integrated review & assessment and announced by MOHW

Temporary insurance reimbursement or benefit applies for 3~5 years

- ✓ Company should generate evidence - such as clinical test, RWE, etc. - for re-assessment for new medical technology during the designated temporary period
- ✓ When conducting clinical test, if the subject collection is completed in early period, the technology can be used in market for **"medical treatment" purpose for the rest of the approved period**
- ✓ When used for "clinical or medical" purpose, temporary insurance(non-reimbursement or selective health benefit) is applied
- ✓ Company should apply for re-assessment for new medical technology within 30 days before temporary period expiration

Reimbursement Assessment (Official Registration)

Based on the evidences and data generated during temporary reimbursement registration period, the technology will be re-assessed for new technology confirmation. This new technology with recognized safety and validity/efficacy will be assessed for official reimbursement registration.

- Based on assessment of the economic feasibility and adequacy of MRP price by special evaluation committee, whether it is reimbursable or not and resource based relative value scale(RBRVS) will be determined

- Announced by the MOHW after deliberation/resolution by the Health Insurance Policy Deliberation Committee

MRP: maximum reimbursement price

Temporary Reimbursement Registration for DTx

Target Technology & Management Method

For DTx or wearables that have been determined as innovative medical technology through a comprehensive integrated assessment:

- ✓ Must be a product that has obtained approval from the MFDS as a DTx product and must also be prescribed by a HCP **(= ETC(Ethical Drug), Ethical Device, prescription only)** .
- ✓ **Prescription Code**: The company must provide a 'code' to healthcare institutions to access the digital therapeutic device, and healthcare institutions should provide the relevant code to patients to enable patient usage.
- ✓ **Managing actual use**: When a patient uses the code to download/access/use the DTx/app, the company should collect usage data and provide it to healthcare institutions (for treatment purposes) or the HIRA (for future insurance price determination based on usage history).

Temporary Reimbursement Registration for DTx

Maximum Reimbursement Price (MRP)

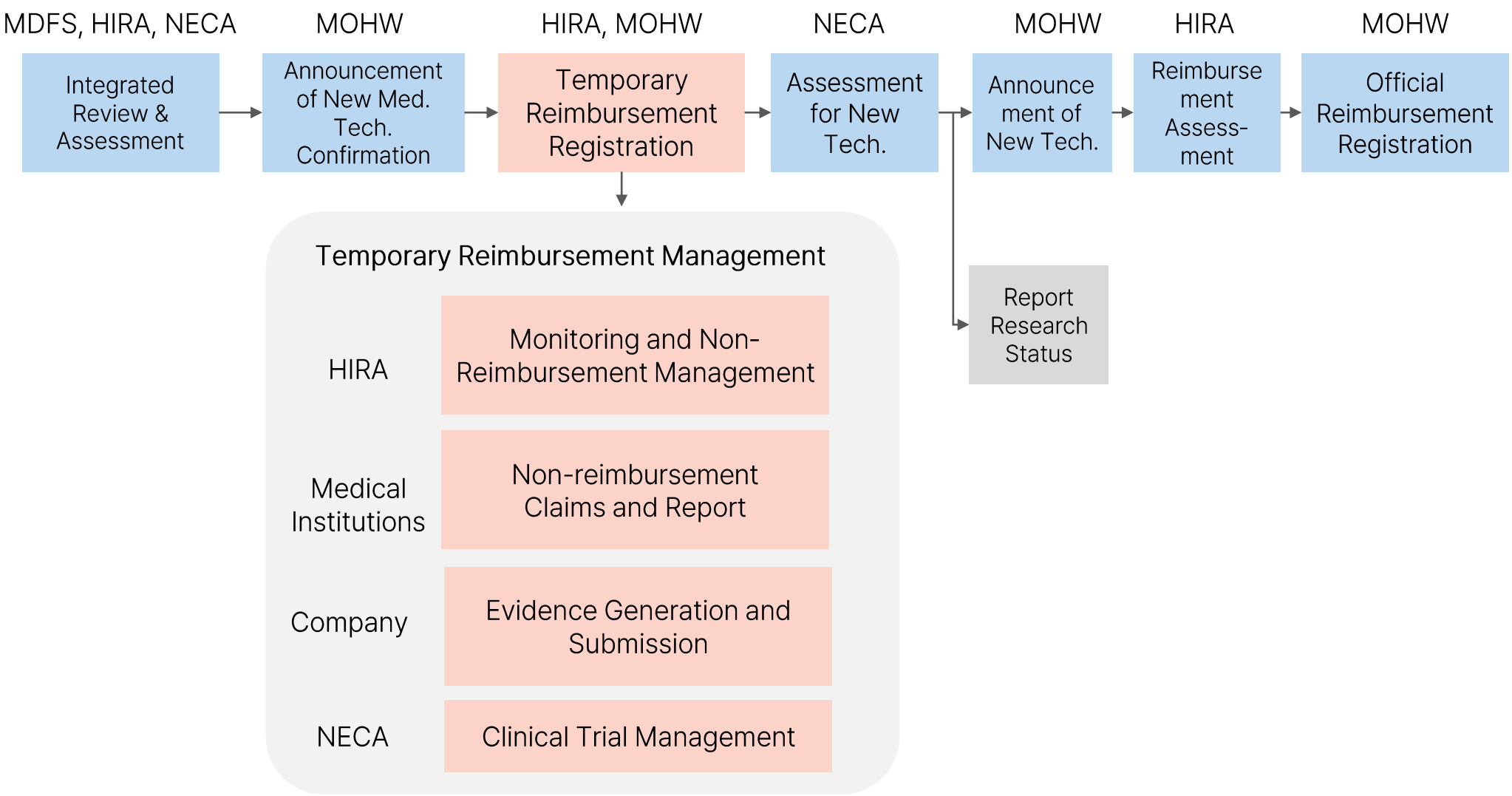
MRP will be determined after the government collects data during the temporary reimbursement period of the DTx

