IMDRF
International Medical Device Regulators Forum

EU2023
EUROPEAN UNION Chair

European Commission

European Union

10:50 – 12:05

Regulatory Updates from IMDRF Management Committee and Official Observers

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

South Korea

Byung-Gwan Kim

Assistant Director of Medical Devices Policy Division,

Medical Devices Safety Bureau (MFDS)

European Commission | European Union

Slide 89

O(0 Please update with Kim, Byung-gwan, Assistant director . no need for picture.
OSTUNI Silvia (SANTE), 2023-03-20T15:32:37.977

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)

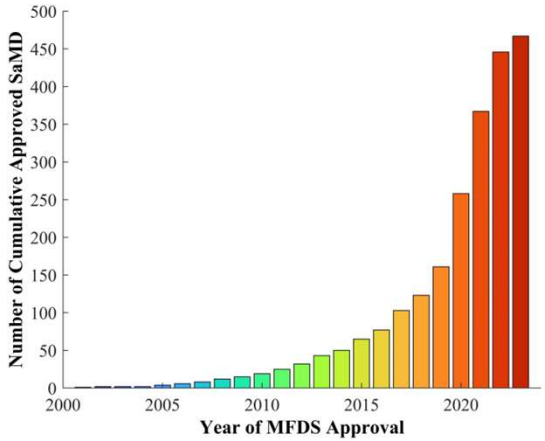
Ministry of Food and Drug Safety

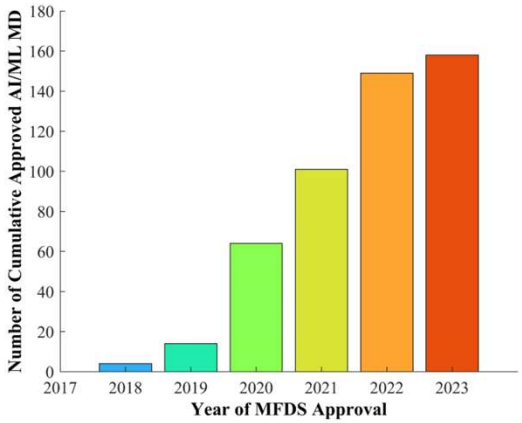
[28, MAR, 2023]

Overview

Background

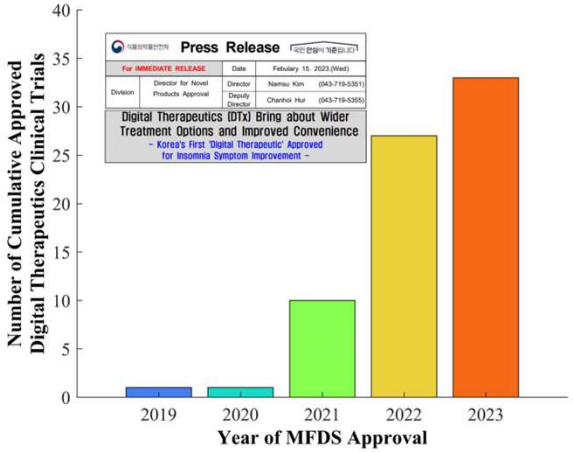
SaMD





AI/ML MD

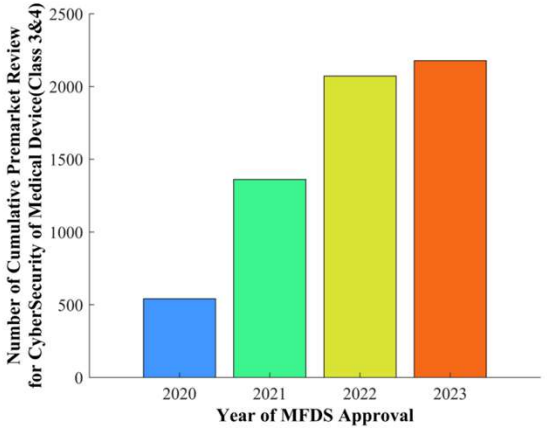
DTX



Press Release

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

bgkim81@korea.kr

Ministry of Food and Drug Safety

IMDRF International Medical Device Regulators Forum

IMDRF International Medical Device Regulators Forum

EU2023 EUROPEAN UNION Chair

11:05 – 11:20

United Kingdom

Harriet Teare

Deputy Director of Partnerships, Medicines and Healthcare products Regulatory Agency (MHRA)

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Update: MHRA, UK

Harriet Teare, Deputy Director for Partnerships

28 March 2023

Overview

- A recap of where we are now
- Overview of the statutory instruments we expect to lay
- Transitional arrangements
- Post-market surveillance
- International Recognition Framework

Where are we now?

- Twelve month extension to the implementation of the future UK Medical Device Regulations
- We are updating the UK Medical Device Regulations 2002 (UK MDR 2002)- to reflect the areas covered within the government response to the public consultation
- We expect to lay statutory instruments in 2023, which will amend the standstill date in the current UK MDR 2002, lay the transitional arrangements and the new post-market surveillance requirements.

Overview of Statutory Instruments (SIs)

Statutory Instrument	Purpose
Transitional Arrangements (*Expected to be laid Spring 2023*)	Intended to amend the end of the standstill date (30 Jun 2023) in the current UK Medical Device Regulations 2002 (UK MDR 2002) and introduce the transitional arrangements for CE marked devices
Post-market Surveillance (*Expected to be laid Autumn 2023)*	Bring into force the new post-market surveillance requirements for CE marked and UCKA devices as laid out in the government response to the public consultation
Future Medical Device Regulations (*Expected to be laid 2024*)	The SI relating to the future regime will bring into force the wider medical device regulations as laid out in the government response to the public consultation

Transitional Arrangements

UKCA marked under current UK regulations	Sooner of: • 3 years for general medical devices • 5 years for IVDs, or • when certifications expire
CE marked under EU directives	As above for UKCA marked devices
CE marked under EU regulations (EU MDR and EU IVDR)	Up to 5 years

Post-Market Surveillance

- More stringent PMS requirements
- Tighter timelines for reporting adverse incidents
- Detail on what should be covered in a PMS plan/PMS systems
- Requirements for health institutions
- Requirements for custom-made devices
- Details on what should be covered in trend reports/FSCA/PSURs etc

International Recognition Framework

UK Life Sciences Council Priority Areas:

1. International recognition
2. Routes for innovation
3. System capacity

International recognition proposals:

- Building on current product recognition routes from the EU, rapidly explore building a UK product regulation equivalence route for the approvals of medical devices to include other trusted jurisdictions.
- Explore greater flexibility over the requirements for physical UKCA markings on parts, instructions and labels before products can be marketed in the UK. Make greater use of registration and traceability mechanisms to ensure patient safety.
- The MHRA has already announced its intention to expand recognition for medicines, and create a new recognition framework by the end of 2023. Aim to align changes to the Medical Devices Legislation to the Medicines legislative timeline if possible.

