IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

10:50 – 11:05

South Korea

Byung-Gwan Kim

Assistant Director of Medical Devices Policy Division,

Medical Devices Safety Bureau (MFDS)

European Commission

European Union

IMDRF International Medical Device Regulators Forum

Korea's Digital Medical Products Regulation Improvement Policies

- Digital Medical Product Act -

Gyuhan Chae (Presented by Byung Gwan Kim)

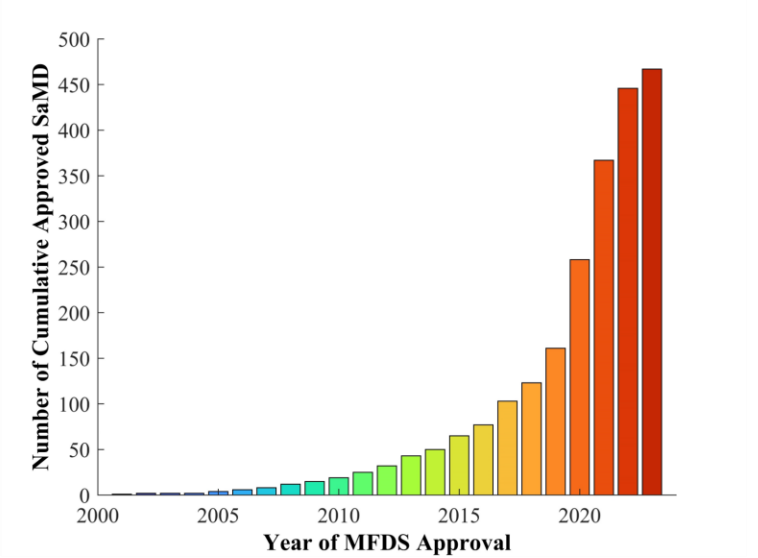
Ministry of Food and Drug Safety

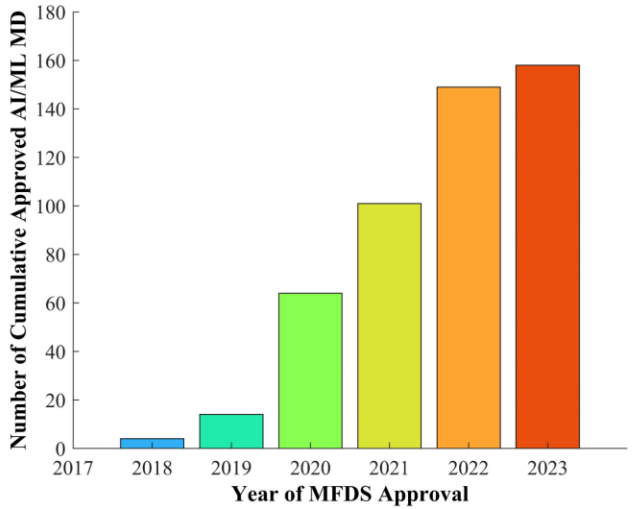
[28, MAR, 2023]