- ✓ Normally, the gov't determines the reimbursement/non-reimbursement of the medical device/product but for DTx, gov't will permit the manufacturers/developers of DTx to decide whether it would want reimbursement/non-reimbursement for its products. However, HIRA will make the final decision after receiving the company's input.
- ✓ After the special evaluation committee reviews the temporary reimbursement qualification, it won't be possible to change reimbursement/non-reimbursement status of product during the temporary reimbursement period.

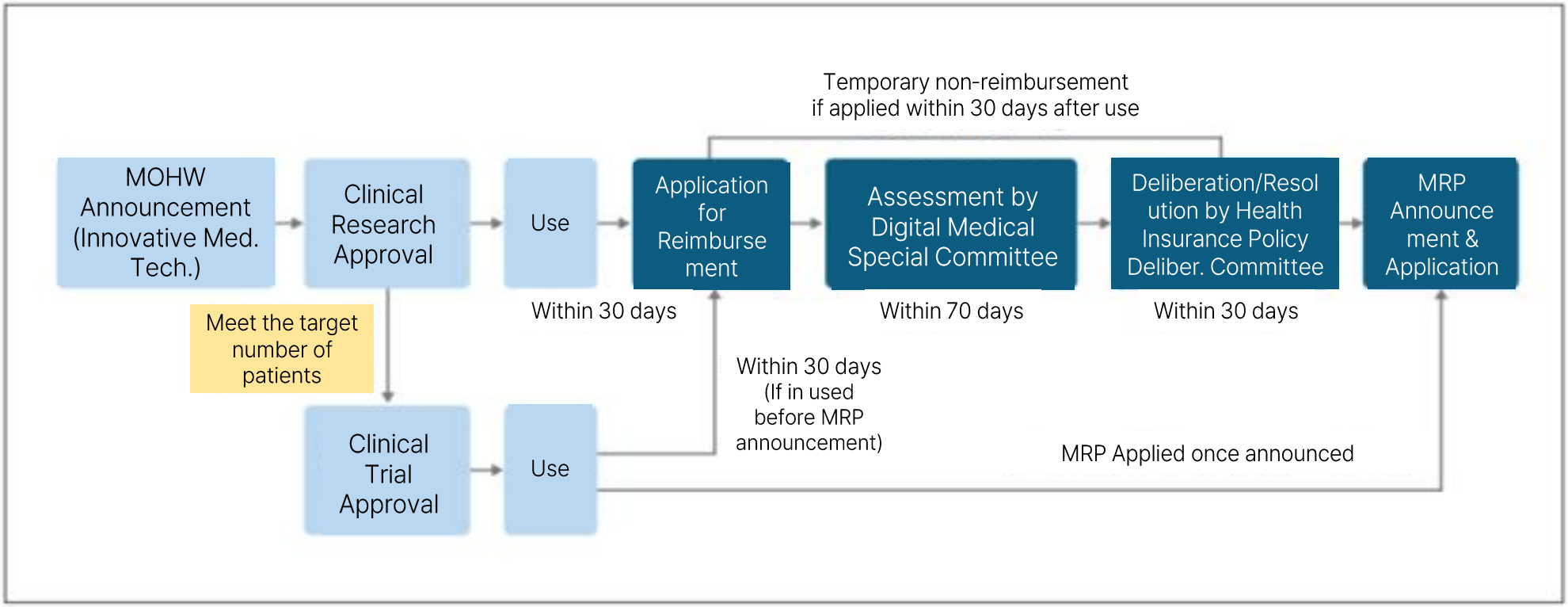
Non-Reimbursement Management

During the temporary inclusion period, if it is determined as 'non-reimbursable,' healthcare institutions must make prior declarations and disclose the non-reimbursable fees specific to each facility. Additionally, healthcare institutions must submit claims to HIRA for 'non-reimbursable' procedures on a facility-specific basis for the purpose of usage monitoring

