Open webinar , stakeholders participation

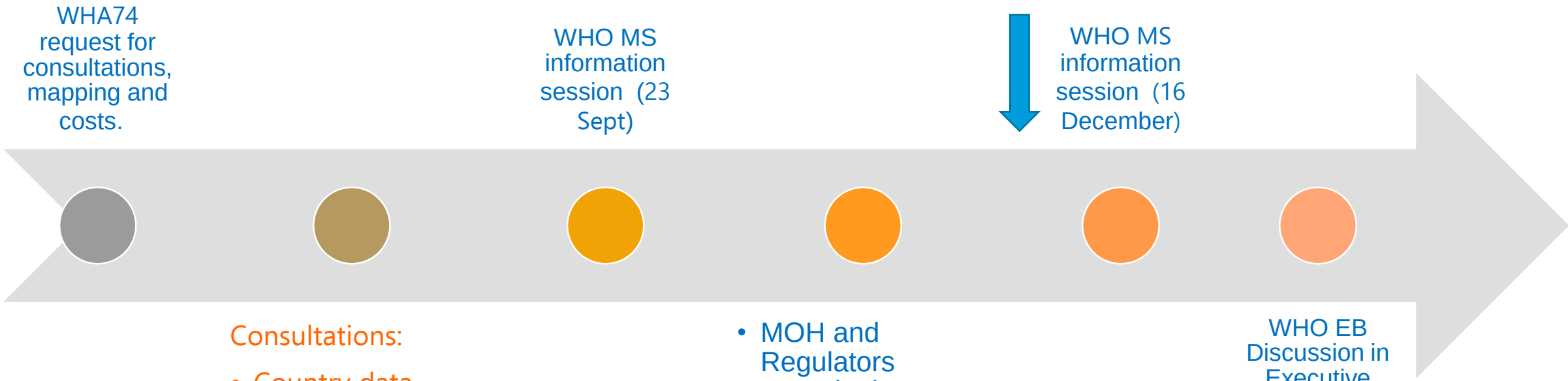
13 December 2021

Nomenclature mapping updates

Adriana Velazquez, Group Lead Medical Devices and In vitro diagnostics, Access to Medicines and Health Products Department

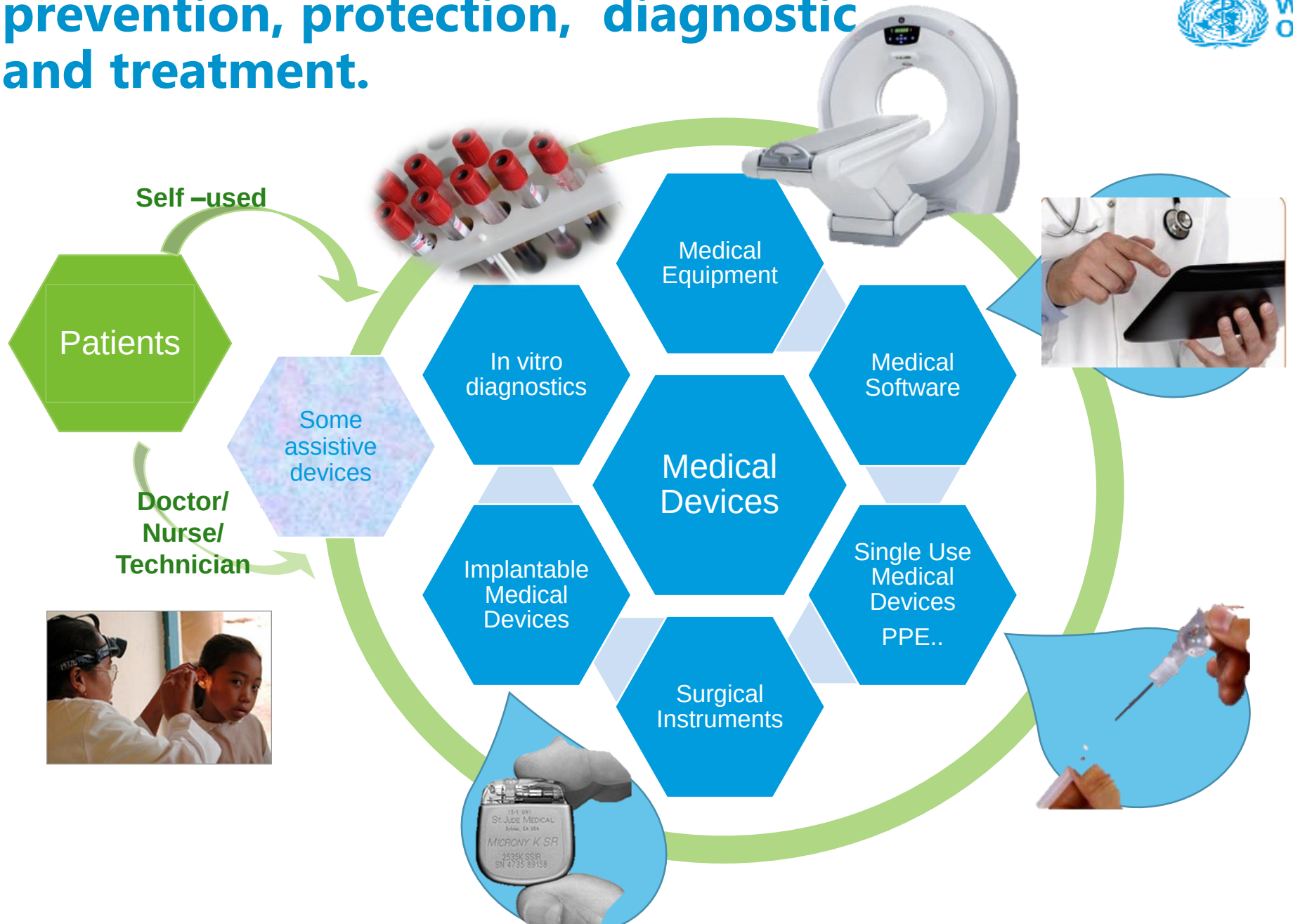
Consultants: Eunice Lourenco, Olga Pineda and Terrie Reed.

Road map towards the EB Jan 2022



Medical Devices include those for prevention, protection, diagnostic and treatment.

World Health Organization



Goal: ensure improved access to safe, good quality, affordable, appropriate, acceptable medical devices

nomenclature is backbone for all medical devices process

World Health Organization

Nomenclature

R&D

- Industry production to comply with regulatory bodies and procurement systems

Regulations

- Regulatory clearance: premarket registration

Assessment

- Selection of medical devices list for procurement or reimbursement (Essential or priority national lists)

Management

- Procurement and supply (trade, customs)
- Operations and training in Health facilities
- Patient safety
- Post market surveillance
- Decommissioning

https://www.who.int/health-topics/medical-devices#tab=tab_1

Recap of last session and Member’s States Information Session updates

Adriana Velazquez

Discussion on standardization of nomenclature in the WHA74, 29 and 31 May 2021

Seventy-fourth World Health Assembly (who.int)

Requests by Member States

Importance of nomenclature, coding and classification of medical device to support regulation, procurement, assessment

Should be transparent, harmonized and evidence based, open systems to be accessible for all

Requested WHO not to create a new nomenclature to avoid duplications

Concerns of EMDN not harmonized with GMDN

Request to: Map EMDN to GMDN to minimize impact,

Costing study, Consultations with IMDRF, and industry.

WHO response 31 of May

Set of countries advocate for proprietary system (GMDN)

Set of countries advocate for open existing systems (ie. EMDN)

WHO confirms will not create a new nomenclature.

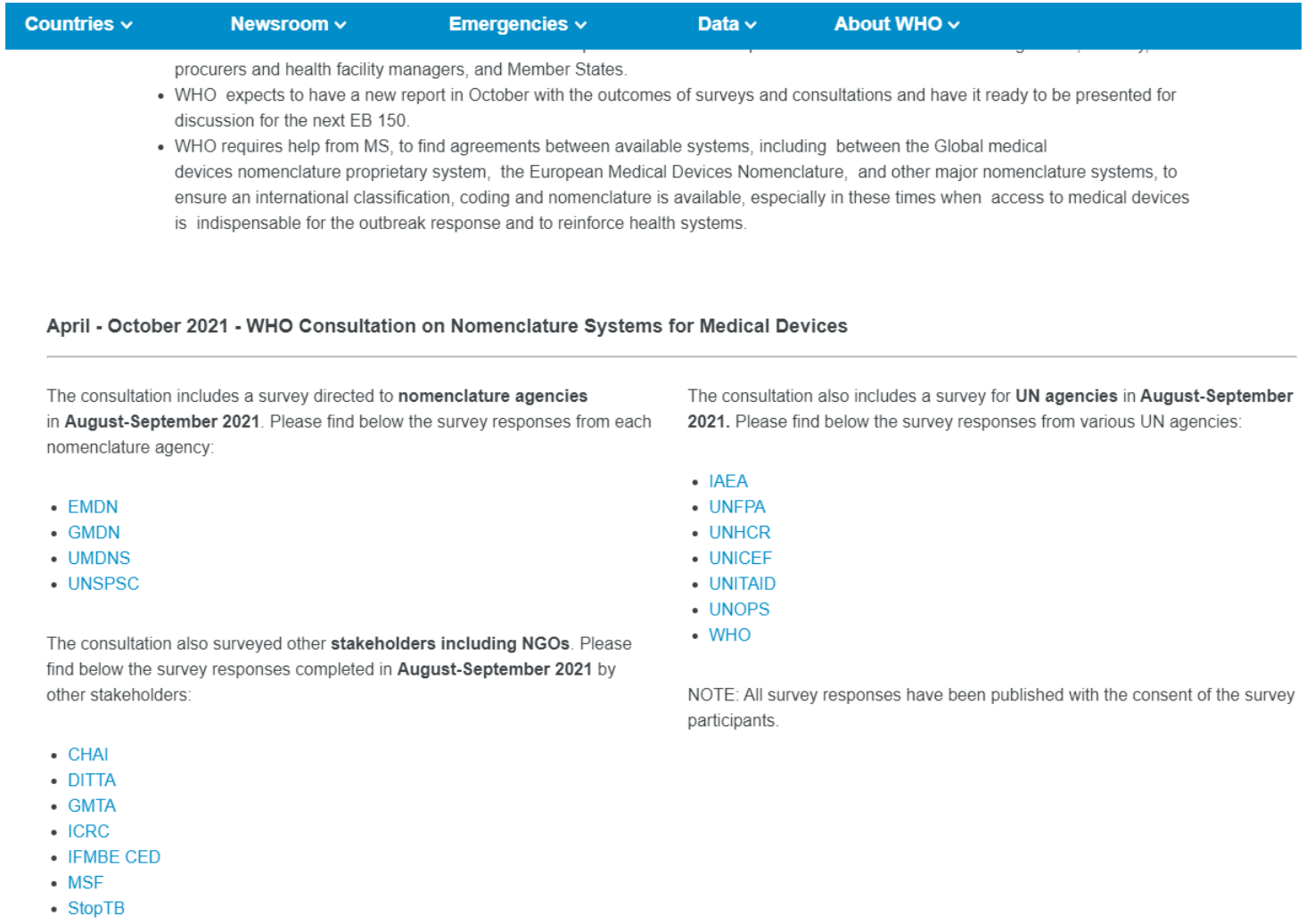
Information and consultation sessions in 2021 to report to Executive Board 150, January 2022.