IMDRF International Medical Device Regulators Forum

Thank you

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International Medical Device Regulators Forum

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11:20 – 11:35

United States of America

Melissa Torres

Associate Director, U.S. Food and Drug Administration

European Commission | European Union

US FDA Update

Melissa Torres
Associate Director for International Affairs
Office of the Center Director
Center for Devices and Radiological Health
US Food and Drug Administration
melissa.torres@fda.hhs.gov

Overview

- Medical Device User Fee Agreements (MDUFA)
  - International Harmonization
  - Digital Health
  - Total Product Lifecycle Advisory Program (TAP)
- Food and Drug Omnibus Reform Act
  - Cybersecurity
  - Predetermined Change Control Plans
- Digital Health Updates
  - Clinical Decision Support Software Guidance

Medical Device User Fee Amendments Update

Medical Device User Fee Amendments (MDUFA) Overview

- Program where industry pays **user fees** which the agency uses to increase review capacity to meet performance goals on review timelines and implement targeted process improvements.
- Helps **assure patients have access to safe, effective, high-quality devices in a timely fashion** and there is a clear, predictable path to market for new innovations.
- The user fees authorized by MDUFA are crucial to enabling CDRH to **continue to modernize** our regulatory programs.
- The program is reauthorized every five years based on new negotiated agreements and new legislation:
  - MDUFA I: FY 2003-2007
  - MDUFA II: FY 2008-2012
  - MDUFA III: FY 2013-2017
  - MDUFA IV: FY 2018-2022
  - **MDUFA V: FY 2023-2027**

Themes of the MDUFA V Agreement

- **Review Performance |** Introducing a new goal structure with opportunities for "add-on" payments, as well as improving goals for PMA Total Time to Decision, 510(k) Total Time to Decision, Pre-Submissions, and De Novo decisions
- **Hiring & Retention |** Providing resources and associated goals to enhance hiring and retention of world-class technical and scientific staff
- **Performance Accountability |** Supporting a high-quality program through regular audits by a quality management team and independent assessments
- **Financial Transparency |** Adding new accountability mechanisms and enhanced reporting
- **Program Improvements |** Launching a ***TPLC Advisory Program Pilot***, as well as enhancing programs to support patient science and engagement, real-world evidence, consensus standards, ***digital health***, and ***international harmonization***

MDUFA V International Harmonization Commitments

- There are **five broad commitments** related to international harmonization efforts:
  1. Expand engagement in international harmonization and convergence efforts through participation with international regulators and other key stakeholders in forums, working groups, projects, and committees
  2. Further support regulatory convergence by creating a mechanism for FDA to work with regulatory partners.
  3. Assess the extent of CDRH implementation of IMDRF technical documents and make this information publicly available.
  4. Support the creation of a forum to engage with relevant stakeholders to identify opportunities for regulators to leverage one another's approach to decision making.
  5. Participate in outreach activities to other regulatory authorities that encourage harmonization

- Issue a strategic plan later this year with additional details and timelines associated with achieving these international harmonization objectives.
  - Publish an annual assessment of our international harmonization activities.

MDUFA V Digital Health Commitments

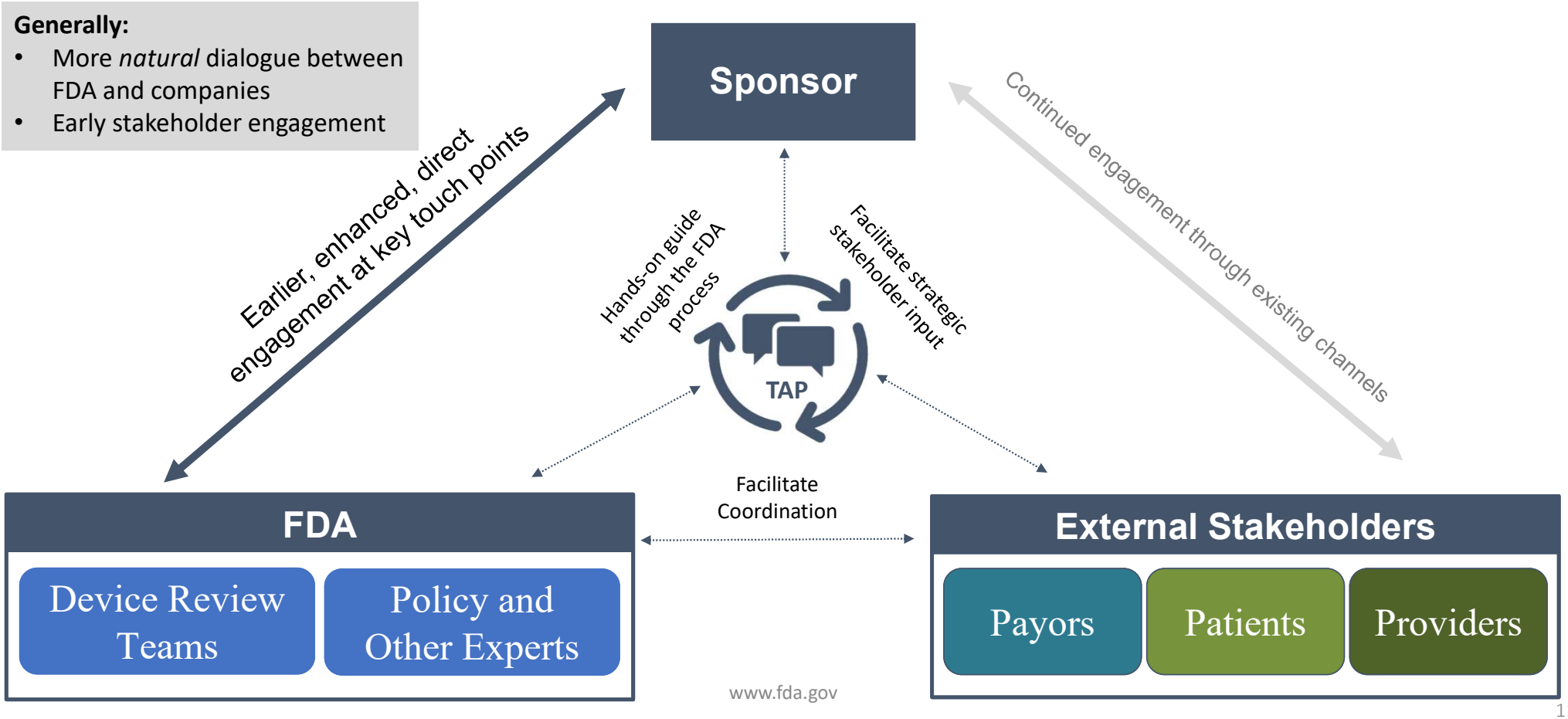
The FDA will continue to build its digital health expertise and continue working to streamline and align FDA review processes with software lifecycles for digital health products.

