MS information session

23 September 2021

Standardization of medical devices nomenclature

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

Consultants: Eunice Lourenco, Olga Pineda and Teresa Reed.

Agenda 23rd September, MS information session

- Message from Assistant Director General: Dr Simao
- Requests from Member States and results from ongoing consultations
- Nomenclature agencies
- WHO IT platforms: ICD-11 and MeDevIS
- Feasibility study
- Stakeholder statements
- Open discussion from Member States
- Conclusions

World Health Organization

Background: EB145, 148, WHA74 … towards EB150 February 2022.

Standardization of medical devices nomenclature, the way forward

Nomenclature to support all process: from development to use

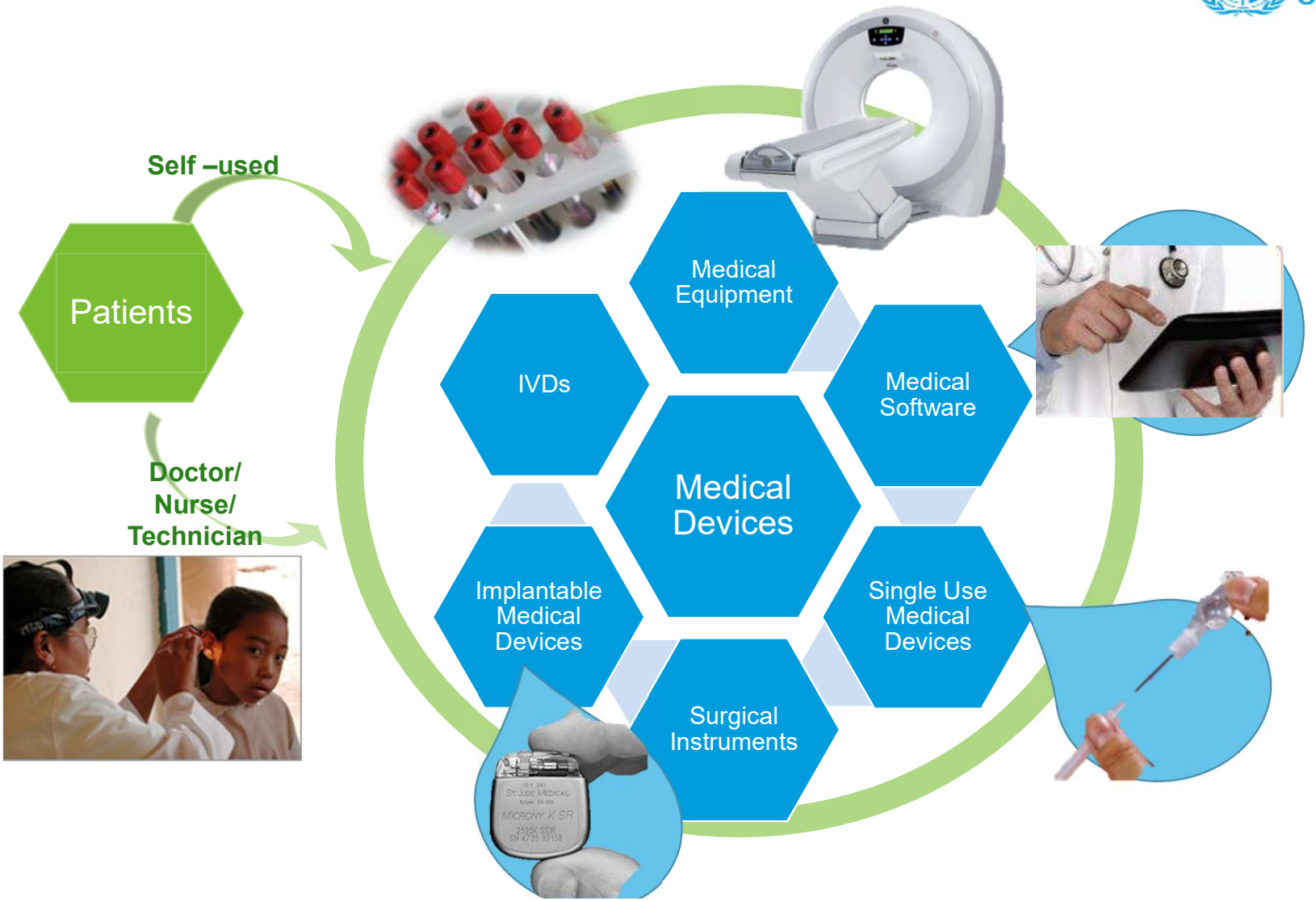
"The goal is to have an international classification, coding and nomenclature for medical devices that would be available to all Member States and that would support:

patient safety,
access to medical devices for universal health coverage,
quality of health care and
achievement of Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages"

http://apps.who.int/gb/ebwha/pdf_files/EB145/B145_3-en.pdf?ua=1

Medical Devices thousands categories with no generic international name, classification and code

World Health Organization



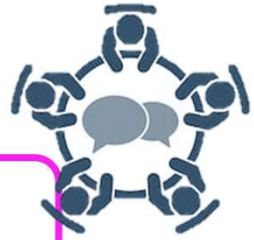
To ensure improved access of safe, quality medical devices, standardized names are the backbone:

World Health Organization

Nomenclature

R&D

- Medical devices industry



Assessment

- Health Technology Assessment
- Priority medical devices lists and Essential in vitro diagnostics

- Regulation process of medical devices
- Lists of approved MD for marketing in country.

