第11屆 台日醫藥交流會議

The 11 th Joint Conference of Taiwan and Japan on Medical Products Regulation

Regulatory Updates in Taiwan

October 5th. 2023

Dr. Shou-Mei Wu, Director-General
Taiwan Food and Drug Administration (TFDA)

Outline

1. Medicinal Products
2. Medical Devices
3. Collaboration with Japan
4. Future Prospects

Outline

Drug Safety Monitoring

Regulations for Drug Safety Monitoring

2023.01.01

PV Range
- Require all of MAH should implement PV system.

Risk Management
- Require MAH should report when finding an emerging safety issue from any source and take actions.

PV Master file
- Draw reporting format.
- If the transfer of MAH shall hand over the safety information to the transferee, and the transferee shall continue to conduct the surveillance or storage .

PV Inspection
- Health authority could inspect MAH to make sure they implement PV.

Developing Regulations for Regenerative Medicine

Regenerative Medicine Act (draft)
再生醫療法

To regulate the clinical practice of regenerative medicine at medical institutes

Regenerative Medicinal Product Act (draft)
再生醫療製劑條例

To regulate the product life-cycle of regenerative medicinal products

Act for the Development of Biotech and Pharmaceutical Industries
(revised Dec. 03, 2021)
生技產業發展條例

To facilitate the development of advanced medical and high-tech products in Taiwan, including regenerative medicines

Pilot Program for Publishing the New Drug Review Reports

Purpose

- To enhance regulatory transparency
- For global regulatory authorities and industries to have better understanding on regulatory decision making and review considerations of TFDA/CDE

Publishing New Drug Review Report in Summarized format was originally implemented in 2010

Publishing New Drug Review Full English Report (with defined format) Start as a 2-year pilot program on July 1st, 2023

- **New Drugs (new active pharmaceutical ingredient, including biologics)** with one of the following features :
  - ✓ Domestic product
  - ✓ Global-first approved
  - ✓ Regenerative medicinal products
  - ✓ Identified with ethnical sensitivity based on the results of BSE
  - ✓ Approved indication different from EU/US/Japan

Currently not applicable for Orphan Drugs

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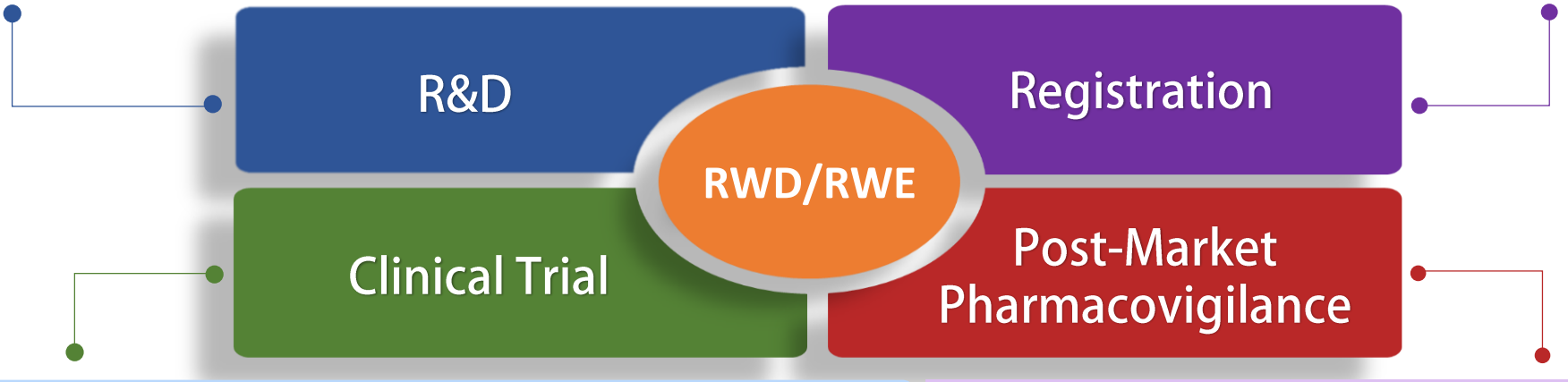
Real-World Data and Evidence in Drug Application – Guidelines in Taiwan