Temporary Reimbursement Registration for DTx

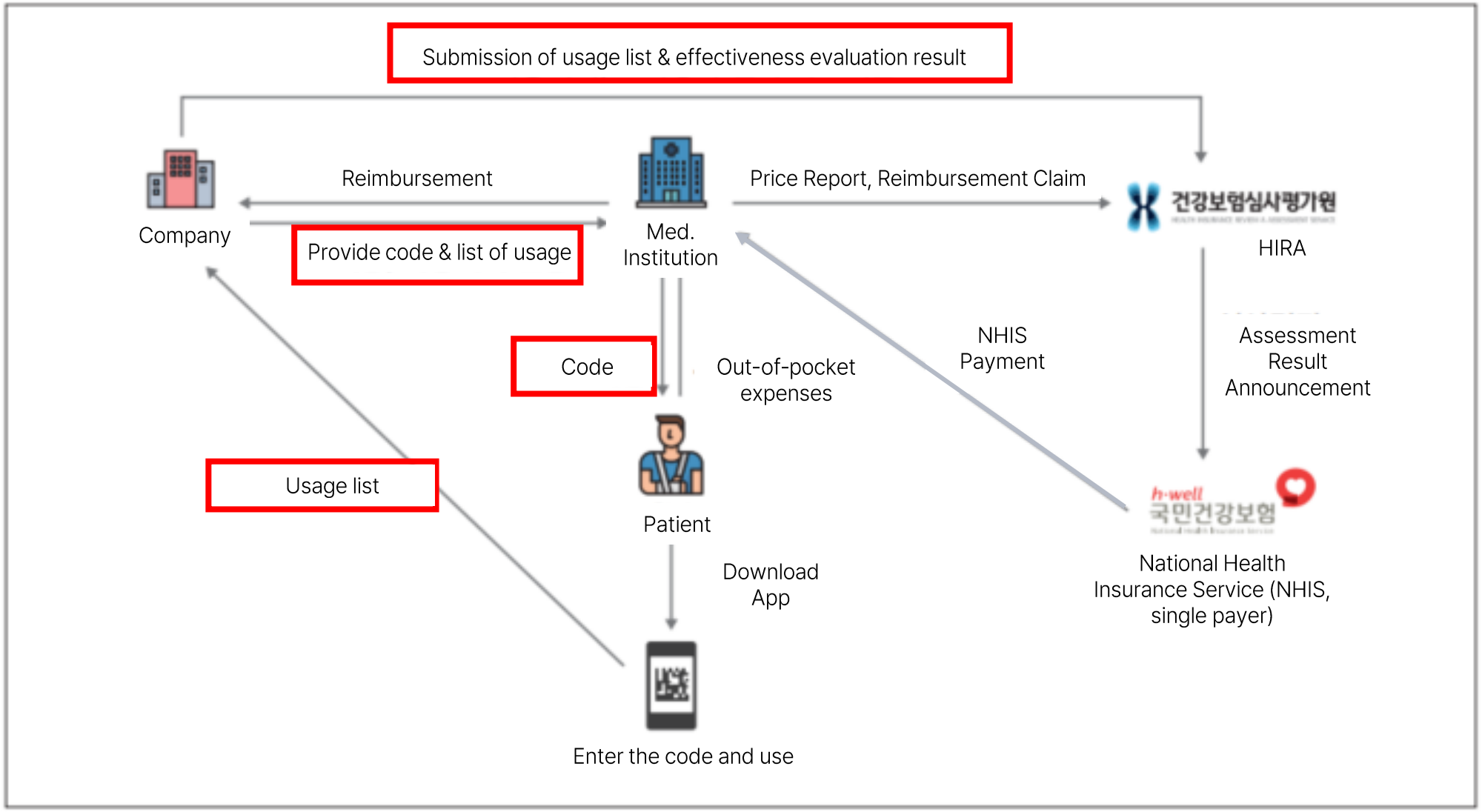


Temporary Reimbursement Registration for DTx



- ✓ Medical institutions must send temporary reimbursement approval within 30 days of first using the DTx product. (After official notice of DTX product qualifying for innovative medical technology)
- ✓ Product can be used in market after obtaining clinical trial approvals and meeting target number of patients

Flow chart for DTx Product Usage



1st DTx Product to qualify for NHI Reimbursement

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MFDS – Status of DTx product approval (as of Oct. 2023)

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Approval Status

- Product Type : Cognitive Therapy Software
- Classification : Class 2
- Product Info :

No.	Company	Product	MFDS Approval #(date)	Purpose of Use	Remarks
1	Welt Co. Ltd.	WELT-IP-A	23-511 (2023.04.19)	Improve insomnia symptoms	Innovative Med. Tech. (2022.12.15)
2	Welt Co. Ltd.	WELT-IP-A	23-4632 (2023.04.14)	Improve insomnia severity	Export only
3	Mimo	ET-101	23-4175 (2023.02.20)	Improve recognition	Export only
4	AimMed	Somzz	23-103 (2023.02.15)	Improve insomnia symptoms	Innovative Med. Tech. (2022.12.15)

Example: DTx Qualifies as Innovative Medical Technology(2023.03.30)

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10. Cognitive behavioral therapy for chronic insomnia use DTx

1) **Name of innovative medical technology**

Cognitive Behavior Therapy for Chronic Insomnia using digital therapeutics

2) **Purpose of Use**

Alleviate insomnia symptoms

3) **Target Patients**

Patients with insomnia symptoms continuing for at least 3 months

4) **Approved term**

June 1, 2023 to May 31, 2026

