Regulatory Updates in Taiwan

October, 20th, 2022

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Taiwan Food and Drug Administration (TFDA)

Outline

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

Emergency Use Authorization for COVID-19 Vaccines/Drugs

VACCINES

- Comirnaty® of Pfizer/BNT
- Spikevax® of Moderna
- Spikevax® bivalent of Moderna
- Vaxzevria® of AstraZeneca
- Nuvaxovid® of Novavax
- MVC-COV1901 of Medigen

Drugs

- Remdesivir of Gilead
- Paxlovid® of Pfizer
- Molnupiravir of MSD
- Evusheld of AstraZeneca

衛生福利部
食品藥物管理署
FDA Taiwan Food and Drug Administration

Three Draft Acts for Regenerative Medicine

Drafts announced on Jan 13, 2022

Regenerative Medicine Development Act (draft)
再生醫療發展法

To facilitate the development of RM in Taiwan

Regenerative Medicine Therapy Act (draft)
再生醫療施行及管理條例

To regulate the clinical practice of RM therapy at medical institute

Regenerative Medicine Product Act (draft)
再生醫療製劑管理條例

To regulate the life-cycle of RM products

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

Guidelines for Using Electronic Healthcare Data to Conduct Pharmaco-epidemiologic Safety Studies
Mar 2022(Draft)

Drug Safety Monitoring

Revise regulations for Drug Safety Monitoring

2022.04.15

01

PV Range

Require all of MAH should implement PV system.

02

Risk Management

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

03

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 .

04

PV Inspection

Government could inspect MAH to make sure they implement PV.

*MAH: Marketing Authorization Holder

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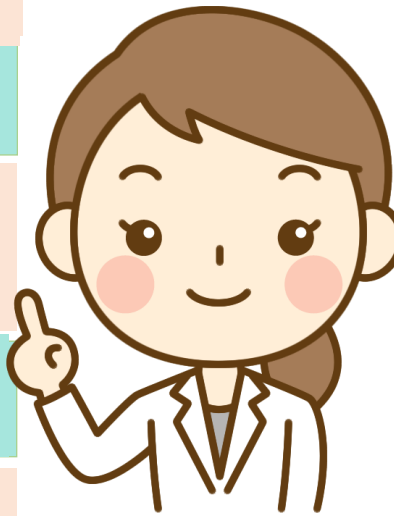
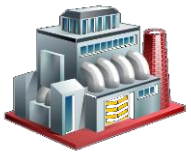
Regulatory updates in clinical trials

2021.10		Revised Principles of Clinical Trial Recruitments
2021.10	ICH E17	Planning and Design of Multi-Regional Clinical Trials
2021.10	ICH M9	Biopharmaceutics Classification System-Based Biowaivers
2022.06		Guideline on Quality and Equivalence Of Topical Products (Draft)
2022.06		Guideline on Equivalence of Locally Applied, Locally Acting Products in The Gastrointestinal Tract (Draft)
2022.07		Guidance on Considerations for Sex Differences Analyses in Clinical Trials (Draft)
2022.08	ICH E14	Clinical Evaluation of QT/Qtc Interval Prolongation and Proarrhythmic Potential for Non-antiarrhythmic Drugs and Q&A (Draft)
2022.08	ICH E18	Guideline on Genomic Sampling and Management of Genomic Data (Draft)
2022.08	ICH E2F	Development Safety Update Report



Prospects for the application of drug e-labeling

Pharmaceutical Companies



TFDA

Open data

- Healthcare information systems
- Clinical decision support systems
- Electronic health record
- Mobile apps or websites

2021

Standardize labeling formats

Edit structured e-labeling by pharmaceutical companies

2022

Pilot Program: Replacing package insert of specific drugs with e-Labeling

Design the XML format standards of structured e-labeling and release to the public