Basic Considerations in Supporting Drug Research and Development with Real-World Evidence Jul 2020

Real World Data Quality Evaluation- Relevance and Reliability Considerations Mar 2021

Precautions for submitting technical documents using RWD/RWE for drug application Jul 2021



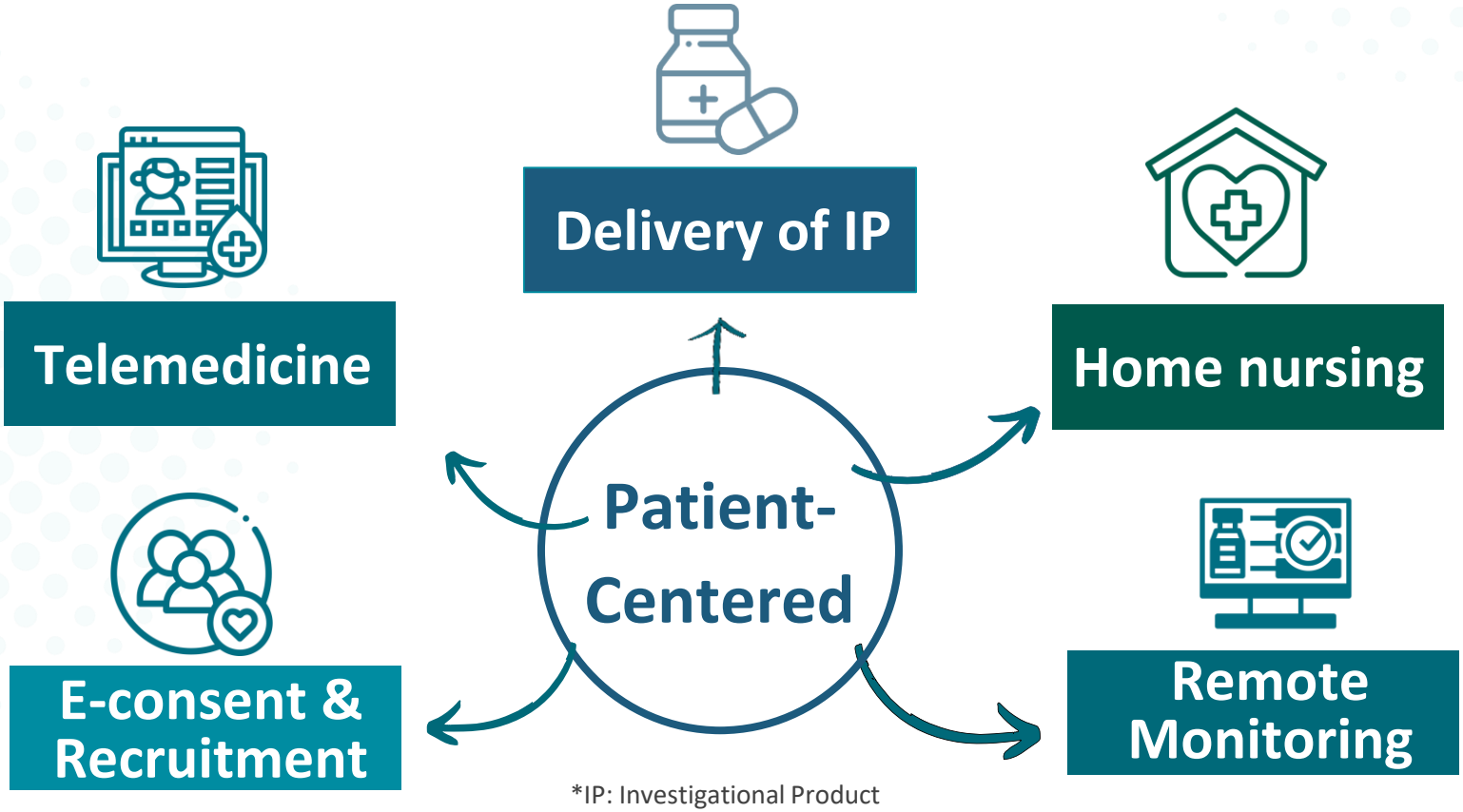
Use of Electronic Medical Record Data in Clinical Studies Nov 2020