Management

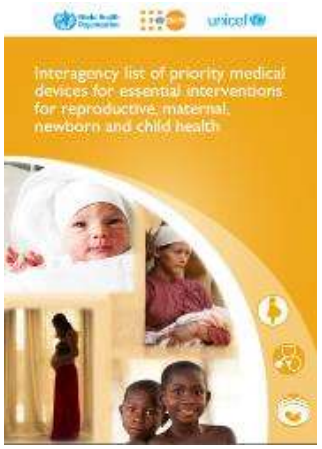
- Technical specifications, procurement and supply
- Installation, inventories, training, maintenance, operations
- Post market surveillance and adverse event report
- Decommissioning, Replacement
- Safe use

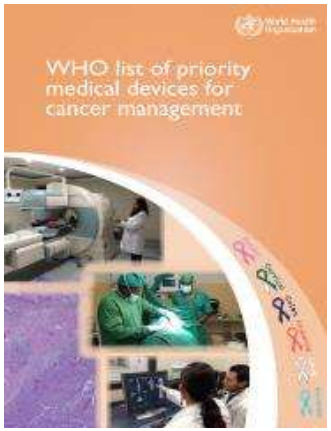
Examples of WHO Publications requiring nomenclature and coding to facilitate access

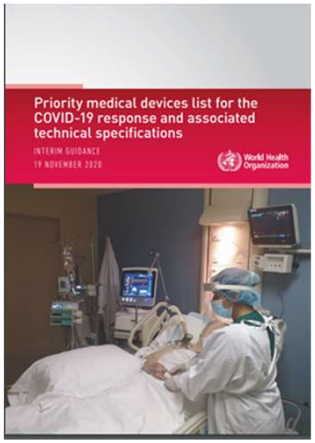
World Health Organization

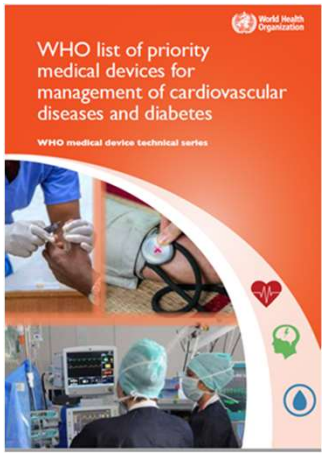