WHO requires support by Member States to find agreements of nomenclature systems to map, have a transparent system to assign codes, and make information openly available, with no IP restrictions.

Stakeholders consultations July to December 2021

- Several meetings with different stakeholders:
  - WHO Regional Advisors (2 and invited to all nomenclature agencies meetings)
  - Medical devices industry associations (6)
  - Bilateral meetings with Nomenclature Agencies (EMDN, GMDN, UNSPSC, UMDNS) (12)
  - Biomedical & Clinical Engineers association (3)
  - UN Agencies and International NGOs (5)
  - MOH, Regulatory agencies (1) AFRO, (1) EURO, (2) PAHO, (1) SEARO (scheduled)
- Minutes shared with participants
- Surveys were elaborated according to each type of entity, discussed with entity, circulated for feedback and now posted in WHO website
- GOAL: To brainstorm about the way forward and discuss possible solutions.

All surveys provided by organizations are uploaded in WHO website on nomenclature MD



Countries | Newsroom | Emergencies | Data | About WHO

procurers and health facility managers, and Member States.

- WHO expects to have a new report in October with the outcomes of surveys and consultations and have it ready to be presented for discussion for the next EB 150.
- WHO requires help from MS, to find agreements between available systems, including between the Global medical devices nomenclature proprietary system, the European Medical Devices Nomenclature, and other major nomenclature systems, to ensure an international classification, coding and nomenclature is available, especially in these times when access to medical devices is indispensable for the outbreak response and to reinforce health systems.

April - October 2021 - WHO Consultation on Nomenclature Systems for Medical Devices

The consultation includes a survey directed to **nomenclature agencies** in **August-September 2021**. Please find below the survey responses from each nomenclature agency:

- EMDN
- GMDN
- UMDNS
- UNSPSC

The consultation also surveyed other **stakeholders including NGOs**. Please find below the survey responses completed in **August-September 2021** by other stakeholders:

- CHAI
- DITTA
- GMTA
- ICRC
- IFMBE CED
- MSF
- StopTB

The consultation also includes a survey for **UN agencies** in **August-September 2021.** Please find below the survey responses from various UN agencies:

- IAEA
- UNFPA
- UNHCR
- UNICEF
- UNITAID
- UNOPS
- WHO

NOTE: All survey responses have been published with the consent of the survey participants.

https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature

WHO standardization of medical devices nomenclature - Calendar

Activities towards the 150 Executive Board in January 2022 and World Health Assembly May 2022

World Health Organization

Date	Activity	Expected outcome
May-June	WHA74 and EB149	----------
24 June, 13 and 16 September	*IMDRF teleconference*	*Briefing of WHA and next steps*
16, 20 July, 3 September	WHO HQ meetings, *ICD-11, MeDevIS*	Status, ongoing activities, nomenclature convergence platform possibilities
19 July, 23 August	WHO Regional Advisors	Status, plan and their input
22 July, from 15 November: weekly meetings 26 August 21 September	**Medical devices industry** Medical devices industry and Regional WHO Meeting with industry and UN	GMTA, DITTA , request for collaboration and feedback on un-matched list Discussion of the outcomes of survey Status, ongoing activities Debrief on nomenclature status
30 July, 10 December 27 August 1 ,3 September 15 October-Ongoing	**UN agencies and NGOs** UN agencies and NGOs and Regional Advisors UNICEF, Global Fund UNOPS	Nomenclature and tech specs uses, updates on feasibility study Discussion of the outcomes of the survey Nomenclature used, catalogue and codes used, challenges UNOPS collaboration on feasibility study
1st round: 29 and 30 of July, 03 August 2nd round: 24 and 25 August 8 September 3rd round: 15 September 4th round: 3 and 4 November 5th round: 9 November From 15 November: weekly meetings	**Nomenclature agencies** Nomenclature agencies and Regional WHO All 4 nomenclature agencies together Each nomenclature agency (EMDN, GMDN, UMDNS, UNSPSC) All 4 nomenclature agencies together	Single agencies and all agencies. Willingness to map, transparent process, fees and copyright issues. Discussion of the outcomes of the survey Findings on bilateral meetings, willingness to map, brainstorm, Symmetric Willingness to share survey, to nomenclature pilot and to participate in MS session Agreements forward collaboration on feasibility study Updates on feasibility study, request for feedback on un-matched list
29 July, 9 December 26 August	**Biomedical and Clinical engineers** Biomedical and Clinical engineers and Regional Advisors	Use of nomenclature in health care facilities, updates on feasibility study Discussion of the outcomes of the survey
21 September,	**Regional regulators and MOH** **AFRO and EURO**	Nomenclature uses and challenges Global Atlas for Medical Devices 2021 review.
23 September	Member States information session	Report on the consultation sessions and defining next steps
TBC (27 Sept - October)	**Other country and regional consultations**	Nomenclature uses and challenges

Date	Activity	Expected outcome
1 October	Report for EB150	Report sent for WHO internal clearance
October – November	Mapping exercise with LMIC	Full mapping of the 4 nomenclatures at an item level for more than 13,000 products registered on the Regulatory database from LMIC Results achieved: mapping can be done
October, November, December	Development of mapping feasibility study; Consultation with stakeholders for feedback on the outputs of the feasibility study	Publish report Revision and consensus and mapping outcomes.
10 and 11 November	UMDNS & internal feedback (WHO MeDevIS) to the process	UMDNS codes and information uploaded on mapping tool
1 October, 12 November	PAHO Regional regulators and MOH	Nomenclature uses and challenges Working session on nomenclature updates, feasibility study
15 November - Ongoing	MD Industry (GMTA, DITTA)	Updates on feasibility study and request for feedback on Un-matched List (pending)
15 November - Ongoing	Parallel reviews on mapping and un-matched list	Feedback on assignments from different stakeholders (industry, nomenclature agencies) Diminished un-matched list
15 November - Ongoing	Internal meetings with nomenclature and MeDevIS team	Define list of products to be uploaded to WHO platform for DEMO
1 December	Presentation of the process to AHWP	Share information on nomenclature standardization
2 December – January 2022	Discussion on nomenclature for the update of the GMRF	Separation on nomenclature and UDI sections
6-13 December	Update mapping and tables based on feedback from Nomenclature Agencies	Feedback updated on mapping tool and tables
9-13 December	Updated list of mapping to be added to MeDevIS	**FOR DEMO** WHO Platform (MeDevIS) with implied mapping loaded
13 December	WHO nomenclature mapping information OPEN webinar	Share results, what has been done, methodology implemented to do the mapping
14 December	**Nomenclature of MD updates for SEARO**	Updates on feasibility study
16 December	**Member States information session**	Presentation of the results of the nomenclature mapping feasibility study
29 January 2022	EB150.	Presentation to the Executive Board

Calendar for upcoming days

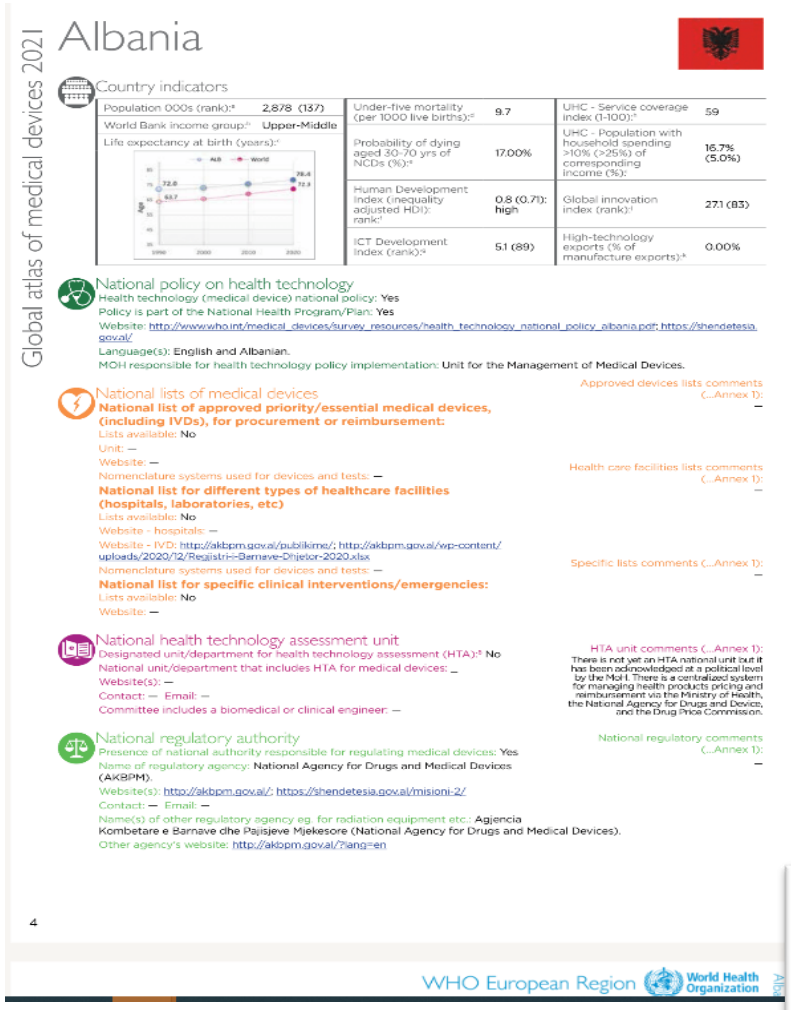
Date	Activity	Expected outcome
9 December	**Biomedical and Clinical engineers**	Updates on feasibility study
10 December	**UN agencies and NGOs**	Updates on feasibility study
13 December	WHO nomenclature mapping information OPEN webinar	Share results, what has been done, methodology implemented to do the mapping
14 December	**Nomenclature of MD updates for SEARO**	Updates on feasibility study
16 December	**Member States information session**	Presentation of the results of the nomenclature mapping feasibility study