Example: DTx Qualifies as Innovative Medical Technology(2023.03.30)

10. Cognitive behavioral therapy for chronic insomnia use DTx

5) Method of Use

Mobile app that is prescribed by HCPs to provide 6-9 weeks training, live feedback, and other behavioral programs to lead to patient improvement. The DTx product contains CBT-I: Cognitive Behavioral Therapy for insomnia protocol that includes stimulus control, sleep restriction therapies, sleep hygiene training, progressive muscle relaxation and cognitive behavioral therapy.

6) Participating Institutions

Healthcare institutions registered by the applicant of innovative medical technology as using the DTx product.

Example: DTx Qualifies as Innovative Medical Technology(2023.03.30)

Expected timeline of temporary reimbursement qualification for DTx treating insomnia

- ✓ Qualified as innovative medical tech. (2023.03.30)
- ✓ Develop clinical trial plan (multiple institutions) and receive NECA/IRB approval

* 2023

Mar. → Apr. → May → ... → Oct. → Nov. → Dec. → ..... → Jan. → Feb. → Mar. → Apr. → May → Jun. → Jul.

* 2026

- ✓ Determine "reimbursable or non-reimbursable" for medical institutions.
- ✓ Medical institutions will apply for temporary reimbursement within 30 days of first use of the DTx product.
- ✓ Can proceed with clinical trials as "non-reimbursable" product before registering for temporary reimbursement.
- ✓ **Notice of temp. reimbursement (expected Dec. 2023 or Jan. 2024)**

- ✓ Apply for new medical technology re-assessment to NECA

• Thank you •

MDREX

Professional service firm that helps digital health and medical device companies with issues in regulatory affairs, quality assess, market assess, and business development in Korea

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