Overview

Background

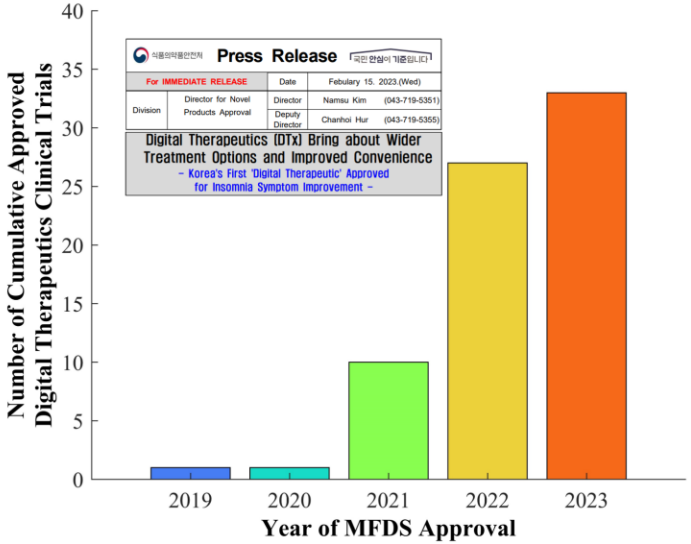
SaMD





AI/ML MD

DTX



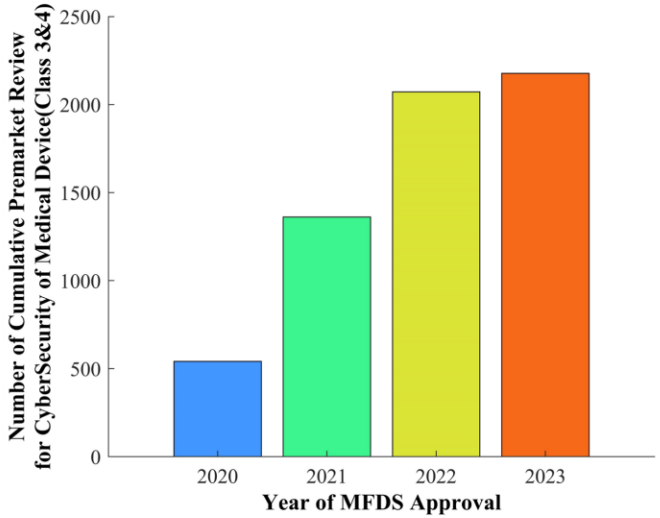
Press Release

For IMMEDIATE RELEASE | Date | Febulary 15. 2023.(Wed)

Division: Director for Novel Products Approval | Director: Namsu Kim (043-719-5351) | Deputy Director: Chanhoi Hur (043-719-5355)

Digital Therapeutics (DTx) Bring about Wider Treatment Options and Improved Convenience

– Korea's First 'Digital Therapeutic' Approved for Insomnia Symptom Improvement –



Cybersecurity

Objective

- Digital Medical Products Regulatory Framework in Place for the Digital Health Era

Definition

- **Digital Medical Device**
  MD with Advanced Digital Tech or these with Supporting Products
- **Medicines with Digital Tech.**
  Pharmaceuticals with Digital MD or Supporting Products
- **Digital Health Supporting Product**
  Support Medical Care / Improve Health (Can be converged with MD / Pharmaceuticals)

Regulation - Digital Medical Devices

- **Clinical Trials**
  - Simplifying approval process for low-risk clinical trials
  - Facilitating decentralized clinical trials
  - Activating the use of pseudonymous(anonymous) data
- **Approval(pre-market certification)**
  - Fast & Temporary classification (New products)
  - Establishing new classification criteria suitable for SaMD
  - Certifying an Excellent SW Company → Incentive(SaMD/SiMD)

Regulation - Digital Medical Devices

- **Approval(pre-market certification)**
  - **Simplifying change procedures(SW)**
  - **Expanding the (change) approvals based on Real-World Evidence**
- **Management**
  - **Improvement of SW sales regulations**
  - **Allowing QM tasks to be entrusted to specialized companies**
  - **SW-specific QMS / National Cyber Security Guideline**
  - **Professional Digital MD(including ETC)(Labeling/Advertising)**

Regulation – Medicines with Digital Tech.

- **Clinical Trials**

  - Activating clinical trials using digital MD/ supporting Products

  - Separation of clinical trial procedures (Medicines / combined MD)

- **Approval(pre-market certification)**

  - Incorporative Review System (Medicines + digital MD)

  - Prevention of Redundancy review (with Approved-digital MD)

  - Review System for “Medicines with Supporting Products”

- **Management**

  - Integrating Quality Management System

Regulation – Digital Health Supporting Devices

- **Performance**
  - Preparation and provision of performance standards

- **Certification**
  - Certification, if desired, at the company's discretion
    ⇒ Marked as a "Certified Performance" on the label
  - Certification procedure for supporting products combined with digital MD or Medicines with digital tech.

- **Management**
  - Voluntary recall/exchange of defective products
    Consumer notification (manufacturer)

Evaluation & ETC

- **Evaluation**

  - MFDS evaluates the health and medical values of digital-MP

  ⇒ Request to the Ministry of Health and Welfare

  i) Expedited decisions for health insurance coverage

  ii) Preferential treatment for health insurance coverage

- **ETC**

  - Preliminary review (including supporting products)

  - Digital acceptability improvement for all consumers

  - Copyright protection (SW), and the like

THANK YOU
감사합니다

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Ministry of Food and Drug Safety