IMDRF International Medical Device Regulators Forum

Regulatory Updates on Medical Devices in South Korea

Ministry of Food and Drug Safety

March 2021

Table of Contents

01

Major achievements in 2020

New Division

- Establishment of Innovative and Diagnostic Medical Device Policy Division under the Medical Device Safety Bureau
  - in charge of the policy on innovative medical devices, IVD devices, etc.

Nomen-clature

- Revision to medical devices nomenclature for SaMD
  - 90 SaMD items in 11 clinical areas newly added

COVID-19

- Official approval for 18 IVDs in response to COVID-19
- Approval for 269 IVDs intended for export in response to COVID-19

Innovative Medical Devices

- 8 innovative medical devices designated
  - MLMD (Machine Learning enabled Medical Device) : 6
  - BNCT (Boron Neutron Capture Therapy) : 1
  - Augmented Reality : 1
- 1 research institute for innovative medical devices and 1 training center for experts designated

※ Data as of March 4, 2021

02

Regulatory Initiatives in 2021

Regulatory Initiatives in 2021

Vision

To create environment where people feel reassured of the use of medical devices in the post COVID-19 era

Goal

- Reinforcement of responsibility with the development of patient-focused safety management system
- Introduction of preemptive measure for balanced growth of innovative technologies and regulations

Development of Regulatory Competency

Strengthening Post Market Regulation of Medical Devices

Strengthening International Cooperation

The Enforcement of the Act on IVDs (since May 1, 2020)

- Development of Regulatory Competency for IVDs -

Supporting in Technology for the Quality Improvement of IVDs

- Designating IVDs manufacturers and cooperating with external experts to evaluate the adequacy of the quality management
- Providing technical support by giving information about the review and approval process, QMS, clinical performance test in a number of jurisdictions
  - Providing information for manufacturers with the database development
  - Information on regulatory requirements in consideration of the development stage of IVDs

The Enforcement of the Act on Nurturing the Medical Devices Industry and Supporting Innovative Medical Devices (since May 1, 2020)

- Development of Regulatory Competency for Innovative Medical Devices -

Supporting Innovative Medical Devices and SaMD

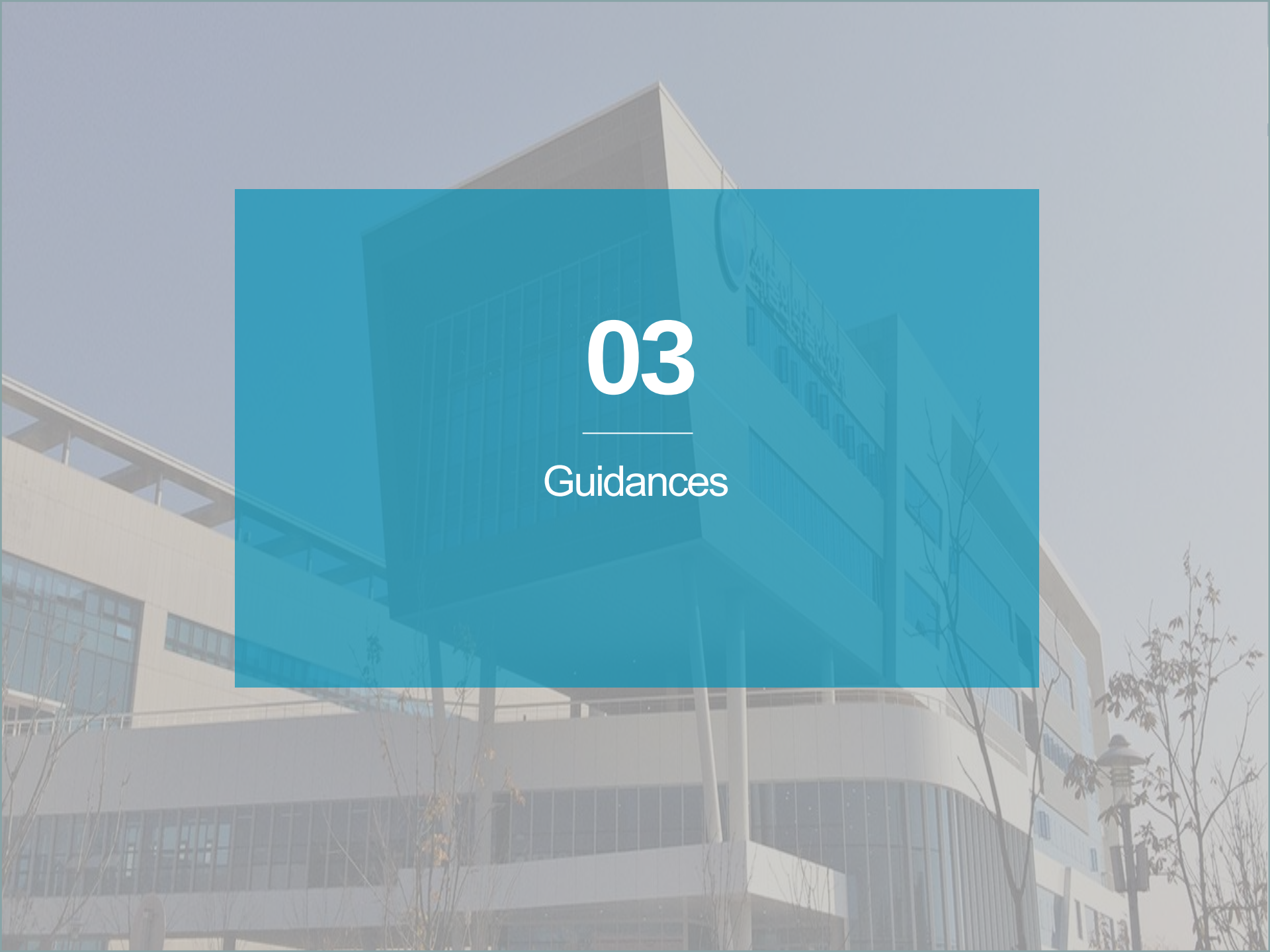
- Streamlining the process and simplifying submissions when applying for the approval of innovative medical devices
- Fine tuning of regulatory framework for the approval of clinical trials protocol with the aim of promoting the clinical trial of SaMD
- Development of guidance on clinical trial protocol for Digital Therapeutics to expedite approval process
- Development of guidance on QMS for SaMD manufacturers
- Leveraging expertise for the quality management of SaMD