1. **Continue to develop software and digital health technical expertise** to provide assistance for premarket submissions that include digital health.
2. **Strengthen efforts to expand staff understanding** of digital health topics and enhance consistent evaluation in submissions
3. **Continue to participate in international harmonization efforts** related to digital health.
4. **Finalize the draft guidance**, "Content of Premarket Submissions for Device Software Functions," by 18 months from close of the comment period.
5. **Publish draft guidance** describing a process to evaluate a predetermined change control plan for digital health devices.
6. **Engage with stakeholders**, including patients, users, and industry, through roundtables, informal meetings, and teleconferences to explore regulatory approaches to digital health technologies.

Total Product Lifecycle Advisory Program (TAP)

Generally:

- More *natural* dialogue between FDA and companies
- Early stakeholder engagement



Enrollment Criteria

- Devices with a granted Breakthrough designation**
- No Pre-Submissions submitted after granted Breakthrough designation**
- Devices will be early in their device development process (e.g., have not yet initiated a pivotal study) at time of enrollment
- Each participant will have a maximum of one device enrolled in the pilot per fiscal year
- Devices regulated by our Center for Biologics Evaluation and Research (CBER) and combination products are outside the scope of the Pilot at this time

***In FY26-FY27, may also include devices with a granted request for inclusion in STeP*

Food and Drug Omnibus Reform Act

Background

- The Consolidated Appropriations Act for 2023 was signed into law December 29, 2022 and includes the Food and Drug Omnibus Reform Act (FDORA)
- FDORA authorized a number of new amendments to the Food, Drug, and Cosmetic Act
- Covers a broad range of areas, including cybersecurity, premarket review and product jurisdiction, pandemic preparedness, inspections, clinical trials, etc.
  - Section 3305 – Ensuring cybersecurity of medical devices
  - Sec. 3308 – Predetermined change protocol plans for devices

Section 3305 Overview
General

- Requires “cyber device” premarket submissions to:
  - Have policies and procedures for addressing vulnerabilities and exploits, including coordinated vulnerability disclosure;
  - Design, develop, and maintain processes and procedures to provide **reasonable assurance that device and related systems are cybersecure**;
  - Ensure device can be updated and patched;
  - Provide a Software Bill of Materials (SBOM).
- Includes provision for FDA to draft regulations to add additional requirements we determine are needed to “demonstrate reasonable assurance that the device and related systems are cybersecure”
- Enables FDA to exempt certain devices or device types from meeting cybersecurity requirements
- Provides tailored prohibited act authority

Section 3305 Overview
Website Updates

- Update public information including FDA website to include:
  - Information on identifying and addressing cyber vulnerabilities for
    - Healthcare Providers
  - Health Systems
  - Device Manufacturers
  - Information on how to access support from HHS, CISA, etc to improve cybersecurity of devices
- First update no later than 180 days from enactment of FDORA
- Annually thereafter

Section 3308 Overview
Predetermined Change Control Plans for Devices

2022 Omnibus Appropriations Bill

Amends section 515 of the FD&C Act so that changes to a device consistent with an approved predetermined change control plan do not require a supplemental application. It may also require that change control plans include labeling required for safe and effective use of the device.

Scope

This provision applies to all devices—it is not specific to software or devices with special controls. It applies to both premarket approvals and 510(k) applications. This is consistent with what FDA has been proposing for several years in both our AI/ML Action Plan and Discussion Paper.

Predetermined Change Control Plans

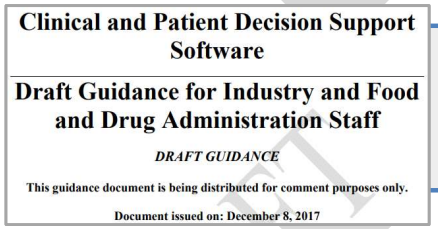
Predetermined change control plans describe planned changes that may be made to the device (and that would otherwise require a supplemental application under section 515) if the device remains safe and effective without any change.

Digital Health Updates

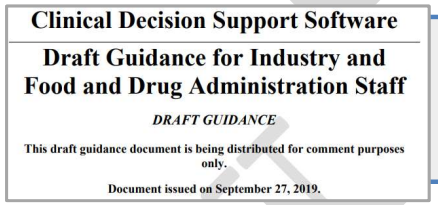
Clinical Decision Support Software Background


One Hundred Fourteenth Congress
of the
United States of America
AT THE SECOND SESSION
Begun and held at the City of Washington on Monday, the fourth day of January, two thousand and sixteen
An Act
To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
(a) SHORT TITLE.—This Act may be cited as the "21st Century Cures Act".
(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

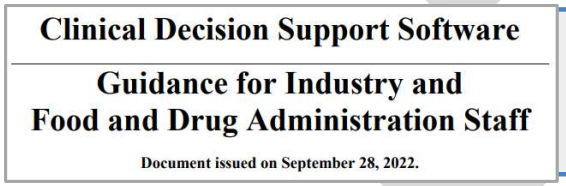
Dec 2016: 21st Century Cures Act:
Amended device definition


Clinical and Patient Decision Support Software
Draft Guidance for Industry and Food and Drug Administration Staff
DRAFT GUIDANCE
This guidance document is being distributed for comment purposes only.
Document issued on: December 8, 2017

Dec 2017: First Draft Guidance:
"Clinical and Patient Decision Support Software"


Clinical Decision Support Software
Draft Guidance for Industry and Food and Drug Administration Staff
DRAFT GUIDANCE
This draft guidance document is being distributed for comment purposes only.
Document issued on September 27, 2019.

Sept 2019: Revised Draft Guidance:
"Clinical Decision Support Software"


Clinical Decision Support Software
Guidance for Industry and Food and Drug Administration Staff
Document issued on September 28, 2022.

Sept 2022: Final Guidance:
"Clinical Decision Support Software"

What is Clinical Decision Support (CDS)?