Global consultations

World Health Organization

1. Global Atlas of Medical Devices
2. Nomenclature Desk review

Country consultation of Global Atlas of Medical



Global atlas of medical devices 2021

Albania

Country indicators

Population 000s (rank):[a]	2,878 (137)	Under-five mortality (per 1000 live births):[c]	9.7
World Bank income group:[b]	Upper-Middle	Probability of dying aged 30–70 yrs of NCDs (%):[a]	17.00%
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[c]	0.8 (0.71): high
		ICT Development Index (rank):[a]	5.1 (89)

UHC - Service coverage index (1-100):[c]	59
UHC - Population with household spending >10% (>25%) of corresponding income (%):	16.7% (5.0%)
Global innovation index (rank):[f]	27.1 (83)
High-technology exports (% of manufacture exports):[a]	0.00%

National policy on health technology

Health technology (medical device) national policy: Yes
Policy is part of the National Health Program/Plan: Yes
Website: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf; https://shendetesia.gov.al/
Language(s): English and Albanian.
MOH responsible for health technology policy implementation: Unit for the Management of Medical Devices.

National lists of medical devices

Approved devices lists comments (...Annex 1): –

National list of approved priority/essential medical devices, (including IVDs), for procurement or reimbursement:
Lists available: No
Unit: –
Website: –
Nomenclature systems used for devices and tests: –

Health care facilities lists comments (...Annex 1): –

National list for different types of healthcare facilities (hospitals, laboratories, etc)
Lists available: No
Website - hospitals: –
Website – IVD: http://akbpm.gov.al/publikime/; http://akbpm.gov.al/wp-content/uploads/2020/12/Regjistri-i-Barnave-Dhjetor-2020.xlsx
Nomenclature systems used for devices and tests: –

Specific lists comments (...Annex 1): –

National list for specific clinical interventions/emergencies:
Lists available: No
Website: –

National health technology assessment unit

Designated unit/department for health technology assessment (HTA):[a] No
National unit/department that includes HTA for medical devices: _
Website(s): –
Contact: – Email: –
Committee includes a biomedical or clinical engineer: –

HTA unit comments (...Annex 1): There is not yet an HTA national unit but it has been acknowledged at a political level by the MoH. There is a centralized system for managing health products pricing and reimbursement via the Ministry of Health, the National Agency for Drugs and Device, and the Drug Price Commission.

National regulatory authority

National regulatory comments (...Annex 1): –

Presence of national authority responsible for regulating medical devices: Yes
Name of regulatory agency: National Agency for Drugs and Medical Devices (AKBPM).
Website(s): http://akbpm.gov.al/; https://shendetesia.gov.al/misioni-2/
Contact: – Email: –
Name(s) of other regulatory agency eg. for radiation equipment etc.: Agjencia Kombetare e Barnave dhe Pajisjeve Mjekesore (National Agency for Drugs and Medical Devices).
Other agency's website: http://akbpm.gov.al/?lang=en

4

WHO European Region — World Health Organization — Albania

WHO European Region — World Health Organization — Albania

Medical device nomenclature system

Official nomenclature system for medical devices: Yes Type: Nationally developed
Use: For procurement purposes
Website: –

Nomenclature comments (...Annex 1): This Italian nomenclature system CIVAB comes with the inventory system called CLINGO.

Medical device incorporation

Procurement
Policy or guideline: Yes Website: –
National level procurement: Yes Website: –
Donations
Policy or guideline: Yes Website: –
Technical specifications
Technical specifications to support procurement or donations: No
Publically available: –
Website: –

Medical device incorporation comments (...Annex 1): It exists the National Policy for management of medical devices in Albania. The procurement of medical devices at national levels is done partially.

Medical equipment

	Total	Density per 1,000,000 population
Magnetic Resonance Imaging:[a]	5	1.58
Computerized Tomography Scanner:[a]	17	5.36
Positron Emission Tomography Scanner:[a]	0	0
Gamma camera or nuclear medicine:[a]	0	0
Mammograph:[a,*]	18	54.4
Radiotherapy:[a]	6	2.08

* Density per 1,000,000 females aged from 50-69 old

Healthcare facility[y]

	Total	Density per 100,000 population
Health posts:	415	13.08
Health centres:	n/a	n/a
General/district hospitals:	23	0.72
Specialized/regional/national hospitals:	9	0.28
Estimation % of health facilities with none or very limited oxygen supply:		n/a

Medical equipment management unit

Unit present: Yes Professionally trained biomedical/clinical engineers: Yes
Unit/Department: Unit for the Management of Medical Devices. Unit website: –
Contact name: Ms. Ledina Picari Contact email: lpicari@moh.gov.al
Website with publically available technical specifications: –
Number of regional/state offices/units: 4

Inventories and medical equipment management software

Type of inventories available: National inventory for medical equipment
Website: –
Use of management software: Yes Software name: Clingo.

Software comments (...Annex 1): The inventory system is called CLINGO. The National Biomedical Centre manages the system. Each hospital (35 regional hospitals are involved) is in charge of adding their own data. It doesn't cover all the hospitals and other public health institutions.

Medical devices workforce

Density of medical doctors (per 10 000 population):[z] 16.47
Number of biomedical/clinical engineers professionals in the country:[t] 55

Contacts

MOH focal point
Name: –
Department: –
Email: –

Other country focal point
Name: Ms. Ledina Picari
Email: lpicari@moh.gov.al

WHO health products focal point:
Name: –
Email: –

WHO Representative/WHO Liason Officer:
Name: Dr. Gerald Rockenschaub
Email: rockenschaubg@who.int

General comments (...Annex 1): Concerning the HT national policy, it was provided the following document: http://www.who.int/medical_devices/survey_resources/health_technology_national_policy_albania.pdf

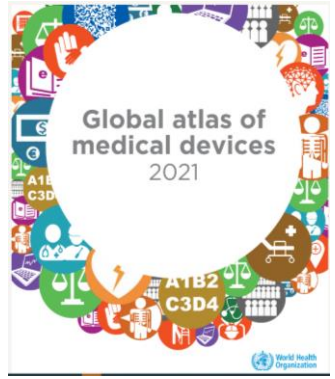
z UN POP WPP 2019 (2020 POP) f UN POP 2019 δ Latest (2015-21) WHO HTAMBP 2021 β Latest (2013-21) WHO GHO(2021

WHO Eastern Mediterranean Region — World Health Organization — Bahrain

Medical device nomenclature system

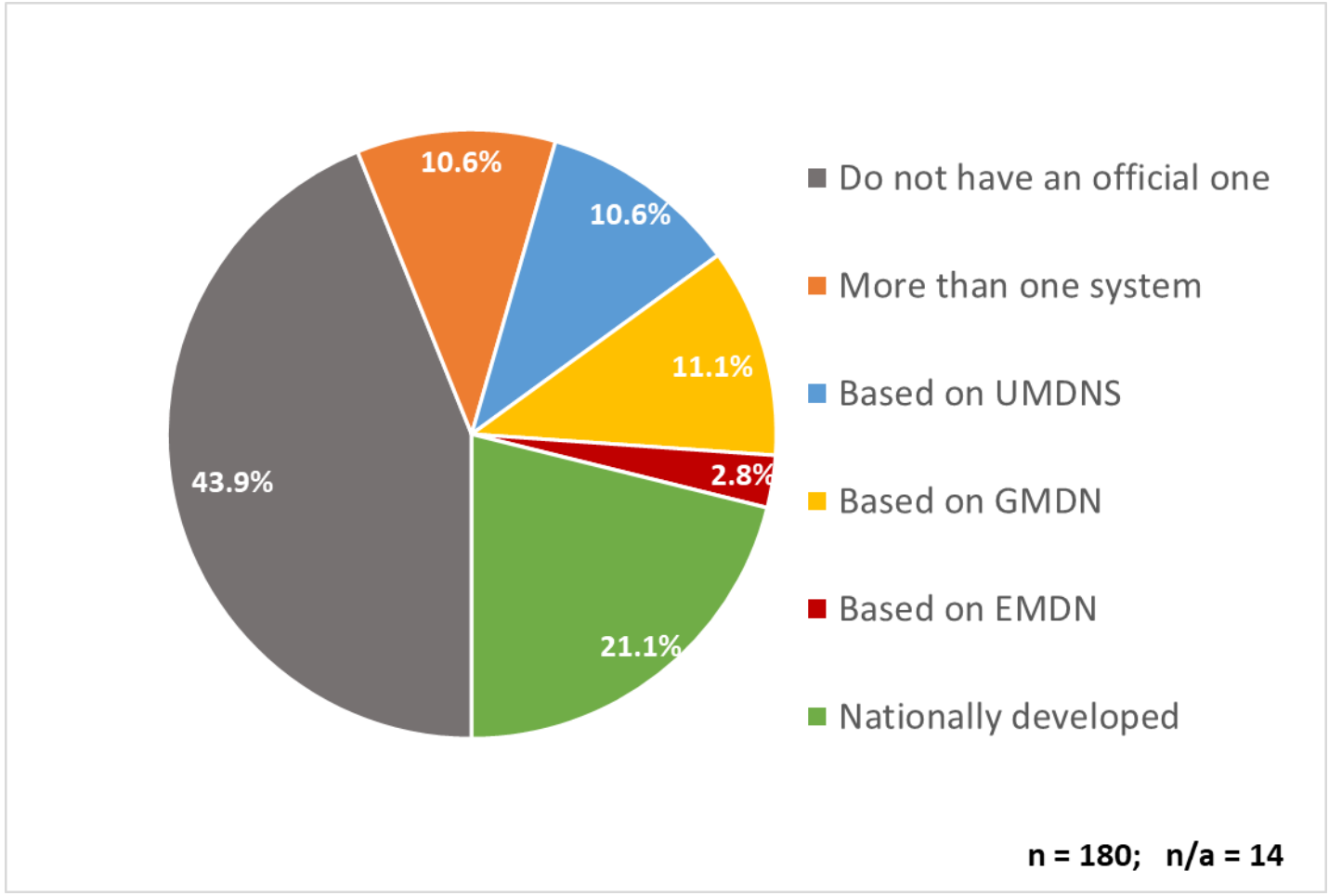
Official nomenclature system for medical devices: Yes Type: Many co-existance of nomenclatures Use: For regulatory and procurement purposes
Website: https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/guidelines/MDR_Guideline_Medical%20Device%20Registration_%20Ver%206.0.pdf; https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHandler/documents/departments/MDR/forms/Medical%20Device%20Registration%20Form%20%2020%20Dec%202020.pdf; https://www.gmdnagency.org/Services/Members#N