Strengthening Post Market Regulations of Medical Devices

- Reinforcing compensation system for patients who are damaged by implantable medical devices
- Mandating regular submission of Usage Record of Medical Devices subject to the traceability system
- Achieving international harmonization of terms and codes regarding Cause Investigation for Adverse Events
- Mandating Reporting of Supply Suspension of medical devices that have huge impact on public health

Strengthening International Cooperation

- Contribution to the harmonized regulatory approach to innovative medical devices as a member of IMDRF
- Establishment of the mid and long term strategies for the international standardization of IVDs, MLMD (Machine Learning enabled Medical Device) and Digital Therapeutics
- Development of a draft of the Infectious Disease Prevention Model (Test-Trace-Treat) and sharing with the international community



03

Guidances

Newly Developed Guidances for Industry

COVID-19

- Guidance on the Review & Approval of IVDs for COVID19(3rd Edition)
- Guidance on the Review & Approval of Medical Respirator

MLMD

- Guidance on the Evaluation of Safety/Performance and Clinical Protocol for Software of Image Detection and Diagnosis Support for Brain, Colon Cancer, Prostate Cancer
- Guidance on the Procedure and Criteria of Certification for Innovative Software Manufacturer

3D Printing

- Guidance on the Review & Approval of Co-Cr Artificial Joint Manufactured using 3D Printing
- Guidance on the Review & Approval of Denture base Resin Manufactured using 3D Printing
- Guidance on the Review & Approval of Aesthetic Crown Manufactured using 3D Printing

English Version

- Guidance on the Review & Approval of IVDs for COVID-19
- Guidance on the Review & Approval of AI and Big data based Medical Devices
- Guidance on the Review & Approval of Digital Therapeutics
- Guidance on the Review & Approval for Cybersecurity of Medical Devices

Ongoing Projects

IVD	Development of Guidance on the Evaluation of Clinical Performance of AI based Digital Pathologic IVDs
DTx	Development of Guidance on the Evaluation of Safety/Performance and Clinical Protocol for Digital Therapeutics
Review Practice	Revision of Evaluation Method of Medical Device Substantial Equivalence for Premarket Approval

Thank you