Clinical Decision Support (CDS) is a tool that provides health care professionals and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1]

CDS includes:[2]

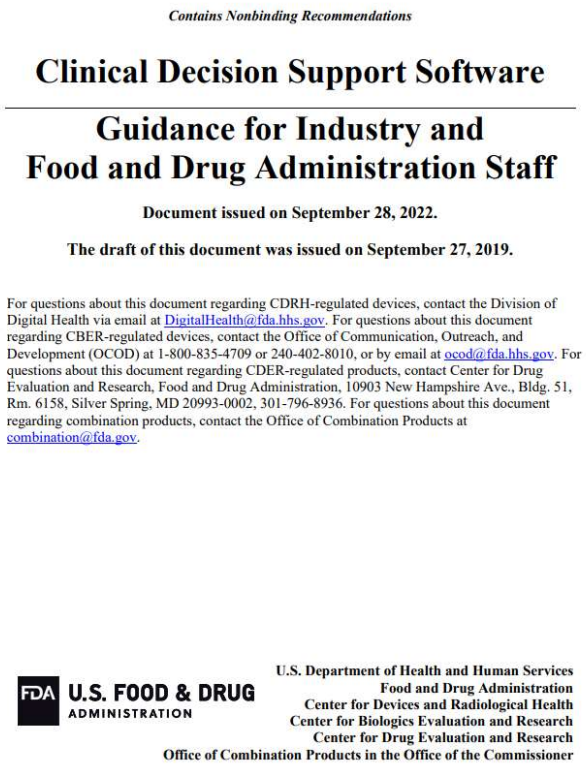
- computerized alerts and reminders for providers and patients;
- clinical guidelines;
- condition-specific order sets;
- focused patient data reports and summaries;
- documentation templates;
- diagnostic support;
- contextually relevant reference information.

[1]*See Office of the National Coordinator for Health Information Technology, "What is Clinical Decision Support (CDS)?" at* www.healthit.gov/topic/safety/clinical-decision-support

[2]FDASIA Health IT Report, April 2014, available at www.fda.gov/about-fda/cdrh-reports/fdasia-health-it-report

Clinical Decision Support Software Guidance Summary

- Focuses on the statutory criteria describing Non-Device clinical decision support software functions
  - Clarifies scope of FDA oversight of clinical decision support software intended for health care professionals as devices
- Provides examples of how FDA intends to consider different kinds of software functions, including non-device clinical decision support functions and device functions
- If unsure of how to apply the guidance/Non-Device CDS criteria:
  - Reach out to DigitalHealth@fda.hhs.gov
  - Consider submitting 513(g) for device determination or Q-Sub for discussion



Contains Nonbinding Recommendations

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

The draft of this document was issued on September 27, 2019.

For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health via email at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner


FDA
U.S. FOOD & DRUG
ADMINISTRATION

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

11:35 – 11:50

Argentina – Official observer

Mariela Aranda

Head of the Service of In Vitro Diagnostic Products, National Institute of Medical Devices

Carolina Magnatti

Office of Monitoring and Risk Management of Medical Devices Establishments, National Institute of Medical Devices

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Regulatory Update - ANMAT- Argentina

Bioq. Mariela Aranda
Bioing. Carolina Magnatti
National Intitute of Medical Devices

March 28, 2023

IMDRF International Medical Device Regulators Forum

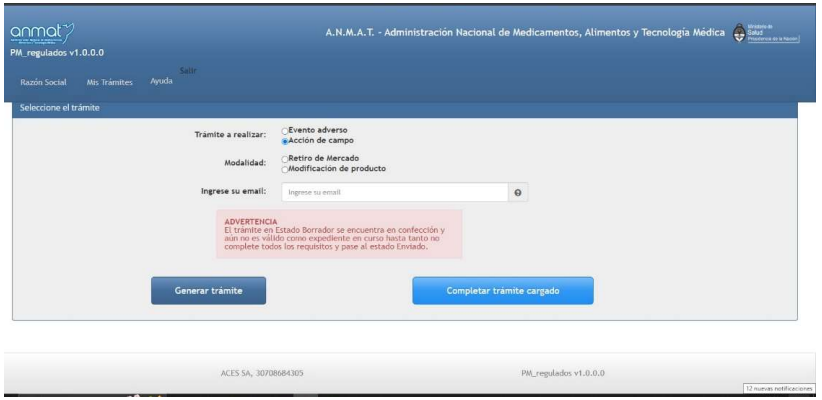
Postmarket Surveillance

Main objectives:

- Update the concepts of Post-Marketing Surveillance
- Establish new deadlines and notification criteria.
- Database available

Stakerholder

ARGOS (software)



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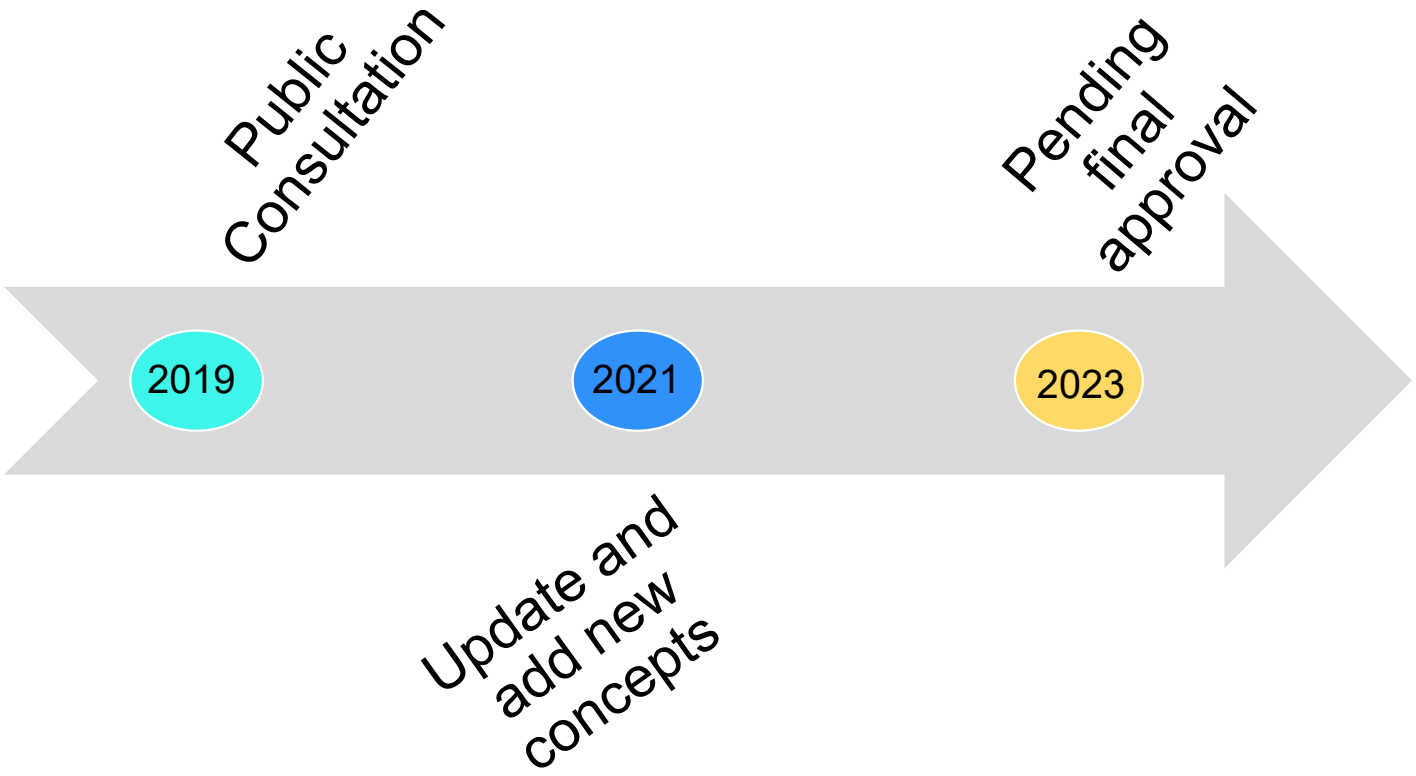
Postmarket Surveillance