Nomenclature comments (...Annex 1): It is needed the GMDN code for registration of medical devices, as well as the HS code.



https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/global-atlas-of-medical-devices

Existence and type of an official nomenclature system for medical devices (data from the GAMD Dec-21 update)



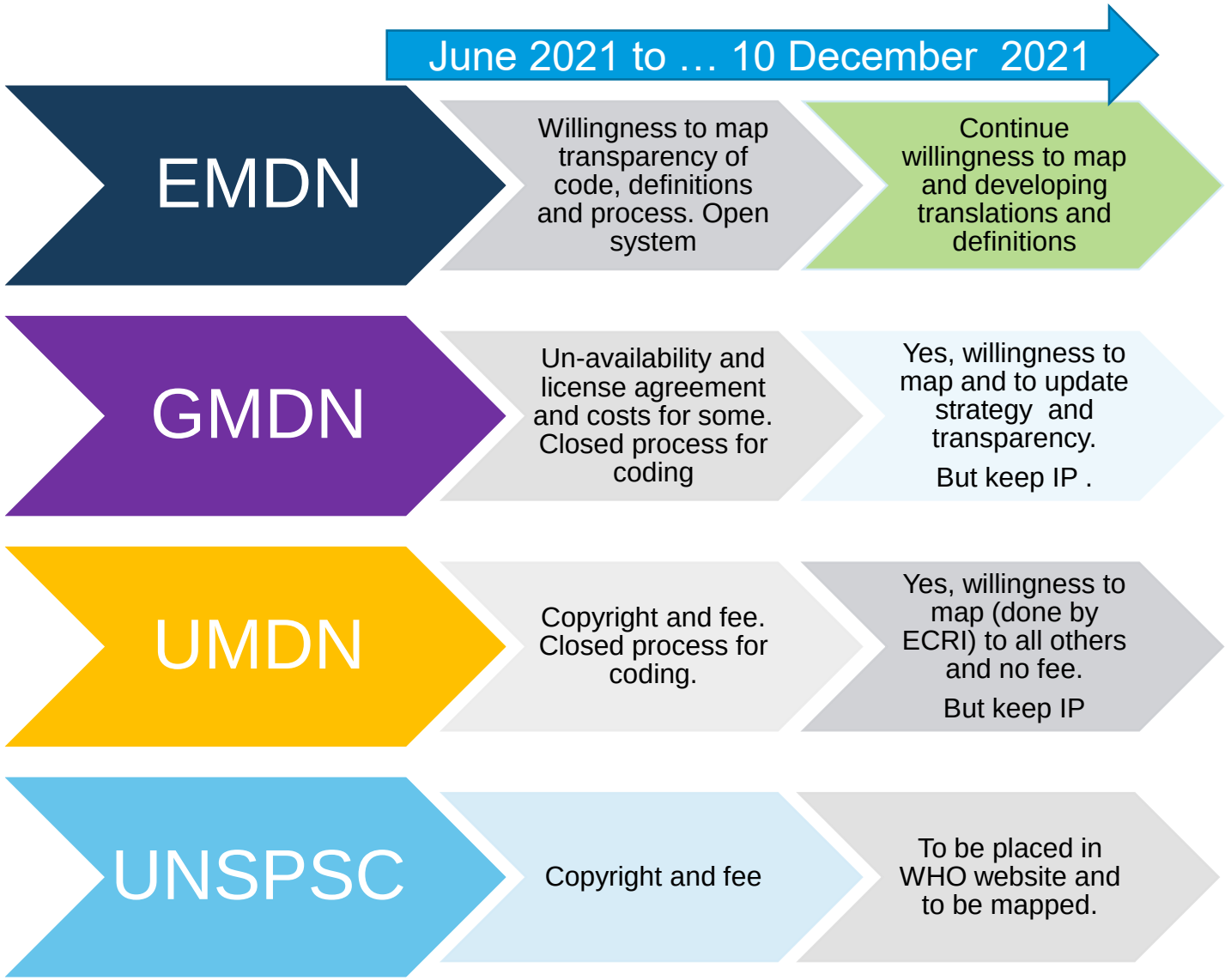
Comparison of characteristics of nomenclature systems