RWE Study Designs- Considerations and Key Points for Pragmatic Clinical Trial Jan 2021

Guideline for Using Electronic Health Record and Medical Claim Data to Support Regulatory Decision Making Apr. 2023(Draft)

Guidelines for Using Electronic Healthcare Data to Conduct Pharmacoepidemiologic Safety Studies Mar 2022

Elements of Decentralized Clinical Trials



*IP: Investigational Product

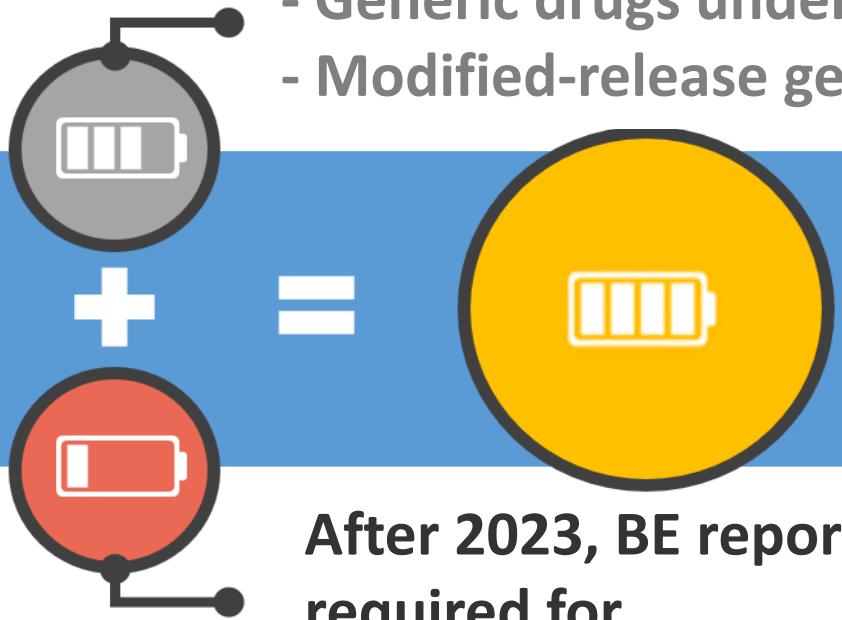
Issued "Guideline on the implementation of decentralized elements in clinical trials with medicinal products" in June 2023.

Regulatory Updates in BA/BE

Revised Regulations for Registration of Medicinal Products & Regulations of Bioavailability and Bioequivalence Studies

Before revised, BE reports or BA + Clinical reports are required for

- Generic drugs under pharmacovigilance
- Modified-release generic drugs



BE reports or BA + Clinical reports are required for all generic drug registration.

After 2023, BE reports or BA + Clinical reports are also required for

Generic drugs not under pharmacovigilance

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Promote electronic drug package inserts (e-labeling)

Information Technology

Easily Accessible | Easy to Read | Advanced Applications

1-Digitized

To provide the pdf files of the drug package insert on the Internet.

2006

2-Standardized

To standardize the templet and sections of the drug package insert.

OTC 2016

2021

3-Structured

To develop the structured drug package insert.

2021

4-Paperless

To promote e-labeling replace paper package inserts.