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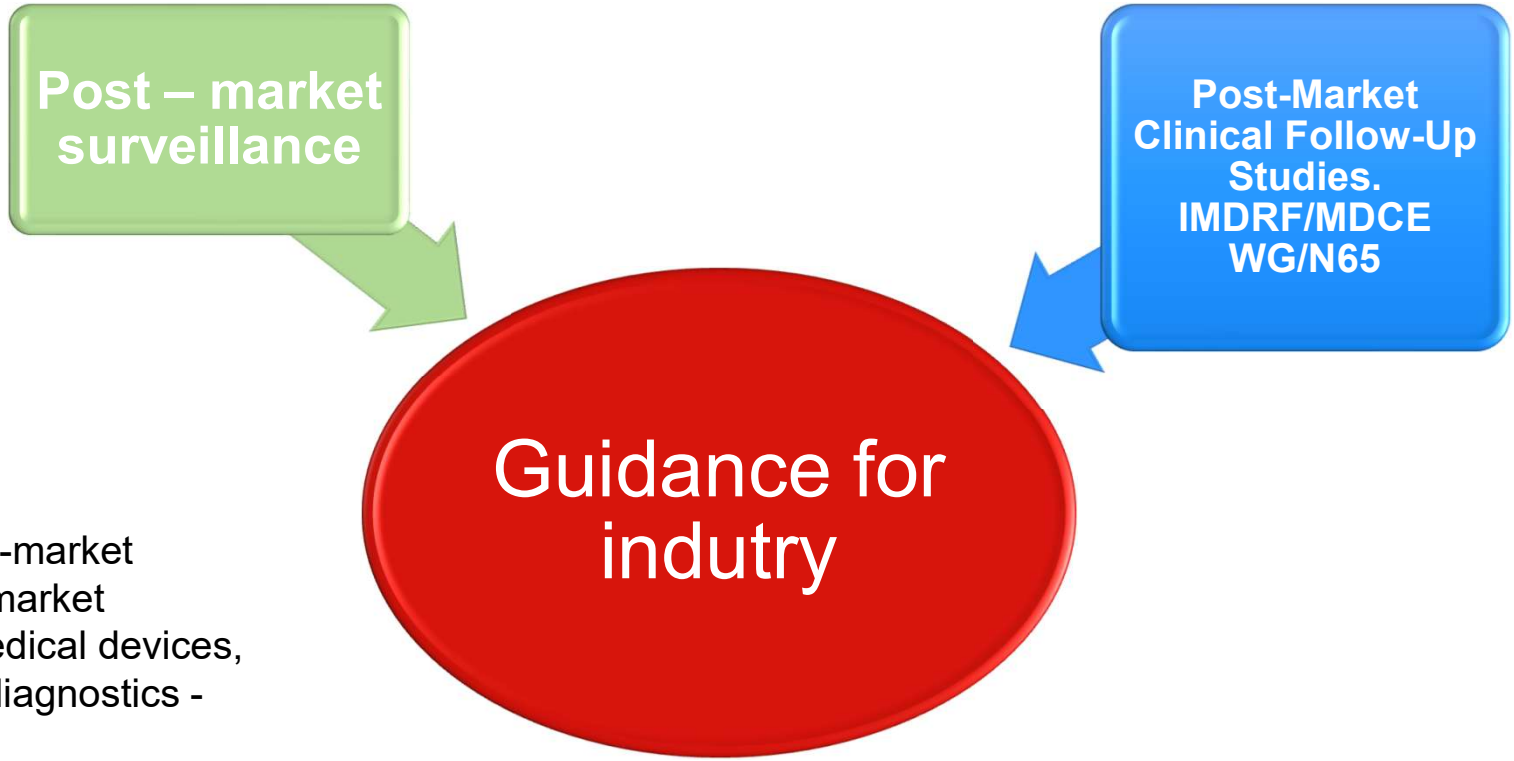
IMDRF MDCE WG/N65FINAL:2021 Post-Market Clinical Follow-Up Studies.

(extensión del grupo de trabajo MDCE)

•**Post-Market Clinical Follow-Up Studies:** El documento proporciona la orientación en relación con las circunstancias en la que está indicado los estudios clínicos post comercialización, la determinación de los objetivos, diseño, la realización del estudio y el uso de la información generada.

IMDRF International Medical Device Regulators Forum



Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics - WHO2021

MERCOSUR

IMDRF International Medical Device Regulators Forum

Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices.

Public Consultation was close in December 2022
Evaluation of comments: in process
Expected approval of the final document: 2023

Based on:
Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018) (IMDRF, 2018)

- Update safety and performance requirements of MD and IVDMD and to restructure the previous regulation
- Alignment of requirements for Mercosur jurisdictions