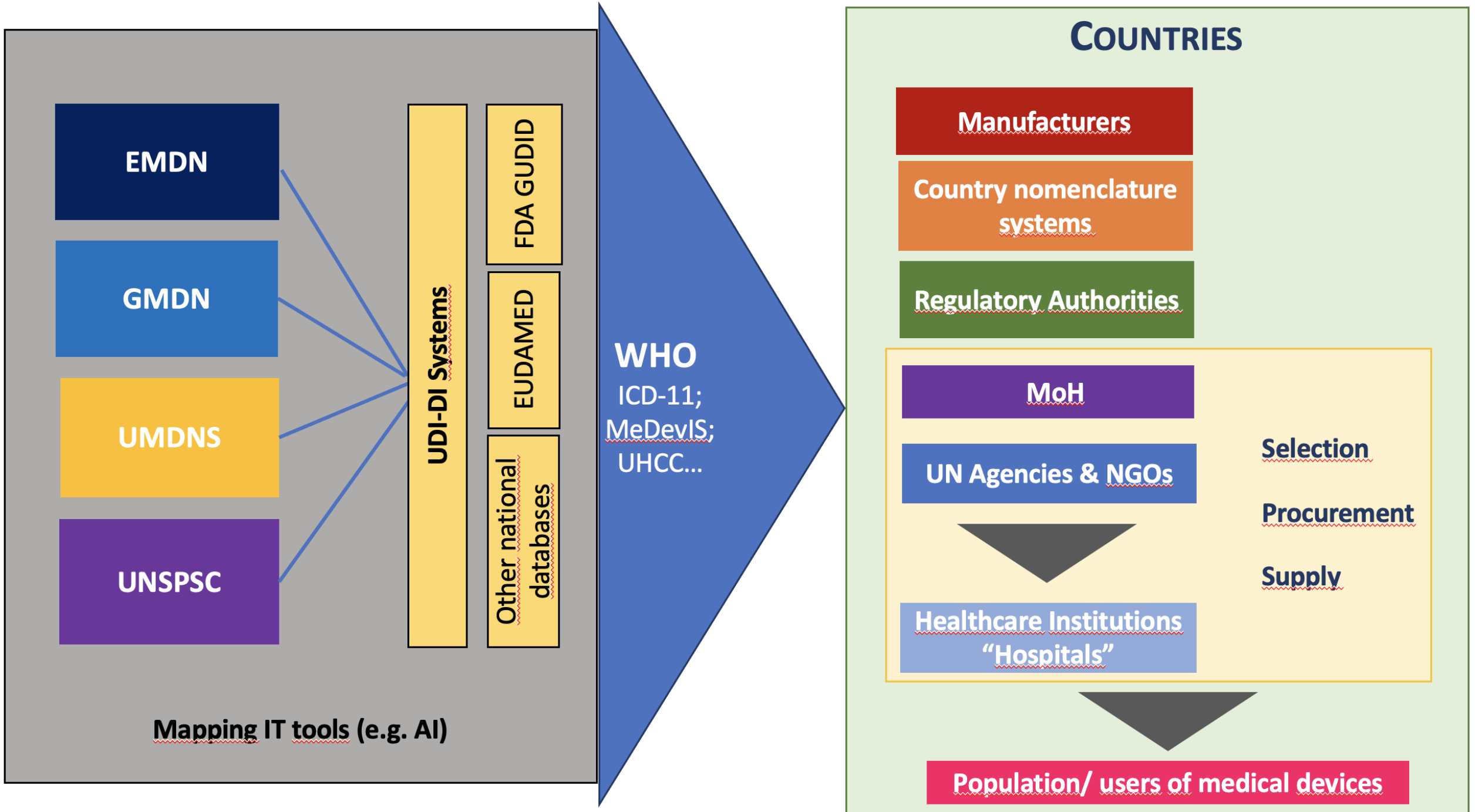
World Health Organization

Updated as of **24 June 2021**

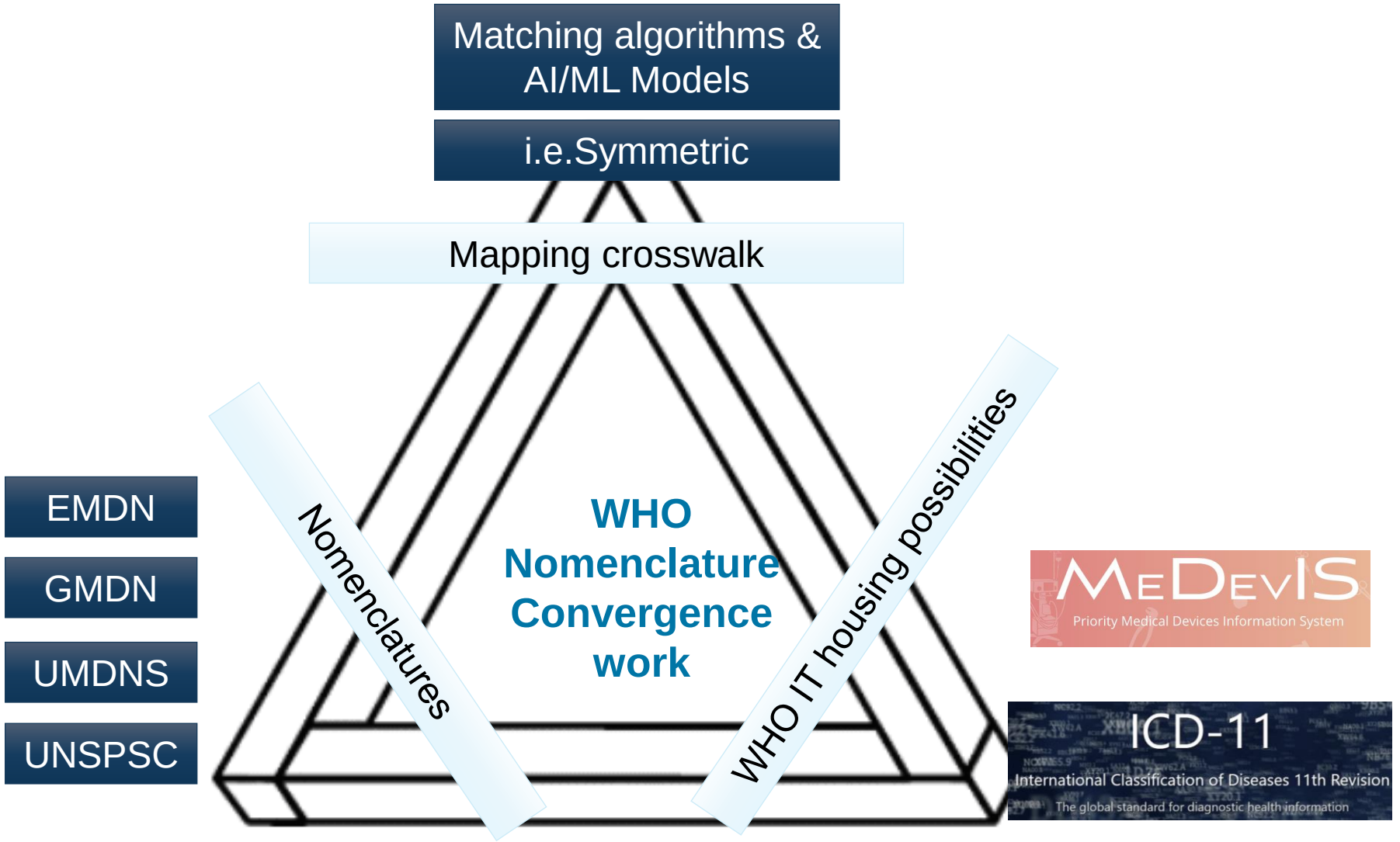
	Universal Medical Device Nomenclature System (UMDNS) 1983..	Global Medical Device Nomenclature (GMDN) 1991		United Nations Standard Products and Services Code (UNSPSC)	European Medical Devices nomenclature (EMDN) May 2021
Host Organization	ECRI Institute	GMDN Agency		GS1 US	European Commission
Transparent methodology, processes for the classification, coding and establishment of nomenclature terms.	✗	✗		✗	✓
Hierarchical organization of terms and codes into categories and subcategories, to meet the various needs of its stakeholders including regulatory and supply systems.	✓	✓		✓	✓
Freely available, downloadable, exportable terms, codes and hierarchies	✗	✗		✓	✓
Possibility to have translation	✓	✓		✓	✓
Non proprietary	✗	✗		✓	✓

Findings up to 13 sept and presented in IMDRF	EMDN	GMDN	UMDNS	UNSPSC
Information freely available	yes	Yes, for all registered users	Yes, for non-commercial users	Yes, fully downloadable after registration
Processes used for: code development and maintenance,	Managed by the Medical Device Coordination Group (MDCG) subgroup on Nomenclature (NOM WG), (each EU Member State is represented	highly qualified technical authors. Requests by companies are analyzed	The ECRI agency creates the codes and descriptions	Only registered users can request codes
License agreement	No need.	Standard license and costs in website. Special license to 8 public entities.	Revised license is coming.	Standard license, no need to pay for PDF.
Willing to work on mapping to other existing nomenclatures?	Yes, to GMDN	*(not responded)* *(updated on 20th to: Yes)*	Yes, to EMDN, GMDN and UNSPSC	Yes, to the other 3 if funded
Willing to provide code, name, definitions and hierarchy to WHO for electronic platforms?	Yes	To be discussed and agreed	Yes for non-commercial	Codes owned by UNDP, so could be shared to UN family


June 2021 to … 10 December 2021
EMDN
Willingness to map transparency of code, definitions and process. Open system
Continue willingness to map and developing translations and definitions
GMDN
Un-availability and license agreement and costs for some. Closed process for coding
Yes, willingness to map and to update strategy and transparency.
But keep IP .
UMDN
Copyright and fee. Closed process for coding.
Yes, willingness to map (done by ECRI) to all others and no fee.
But keep IP
UNSPSC
Copyright and fee
To be placed in WHO website and to be mapped.


EMDN
GMDN
UMDNS
UNSPSC
UDI-DI Systems
FDA GUDID
EUDAMED
Other national databases
Mapping IT tools (e.g. AI)
WHO
ICD-11;
MeDevIS;
UHCC…
COUNTRIES
Manufacturers
Country nomenclature systems
Regulatory Authorities
MoH
UN Agencies & NGOs
Healthcare Institutions "Hospitals"
Selection
Procurement
Supply
Population/ users of medical devices

Towards a Global Public Good, mapping feasibility study



Feasibility study updates

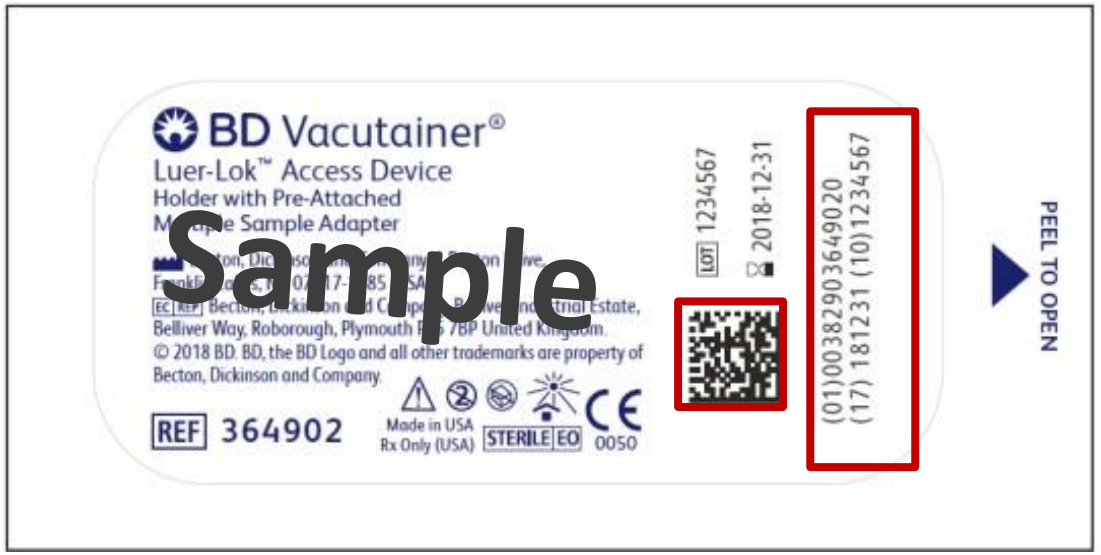
Terrie Reed

UDI & the Device Label

World Health Organization

1974 - UPC

1976 - NDC



2013 – UDI

UDI-DI: Device Model +
UDI-PI: Lot, Serial, Expiration Date, Distinct ID Code

UDI-DI in Public Sources

World Health Organization

Manufacturer submits UDI-DI & attributes to UDIDs; Nomenclature is required

ACCESS GUDID
IDENTIFY YOUR MEDICAL DEVICE

Enter Device Identifier, Name, or Company

HOME | ABOUT | NEWS | API | DO

DEVICE: Zolid (E4947668951)

DEVICE RECORD HISTORY | DOWNLOAD: XML

VIEW ALL SECTIONS | CLOSE ALL SECTIONS

DEVICE IDENTIFIER (DI) INFORMATION

Brand Name: Zolid
Version or Model: Zolid gen-x B4 98x25
Commercial Distribution Status: In Commercial Distribution
Catalog Number: 766895
Company Name: Amann Girrbach AG

Primary DI Number: E4947668951
Issuing Agency: HIBCC
Commercial Distribution End Date:
Device Count: 1
Labeler D-U-N-S® Number*: 300708950 *

GMDN [?]

GMDN Names and Definitions: © Copyright GMDN Agency 2015. Reproduced with Permission from the GMDN Agency.

GMDN Preferred Term Name	GMDN Definition
Dental appliance fabrication material, ceramic	A dental material made of ceramic materials (e.g., zirconium oxide) intended to be used to manufacture a final dental prosthesis (e.g., a dental implant, removable dentures, crown, bridge) for patient use. It is used to create implantable and removable restorations using manual or computer-aided design/computer-aided manufacturing (CAD/CAM) technology. After application, this material cannot be reused for fabrication.