2022

TFDA

Pharmaceutical Factory

Pharmaceutical Company

Hospital

Pharmacy

Clinic

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2023 Regulatory Updates on Medical Devices

Jan. 2023 — Product Items of Medical Device that Require Testing for Registration (Revised)

Feb. 2023 — Requirements for Indicating the Unique Device Identifier on Medical Device Labels (Revised)

Mar. 2023 — Medical device product items that the instructions may be replaced by electronic instructions and medical device firms shall indicate the particulars on the labels or package (Revised)

Jul. 2023 — Amendments drafted on partial articles of the "Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration" as well as Appendix 1 of Article 5, Appendices 2 and 3 of Article 6

Aug. 2023 — Amendments to Article 7 and to the Annex to Article 4 of the Regulations Governing the Classification of Medical Devices

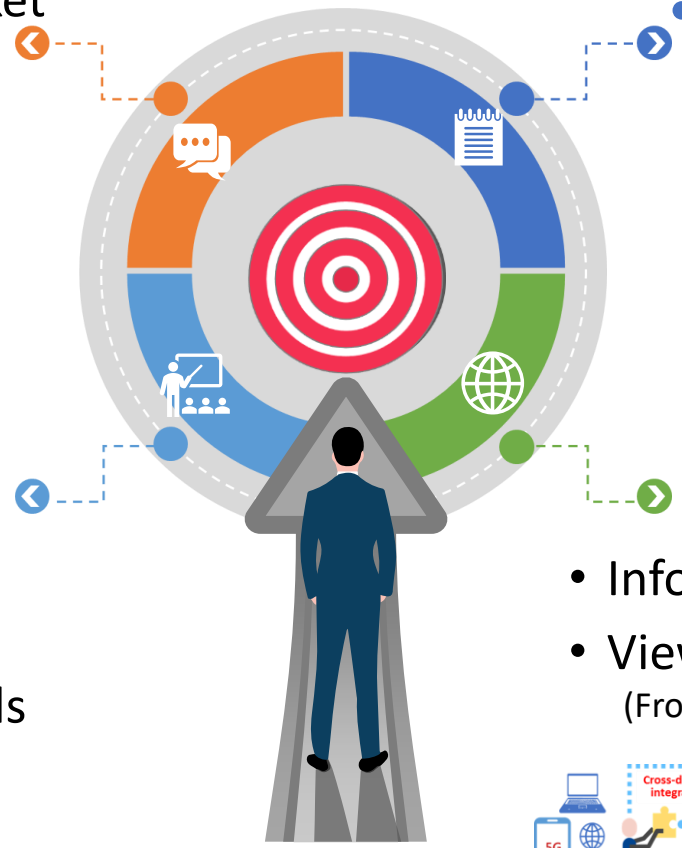
Strategies for Promoting the SaMD Industry

Consultation Service

- ↓ Product time-to-market
- For **domestic** AI-SaMDs
- **12** AI-SaMDs launched
  (From 2021 to July 2023)

Training Courses

- Meeting industry needs
- **140+** courses
- MDs e-learning platform

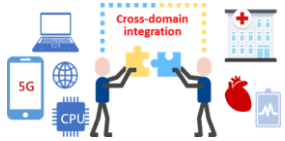


Guidelines Developed

- Regulatory environment
- **17** documents published
  - ✓ 11 guidelines
    (4 related to AI-SaMDs)
  - ✓ 1 reference template
  - ✓ 5 FAQs

AI/ML Platform

- Information and matchmaking
- Views : 34,000+
  (From 2021 to July 2023)



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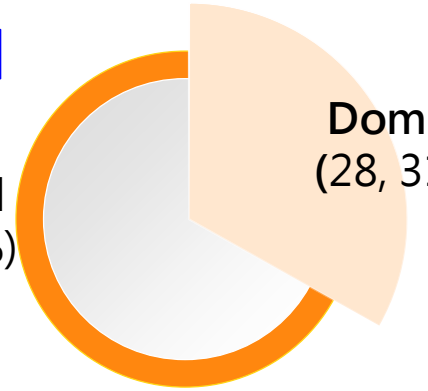
SaMD: Software as a Medical Device