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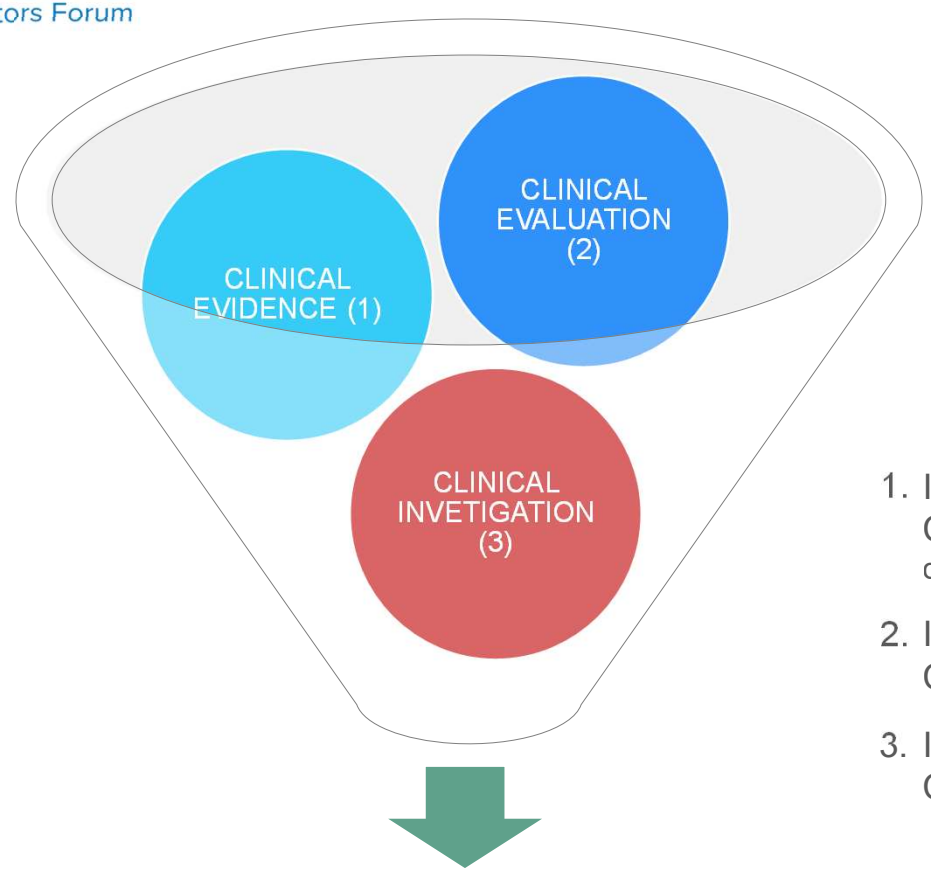
Medical Device Clinical Evaluation



1. IMDRF MDCE WG/N55:19 CLINICAL EVIDENCE - Keys definitions and concepts
2. IMDRF MDCE WG/N56:19 CLINICAL EVALUATION
3. IMDRF MDCE WG/N57:19 CLINICAL INVESTIGATION

Internal working group for the implementation of these documents

IMDRF International Medical Device Regulators Forum

ANMAT participation in working groups:

- ✓ Artificial Intelligence Medical Devices (AIMD)
- ✓ Medical Device Cybersecurity Guide
- ✓ Personalized Medical Devices
- ✓ Software as Medical Devices
- ✓ Clinical Evidence of Medical Products for IVD (Close)

IMDRF International Medical Device Regulators Forum | EU2023 EUROPEAN UNION Chair

11:50 – 12:05

World Health Organization – Official observer

Irena Prat

Team Lead, In vitro diagnostics assessment,
Prequalification Unit

European Commission | European Union

IMDRF International Medical Device Regulators Forum

Update from the World Health Organization

Irena Prat, Team Lead

World Health Organization

28 March 2023

Overview

Regulatory system strengthening activities

Prequalification and EUL of IVDs

Nomenclature and EDL

Revision of the WHO Global Model Regulatory Framework (GMRF) for medical devices

New Table of contents

Chapter 1. Introduction

Chapter 2. Definition, classification, essential principles, and conformity assessment of medical devices

Chapter 3. Enabling conditions for effective regulation of medical devices including IVDs

Chapter 4. Establishing a stepwise approach to regulating medical devices

Chapter 5. Regulatory pathways *New*

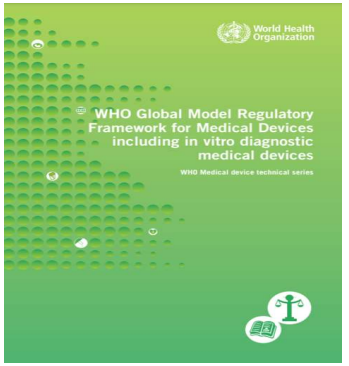
Chapter 6. Additional topics

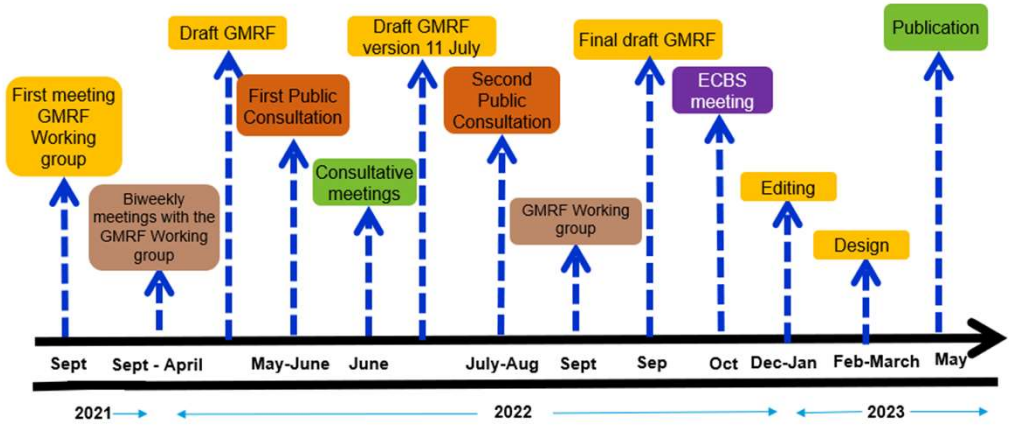
Chapter 7. Implementation *New*

**** Chapters have been expanded from 5 chapters in the 2017 version to 7 chapters in the revised version***

WHO GMRF for medical devices including in vitro diagnostics was successfully revised and endorsed during the 76th meeting of the WHO Expert Committee on Biological Standardization (ECBS) held from 24 to 28 October 2022

Final editing and design of the revised Model and publishing in May 2023





IMDRF International Medical Device Regulators Forum

Technical support and reliance

Support to AMRH Technical Committee

In 2022, development of a five-years AMDF Strategic Plan & four (4) guidelines

- 4 guidelines are planned for development in 2023

Good Regulatory Practices (GRP) and Good Reliance Practices (GRelP)