European Commission | EN English

EUDAMED - European Database on Medical Devices

Home | Actors | Devices | Certificates | News

UDI-DI details

Version 1 (Current) | Last update date: 19/10/2021 15:26

UDI-DI code	E4947668951 / HIBCC
Status	On the EU Market
UDI-DI from another entity (secondary)	-
Nomenclature code(s)	Q010699: Materials for the preparation of custom-made dental devices - other
Name/Trade name(s)	Zolid gen-x B4 98x25
Reference-catalogue number	766895

Actor/Organisation name	Amann Girrbach AG [DE]

Summary of Trade Items selected for Feasibility Study

Goal: To include a representative sample of products with the following characteristics:

- Broad range of global manufacturers
- Product types of high impact to WHO initiatives
- Intersection of products in 2 major public data sources - GUDID and EUDAMED (interpolated from Italian Ministry of Health)

Summary of Items Selected	
Manufacturers	510
Device Types	
• IVDs	306
• Respiratory	262
• Implantable	214
• Cardiocirculatory	654
• PPEs*	417

* PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)

Improve crosswalk assignment – automated outlier detection

World Health Organization

Regulatory Nomenclature Assignments	Non-regulatory Nomenclature Assignments
EMDN - V0402 CLINICAL USE TRAYS AND BOWLS	UNSPSC – 42281908 Sterilization instrument tray liners
GMDN – 12143 Instrument tray, reusable	UMDNS – 12143 Trays Instrument

Automated Mapping

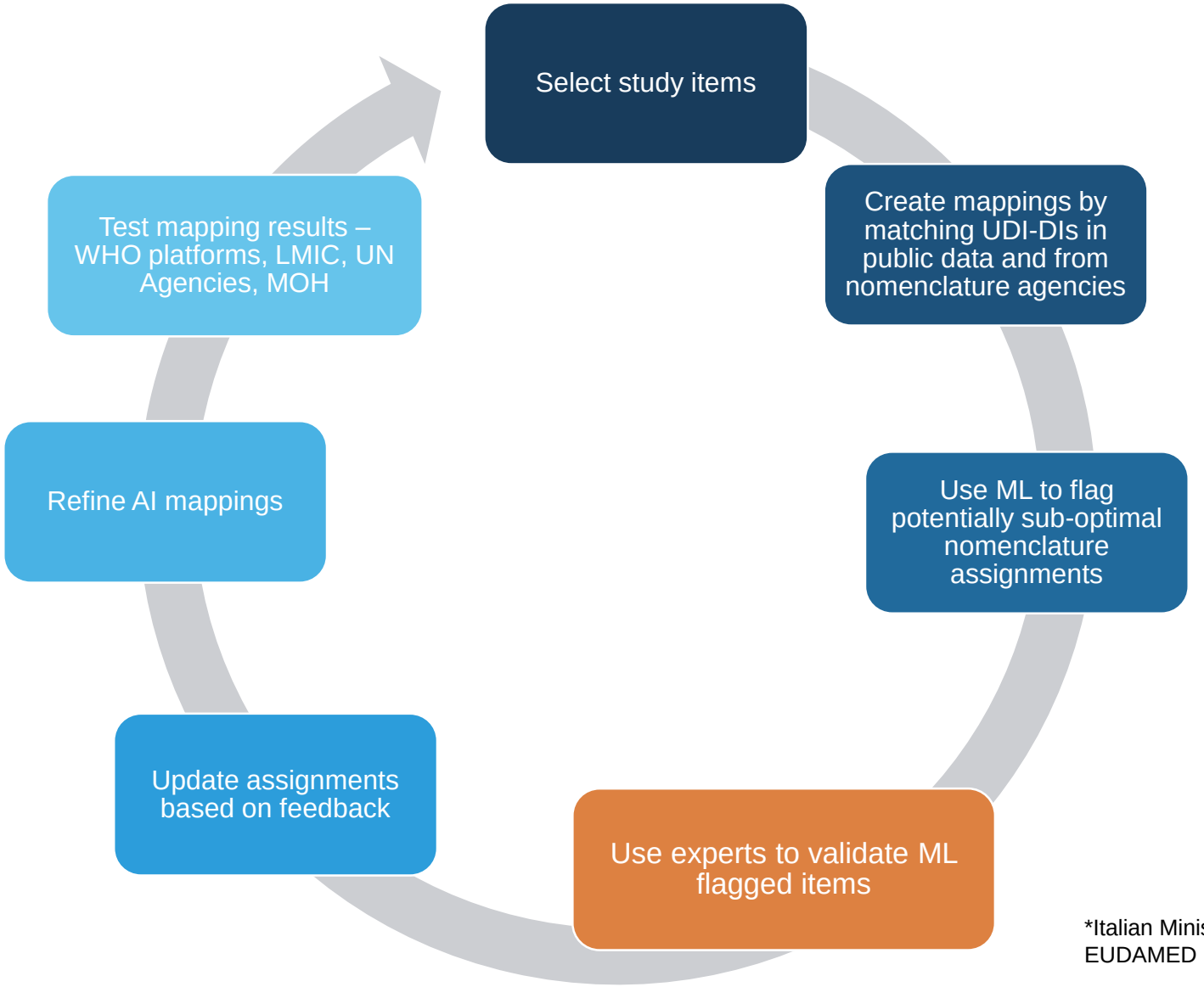
GUDID DATA	GMDN - FROM GUDID	EMDN - FROM ITALY CND -> EMDN Mapping	UMDNS	UNSPSC	Outliers
primary_di	gmdn	emdn	umdns	unspsc	is_outlier
04546540538437	13730-Sterilization/disinfection contai	V0402-CLINICAL USE TRAYS AND BOWLS	13730-Sterilization Containers	42281807-Sterilization indicator tapes	Outlier
00650862164008	63652-Thoracic suction collection cont	A060203-PLEURAL DRAINAGES WITH VALVE AND	10817-Drainage Systems Pleural	42295453-Surgical drains or drain sets	Not Outlier
10705034195438	46479-Surgical implant template, reus	V030299-DIMENSIONAL CLINICAL PARAMETERS I	41918-Bone Depth Gauges	42293002-Surgical measuring gauges or rods	Not Outlier
10705034219097	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219103	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219110	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
04048675041610	42411-Neonatal/adult intensive-care v	Z1203010502-ADULT PULMONARY VENTILATORS	17429-Ventilators, Intensive Care	42272220-Ventilator accessories	Not Outlier
10705034219141	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219158	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219165	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42294200-Surgical instrument sets and syste	Not Outlier
10705034219172	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10705034219219	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10705034219226	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10705034219233	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42281509-Sterilization containers or trays	Not Outlier
10884521181229	17148-Pulse oximeter, line-powered	Z1203020408-PULSE OXIMETERS	17148-Oximeters, Pulse	42181918-Multiparameter vital sign unit acce	Not Outlier
10603295116691	12143-Instrument tray, reusable	V0402-CLINICAL USE TRAYS AND BOWLS	12143-Trays Instrument	42295100-Surgical equipment and accessorie	Not Outlier

[1] GMDN ®. © GMDN Agency 2005-2021

Feasibility Study Scope

- Develop an innovative, sustainable, affordable mapping solution across major globally used nomenclatures
- Engage a community of medical device experts (regulatory, supply chain, biomedical engineering, clinical, research) that contribute to solution success
- Test the mapping results in real world applications
  - Load mapped nomenclatures into MeDeVIS application
  - Show potential for mapping exercise to improve identification of data in LMIC and UN agencies

Feasibility Study process – Methodology overview



*Italian Ministry of Health Database acted as surrogate for EUDAMED

Expected Benefits

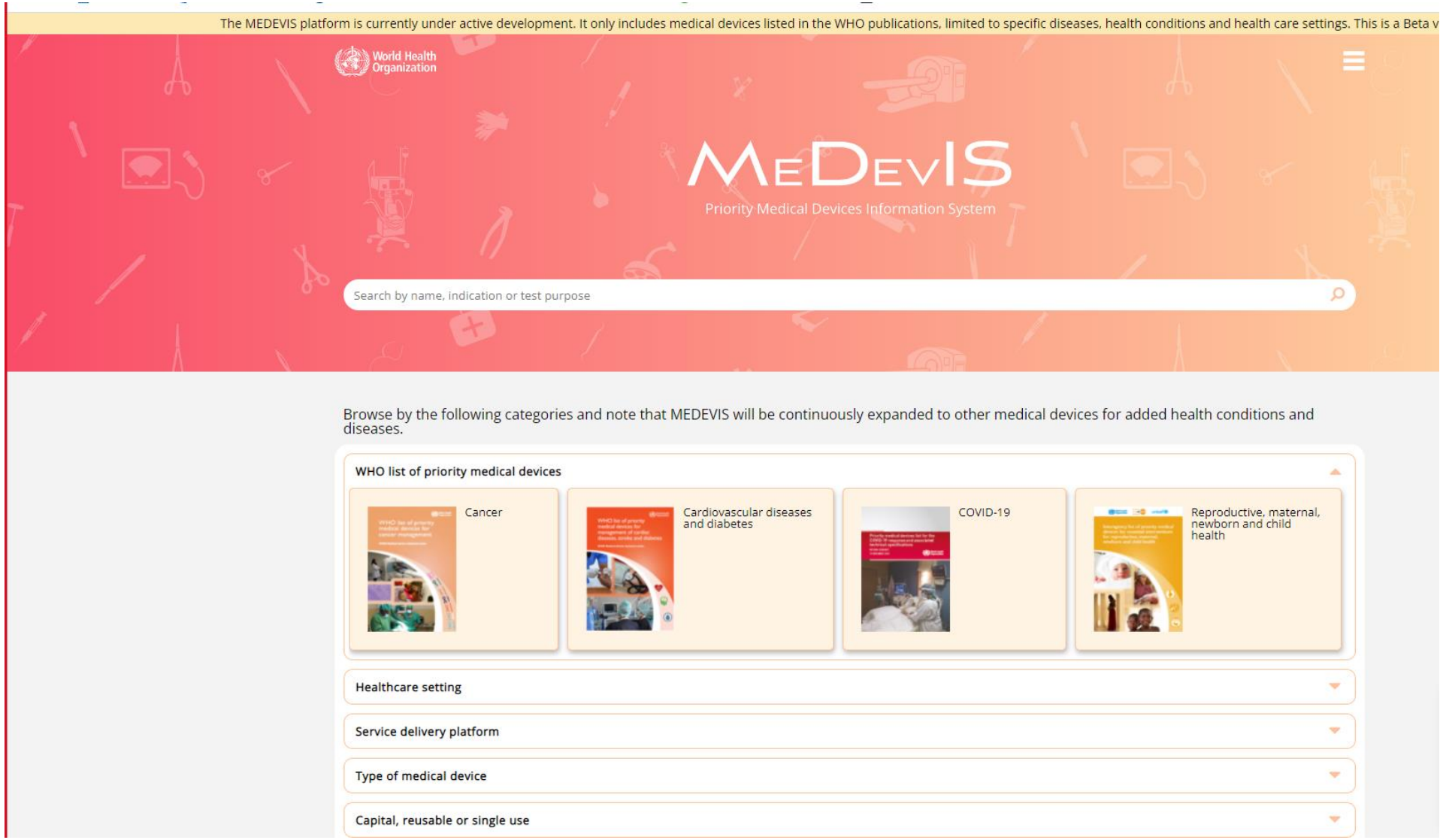
A mapping methodology that relies on publicly available nomenclature assignments to items (UDI-DIs) will:

- decrease the overall costs of nomenclature mapping
- increase the accuracy of mapping
- allow for measurable improvement over time
- improve the quality and consistency of nomenclature assignments to trade items in public UDI databases

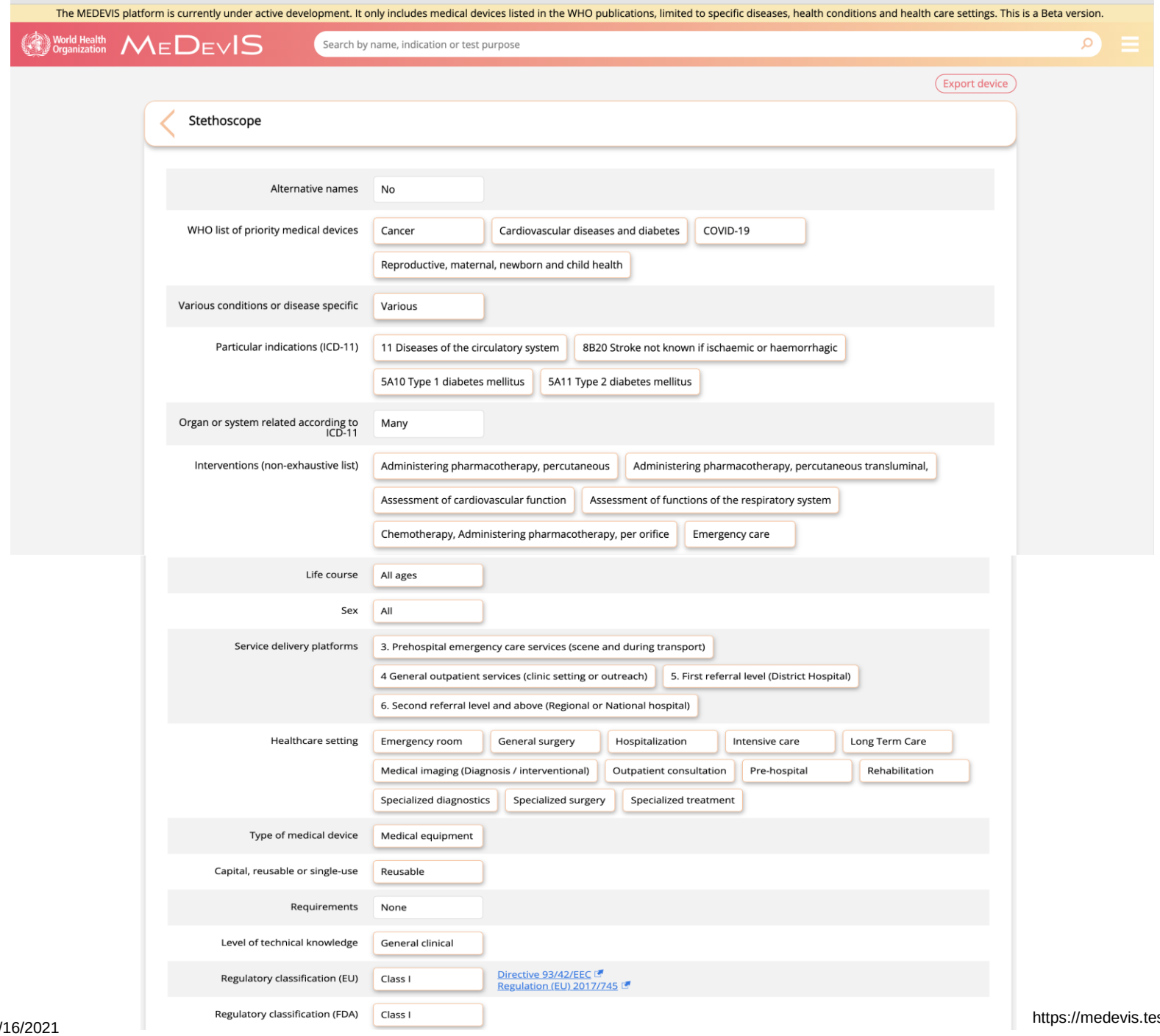
MeDevIS

Eunice Lourenco

MEDICAL DEVICES INFORMATION SYSTEM



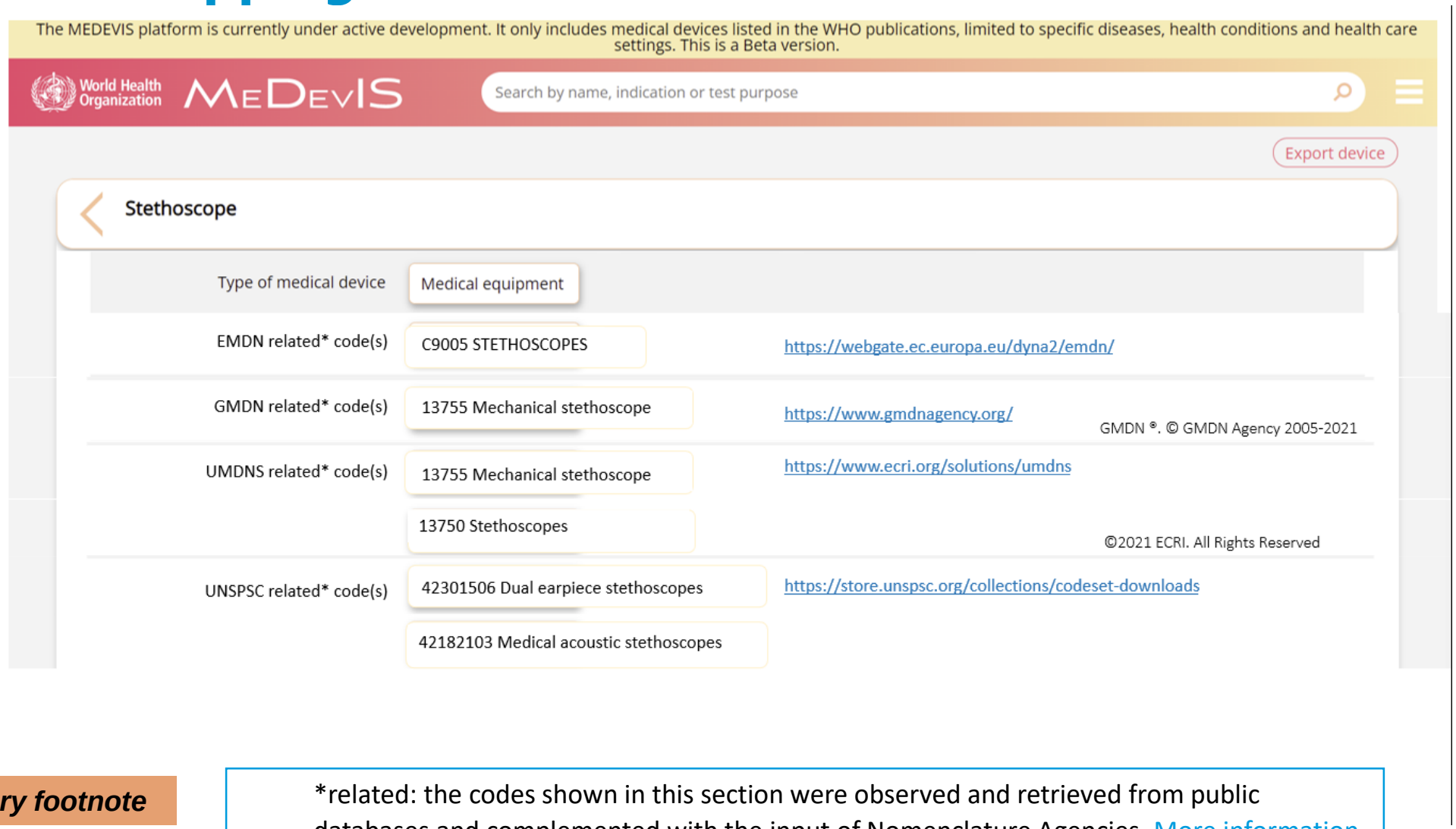
https://medevis.test.evidenceprime.com/



World Health Organization

https://medevis.test.evidenceprime.com/devices/COM_326

Proposed mapping to be shown in MeDevIS



Explanatory footnote

*related: the codes shown in this section were observed and retrieved from public databases and complemented with the input of Nomenclature Agencies. More information

Mapping exercise with LMIC, UN Agencies and NGOs codes

Olga Pineda

Mapping exercise with LMIC – Regulatory Agency from El Salvador

Methodology implemented

- Identification of Sources

a) 2 Major public data sources - AccessGUDID and EUDAMED (interpolated from Italian Ministry of Health)

b) Regulatory Agency shared their database (list of products registered, including information of the manufacturer, model, brief description and manufacturer catalog number)

- Symmetric applied an automated matching tool to match trade item level data (UDI-DIs) in AccessGUDID and EUDAMED to the same item in El Salvador product data
- Once the El Salvador product data matched to UDI-DIs, the methodology of the Feasiblity Study was applied to map nomenclatures

GMDN - FROM GUDID		EMDN - FROM ITALY CND		UMDNS (not updated)		UNSPSC		MEDEVIS	El Salvador	
gmdn_pt_code	gmdn_pt_name	emdn_code	emdn_en_name	umdns_code	umdns_concept	unspsc_code	unspsc_title	medevis_tab_code	correlativo	id_producto
37710	Anaesthesia workstation, general-purpose	Z1203010101	ANAESTHESIA DEVICES	10134	Anesthesia Units	42270000	Respiratory and anesthesia and resuscitation	Cancer(CAN_284)-Cancer(COM_300)	152320	IM090019082021
41126	Bronchoscopy tube	Z12020801	BRONCHOSCOPES	23504	Endoscopic Telescopes	42296305	Bronchoscopes	Cancer(CAN_054)	234235	IM221814122017
35171	Rebreathing oxygen face mask	R03010201	AIR/OXYGEN MASKS	11001	**Positive Airway Pressure Units Continuous**	42272213	Continuous positive airway pressure CPAP masks or straps	Cancer(CAN_323)-COVID database(COV_044)	132408	IM078304102019
46786	Direct ophthalmoscope	Z12120114	OPHTHALMOSCOPES	12815	Ophthalmoscopes	42183000	Ophthalmic diagnostic exam products	Common database(COM_012)-CSD(CSD_100)-CSD(CSD_177)-CSD(CSD_234)	22164	IM019225012018
17433	Infant warmer	Z12080407	NEONATAL RADIANT WARMERS	17433	Warming Units, Patient, Radiant, Infant, Mobile	42000000	Medical Equipment and Accessories and Supplies	RMNCH(RMN_250)	3279	IM002610012019
17595	Intubation teeth protector	T0399	PROTECTION DEVICES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT PPE) - OTHER	17595	Protectors Teeth	42294948	Endoscopic mouthpieces	Cancer(CAN_149)	174199	IM120911062015