Status of Approved AI-SaMDs in Taiwan

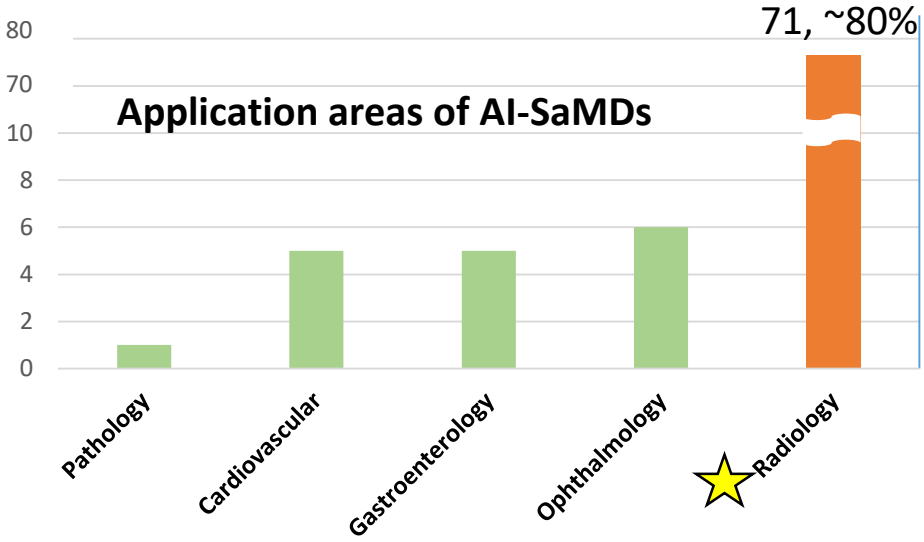
89 cases in total



(From 2020 to July 2023)

e.g.

- ICH (brain bleeding)
- DR & AMD
- MI & Arrhythmia
- Lung nodules
- Pneumothorax
- Breast cancer
- Bone age
- Scaphoid fracture
- Pancreatic cancer
- Colorectal cancer
- Osteoarthritis
- Bone marrow cells



Red: Top 10 causes of death
Blue: Aging-related

ICH: Intracranial hemorrhage
MI: Myocardial infarction
DR: Diabetic retinopathy
AMD: Age-related macular degeneration

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International Cooperation

Asia-Pacific Economic Cooperation

- RHSC Medical Device Priority Work Area Center of Excellence (CoE) for Regulatory Science (since 2019)

IMDRF International Medical Device Regulators Forum

- Affiliate Member (2023)

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- Work Group 2 - Pre-market: IVDD Chair (since 2012)
- Work Group 3 - Pre-market: Software as a Medical Device Chair (2023)
- Work Group 9 - UDI & Nomenclature Member (since 2019)

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Collaboration with Japan

Pharmaceutical Working Group

1. Developed Position Paper and Q&As for New Drug Review Scheme; 6 cases were adopted and 5 were completed..
2. Established the Information Sharing model of post-marketing surveillance information.

Medical Devices Working Group

Exchanged experiences and regulatory innovation on digital transformation:

- DASH for SaMDs; AI/ML-based SaMDs
- Electronic submission system
- E-labeling system
- Cybersecurity

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Progress for the QMS Working Group of Medical Devices

2014
- Establishment of **QMS WG**.

2018
- **MOC** was signed on November 30.

2019
- **Abbreviated mode** start up.

2020
- **Q&A for MOC** was published on December 21.

2023
- Till August 23, 2023, **59 manufacturers were approved** under abbreviated mode.

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Future Prospects

To Complete Accessible Information Platform

To Establish Professional Review Team

To Establish Forward-looking Legislation

To Optimize Quality Compliance & Management

To Enhance International Regulatory Collaboration

To Provide Efficient Communication & Services

ありがとう！

Thank You!

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