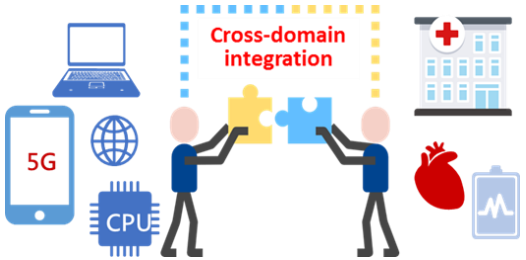
2023

Optimize the operational platform at the new system

Establishment of a Dedicated Office for AI Medical Device

Inauguration on May 7, 2021

- Implement consultation for **domestic AI-based MD**
- Conduct training and promotion activities
- Provide assistance in **developing relevant policies and guidances**
- Establish an AI/ML MD information and matchmaking platform



Related Documents for SaMDs

Totally 17 documents

1 Reference Template

- Cybersecurity Evaluation Analysis

11 Guidances

- Categorization and Classification
- QMS
- Validation
- Cybersecurity
- ……etc

Registration

- AI/ML-based SaMD
- CADt SaMD
- CADe/CADx SaMD
- NSR Clinical Trial

5 FAQ

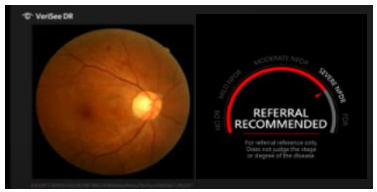
- Registration AI/ML MD
- QMS Compliance
- ……etc

SaMD : Software as Medical Device
QMS : Quality Management System
NSR : Nonsignificant risk

CADt : Computer Aided Triage
CADe : Computer Aided Detection
CADx : Computer Aided Diagnosis

Examples of Approved, Domestic AI-based SaMDs

Totally 54 AI-based SaMDs have been approved.
(From 2020 to 2022.9)



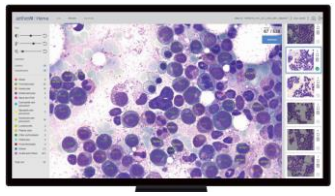
VeriSee DR

Identify the **Diabetic Retinopathy**

acer Medical

aetherAI Hema

Identify, classify and count the types and numbers of **bone marrow cells.**



aetherAI 雲象科技

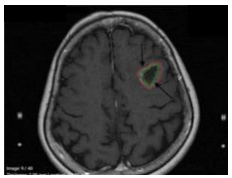
Bu-CAD

Analyze the breast ultrasound images of patients with **soft tissue breast lesions** suspicious for breast cancer

TaiHao Medical Inc.

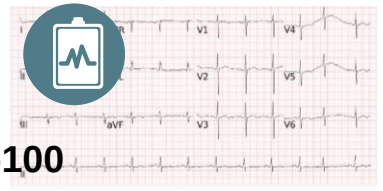
DeepMets

Provide initial **contours of diagnosed brain metastases** on MR images.



TAIMedimg

ECG-EC-100



Identify 12 types of **arrhythmia and acute myocardial infarction** from 12-lead electrocardiograms (EKG / ECG).

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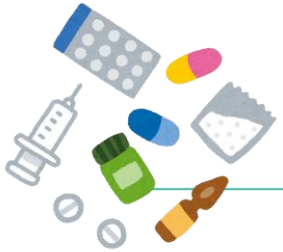
Collaboration with Japan



Pharmaceutical Working Group

- ✓ Completed Position Paper (NDA review and registration), Five cases have completed.
- ✓ Established the Information Sharing model of post-marketing surveillance information.

Medical Devices Working Group

1. Established a position paper aimed to continuously collaborate and renew the Q&As of products registration for the benefit of stakeholders
2. Updated the regulations or guidelines relating to cybersecurity, artificial intelligence/machine learning medical devices

Progress for the QMS Working Group of Medical Devices

Q&A for MOC was published on December 21.

Till September 06, 2022, **44** manufacturers were approved under abbreviated mode.

MOC was signed on November 30.

2014

Establishment of QMS WG.

2018

2019

Abbreviated mode start up.

2020

2022

Future Prospects

Foresighted-Legislation

Accessible Information Platform

Professional Review Team

Quality Compliance and Management

Efficient Communication and Services

International Regulatory Collaboration

ありがとう!

Thank You!

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