Outcomes of the mapping exercise with LMIC

- More than 1,300 products were mapped to the 4 nomenclature codes, using existing data in El Salvador’s product catalog
- The amount of matches could have been more, but at the moment ot the exercise EUDAMED has not enough records to find coincidences and a lot products registered in El Salvador database come from Europe
- Mapping is possible and through this exercise has been demostrated

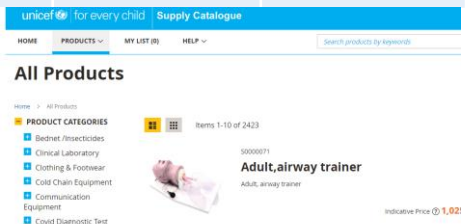
Nomenclature used by UN Agencies and NGOs

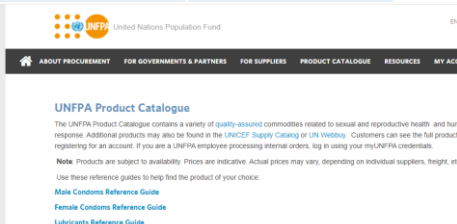
Agency/NGO	EMDN	GMDN	UMDNS	UNSPSC	None of the 4	Developed by their own	Comments: reference to any the 4 is for internal use only.
IAEA		X					GMDN descriptions to the most appropriate-helpful
UNDP		X		X			GMDN at a basic level and UNSPSC for budgeting and reporting
UNFPA				X		x	UNFPA Product Catalogue does not reflect any of the 4
UNHCR					X	X	
UNICEF		X	X	X		X	UNICEF Catalogue does not reflect any of the 4
UNITAID					X		
UNOPS				X			Or May adopt Country specific or Manufacturer's coding/nomenclature systems as per applicable, does not reflect any of the 4
WHO	X	X	X	X		X	EMDN from 2021 and future, UNCCS (will change to full adoption to UNSPSC in new ERP system)- Before 2020: GMDN, UMDNS, UNSPSC WHO Global Supply Catalogue does not reflect any of the 4
CHAI					X		--
ICRC		X					not used in the entire organization
Global Fund		X				x	WAMBO catalogue does not reflect any of the 4 (taken from the meeting with GF on September 3rd)
MSF		X				x	Nomenclature developed by MSF is based on GMDN terms. Planning to star using EMDN
PATH							Not received yet
StopTB						X	**For internal use only**

Manual mapping to UN Agencies and NGOs codes (COVID-19 related products), noting that today each agency has it own code

World Health Organization

MeDevIS https://medevis.test.evidenceprime.com/devices/COM_326		WHO https://www.who.int/publications/m/item/emergency-global-supply-chain-system-covid-19-catalogue		UNICEF https://supply.unicef.org/all-materials.html		MSF https://extranet.msfsupply.be/ITC2021/MSF_Docs/eng/MSF_reference_books_eng.html		The Global Fund (Wambo) https://www.theglobalfund.org/media/10233/covid19_diagnosticsreferencepreices_table_en.pdf		UNFPA https://www.unfpaprocurement.org/es/products	
Code	Product	Code	Product	Code	Product	Code	Product	Code	Product	ITEM ID	Product
COM_014	Pulse oximeter, handheld	BIOPUOX001	Pulse oximeter - portable handheld, with cables and sensor	S0845017	Pulse oximeter,handheld, incl.resp. rate	EEMDPOXE4--	PULSE OXIMETER (Masimo RAD-5) + accessor (specific product)	13303	Pulse oximeter,handheld,w/access & probes	OXIMETER	Pulse oximeter, portable and accessories
COM_341	Patient monitor multiparametric, intermediate	BIOPAMO001	Patient monitor multiparametric with ECG, non-invasive blood pressure (NIBP), oxygen saturation (SpO2), respiratory rate (RR), and temperature (TEMP) sensor	S0002031	Monitor,patient,portable,w/access - 6 parameters	EEMDMONE10-	MONITOR, multiparameter (B125)+ accessories, 230V (specific product)	13318	Vital signs monitor, 6 parameters, portable, w/access	MONITORBEDSIDE	Monitor, bedside
COM_321	Oxygen concentrator	BIOCONO033	Oxygen concentrator, portable (**without** additional accessories, spare parts or consumables) – 10 L	S0845038	Oxygen concentrator, 10 LPM, single flow	EEMDCONE4--	CONCENTRATOR O2 (DeVilbiss 525KS) 5l, 220V + access. (specific product)	13066	Oxygen concentrator, 10LPM, Single flow	OXYCONCENTRATOR	Oxygen concentrator, w/set

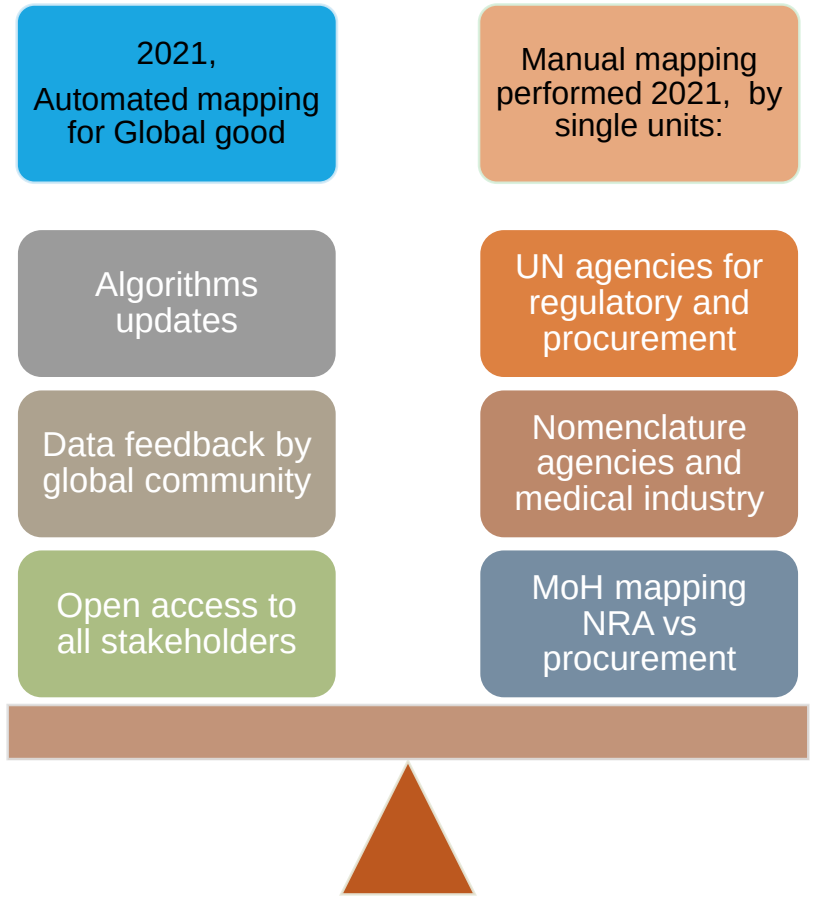




Feasibility study in December: Comparison procedures automatic vs manual.

ie. Volunteer usability testing: El Salvador, MSF, South Africa, UNOPS, WHO.

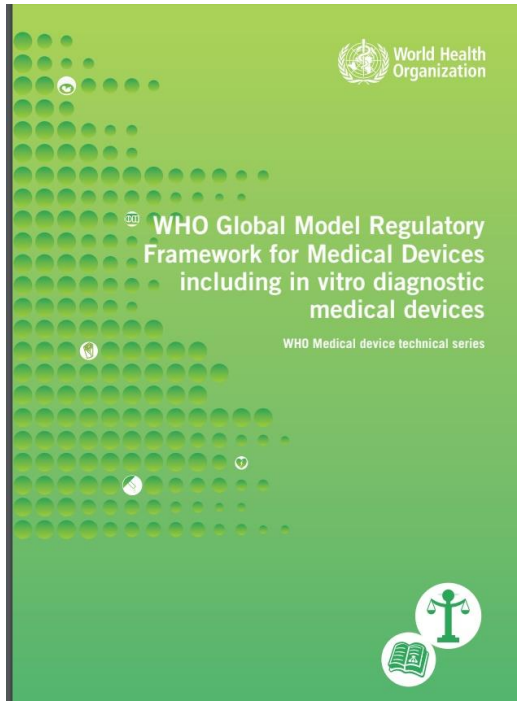
Analyze: time, costs, sustainability, benefits, challenges, impact



Update of the WHO Global Model Regulatory Framework,
September 2021 to March 2022

World Health Organization

Book published 2017



New topics. Review of book and meetings every other Thursday

Artificial intelligence

Software as medical device

Nomenclature and UDI

Donations of medical devices

https://apps.who.int/iris/handle/10665/255177

Next steps

- 16 December Member States information session
- Voluntary application /test the nomenclature mapping and feedback collaboration. (usability testing)
- Disseminate the importance of using an international nomenclature, UDI, do not create more personalized systems.

Everyone needs medical devices for protection, diagnostic, monitoring, treatment, rehabilitation or palliative care

World Health Organization

Need to ensure they are: safe and good quality, affordable, available, accessible, acceptable and that there is a

STANDARDIZE NAME FOR EACH ONE

Gracias
Thank you
Merci
Shokran
Xie xie
Spasiva

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1211 Geneva

Switzerland

Medical devices

Email: medicaldevices@who.int

website:https://www.who.int/health-topics/medical-devices#tab=tab_1