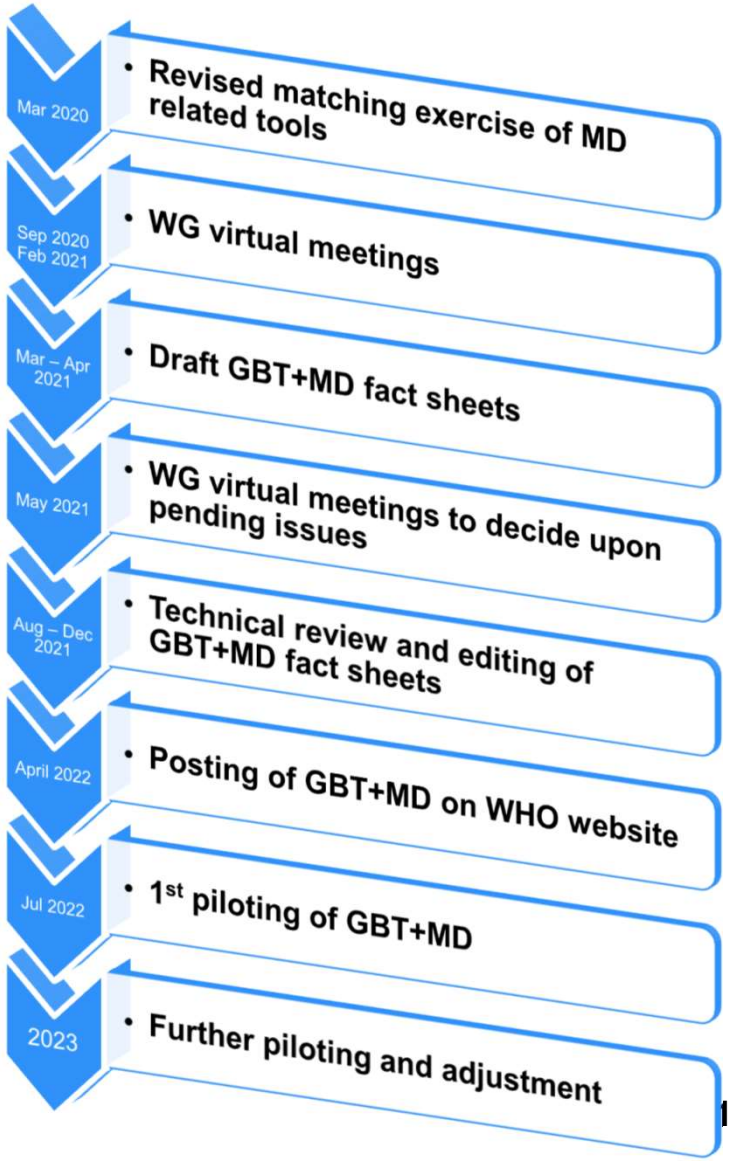
- Promoting adoption of the principles and concepts in both GRP and GRel documents
- e-learning Module on GRelP on OPEN WHO https://openwho.org/courses/good-reliance-practices

Promoting Collaborative Registration Procedure (CRP) for IVDs

- Over 20 advocacy workshops/meetings including 10th annual CRP meeting in Dec 2022
- Increased NRAs' interest to sign to CRP & IVDs registered e.g., from 16 in 2021 to 26 in March 2023

Global Benchmarking Tool (GBT)

- GBT represents the primary means by which the WHO **objectively evaluates regulatory systems** (*Resolution WHA 67.20*)
- GBT (medicines & Vaccines) introduced in 2016 and revised in 2018
- GBT **replaces all tools previously used** by WHO, representing the first truly 'global' tool
- Nov. 2019, **GBT+Blood** (whole blood, blood components and plasma derived blood products) integrated into the GBT
- April 2022: **GBT+Medical Devices** including IVDs integrated into the GBT (link)



Development of GBT+MD

GBT+MD developed in **consultation with regulators (including global ad regional networks), WHO regional offices**

- Several virtual meetings with over **50 participants** from **20 countries representing all six WHO regions**

GBT+MD **piloted** for the first time in **July 2022**

- confirmed its value in benchmarking of medical devices regulatory systems in LMICs
- Revealed some **areas** which **need further improvement** particularly with respect to **terms** and **terminology** and the role of **conformity assessment bodies (CAB)**
- Lessons will help further refine the tool

Further piloting planned in **2023** in order to get feedback for **refining and adjusting** the tool

Post-market surveillance and market surveillance

Supporting WHO Member States

- Highlighting reliance/recognition for review of investigation reports and field safety corrective actions
- Assessing need for a global database on field safety notices for medical devices
  - FSN are publicly available but not very accessible

WHO e-learning, launched 9 March 2023

- Basics of how to respond to substandard/falsified medical devices

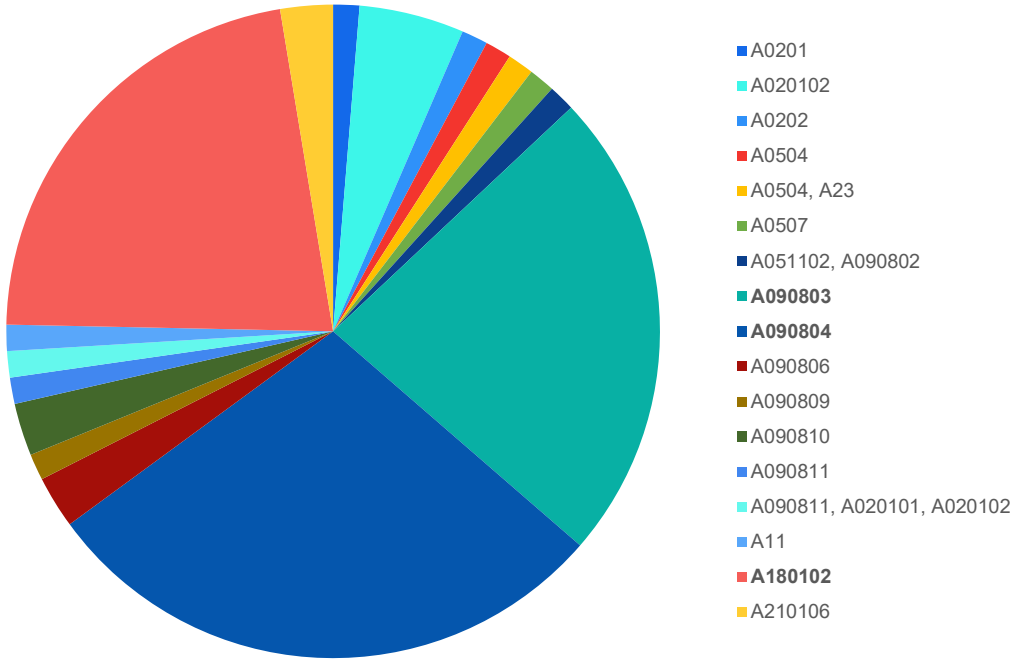
WHO Global Surveillance and Monitoring System

Substandard and falsified IVDs

- In last 12 months, 77 incidents reported to WHO
  - 78% reported by manufacturers

AER terminology used

- False positive (28.4%)
- False negative (25.4%)
- Contaminated (22.1%)



WHO Prequalification: Eligibility expansion and new guidance for manufacturers

PQ technical specifications finalized and published for IVDs detecting **Hepatitis B virus** (RDTs and EIA for HBsAg and HBV NAT)

- January 2023, HBV NAT assays eligible for PQ assessment

Draft PQ technical specifications for **HbA1c** POC IVDs published for public comment end 2022

Plan to publish draft PQ technical specifications for **blood glucose monitors** in Q1/2 2022, **haemoglobin POC** analyzers, and updated requirements for **Malaria** RDTs in Q2 2022.

EUL assessment for **SARS-CoV-2** detection IVDs likely to transition to PQ assessment (timeline and scope to be determined)

PQDx IVD product dossiers and inspections

WHO PQ has implemented the **ToC format for dossiers** and review reports

- As of 2023 Manufacturers are expected to provide product dossiers in ToC format only
- Dossier requirements, and dossier review documents have been updated to reflect ToC
- Training for assessors, and guidance for manufacturers will be provided

Inspections in 2022:

- Inspections
  - 13 Onsite
  - 1 Desk assessment
- Emergency use listing
  - 12 new applications (1 rejected)
  - 12 renewals (1 delisted)
- Training and workshops
  - Collaborative registration procedure for IVDs
  - EUL workshop for Turkey
- Guidance
  - Guidelines review committee
  - Artificial intelligence Medical Devices IMDRF WG

WHO EUL IVD and related projects

- Over 200 EUL applications received

ECBS 2022: **1st WHO International Standard for SARS-CoV-2 antigen (21/368)** was established https://www.who.int/publications/m/item/who-bs-2022.2426-rev

- lyophilized preparation of formaldehyde-inactivated cell culture-grown SARS-CoV-2 Omicron BA.1 subvariant
- assigned unitage of 5000 IU/ampoule
- availability: https://www.nibsc.org/

Independent Performance Evaluation of SARS-COV-2 Ag RDTs

- supports WHO EUL (applicable to listed products and products under assessment)
- collaboration PATH, FIND & WHO
- focus on analytical performance
- start date: Q1/Q2 2023

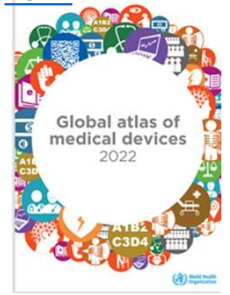
* cancelled in Feb 2023

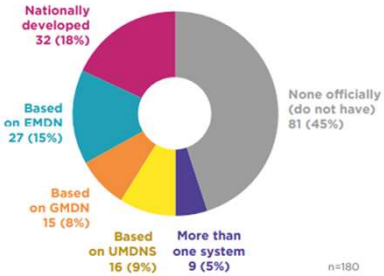
WHA72(25), Standardization of medical devices nomenclature, International classification, coding and nomenclature of medical devices Decided to request the WHO Director General

To integrate available information related to medical devices, including terms, codes, and definitions, in the web-based database and clearinghouse established in line with resolution WHA60.29 (2007) and now available as the Medical Devices Information System (MEDEVIS);

and to link this to other WHO platforms, such as the International Classification of Diseases, (ICD-11) to serve as a reference to stakeholders and Member States

Global Atlas Medical Devices 2022





Relation terms and codes EMDN - GMDN Dec- July 2023

Webinars and consultations MOUs with nomenclature agencies Q2-Q3

Publication and work on updates Q4

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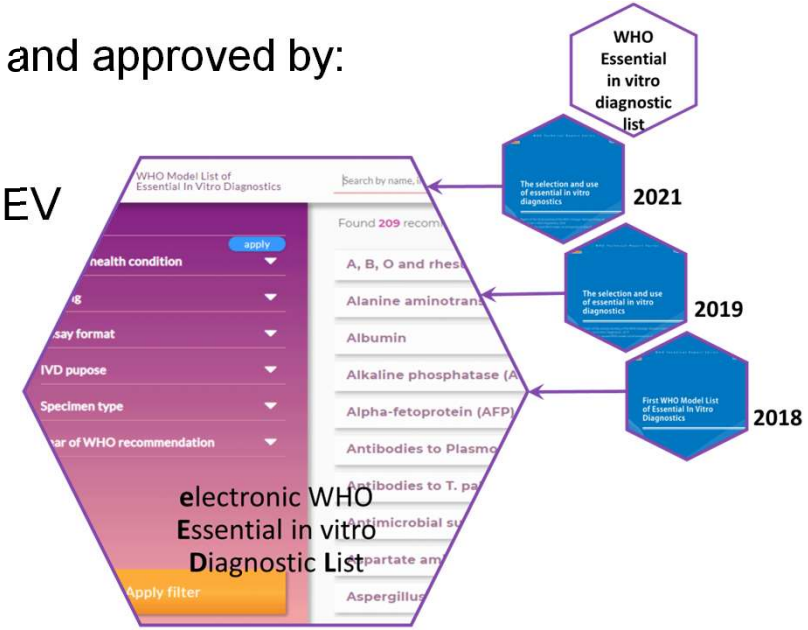
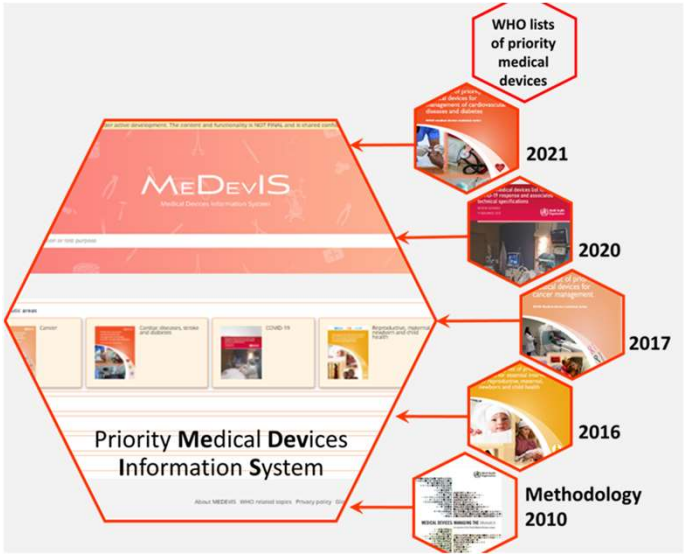
Update of WHO Priority Medical devices list and Essential in vitro diagnostics list: both in electronic platforms

Evidence based and approved by:

- SAGE IVD
- STAG MEDEV





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Thank you/Questions

Irena Prat
prati@who.int