List of essential/ priority

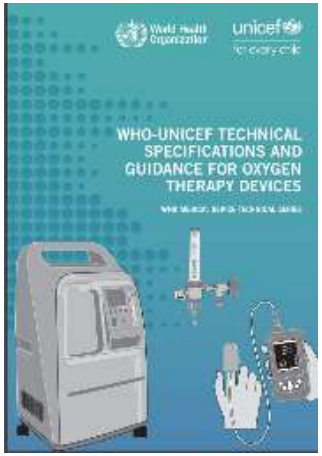
Technical specifications

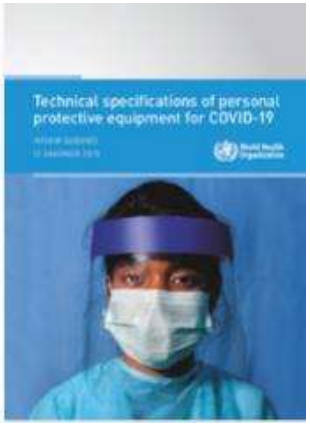


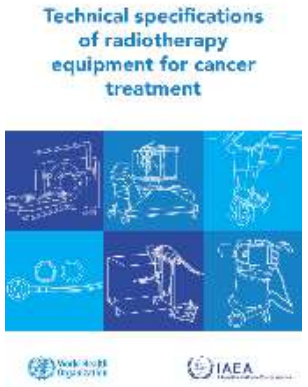






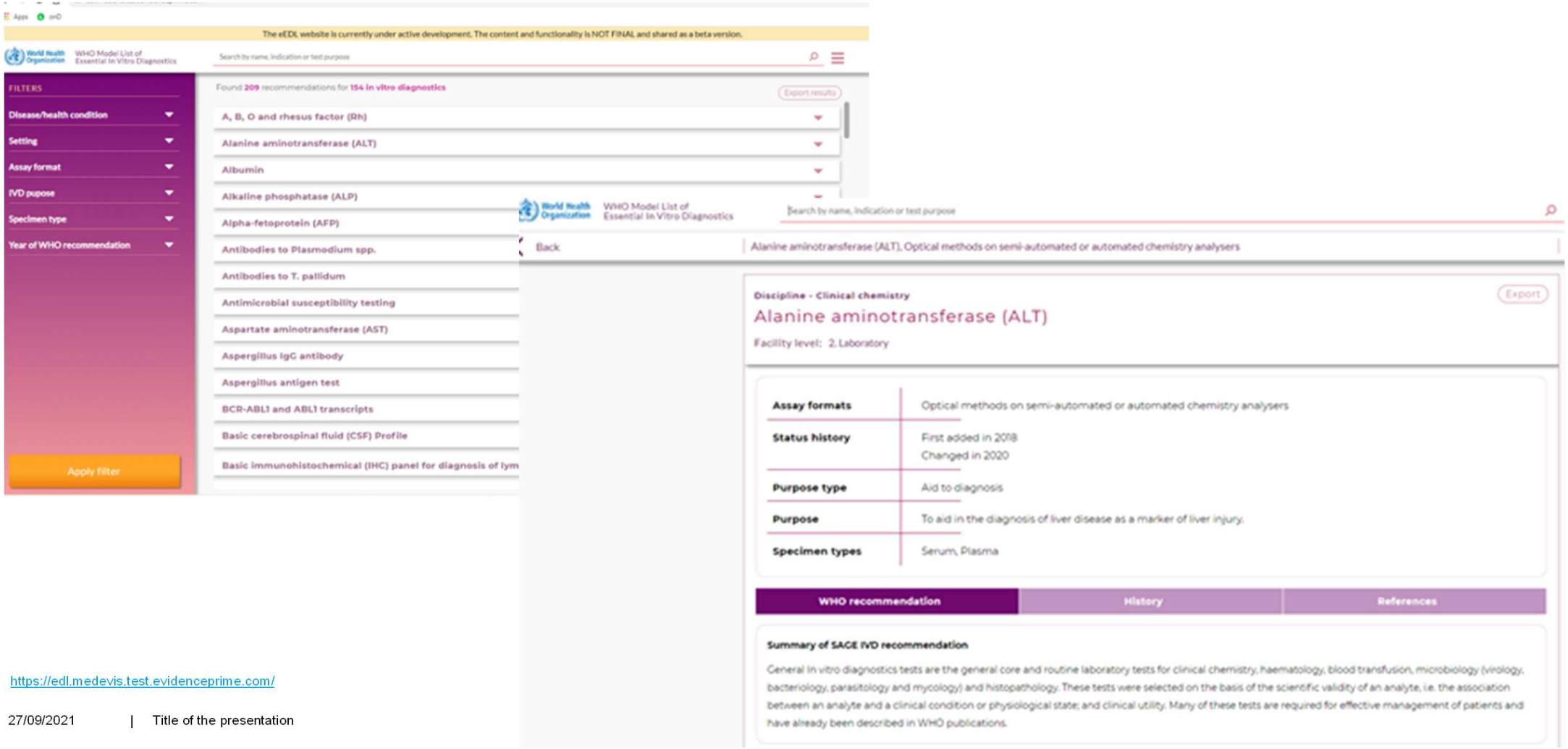






Electronic WHO Essential in vitro diagnostic list, (e-EDL)

Beta version 29 January 2021, does not include any nomenclature yet, https://edl.medevis.test.evidenceprime.com .

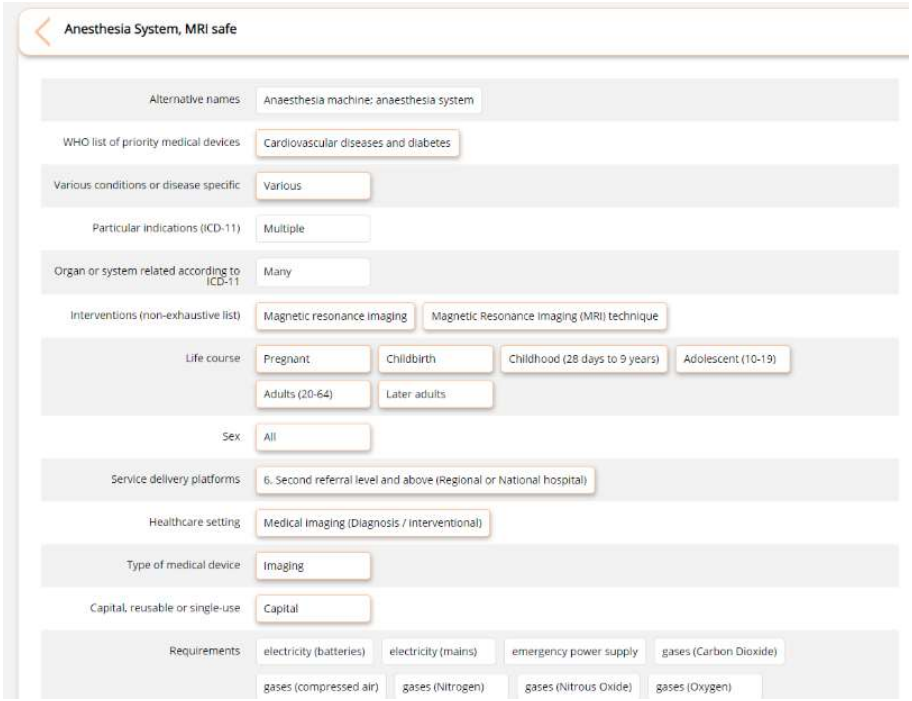


https://edl.medevis.test.evidenceprime.com/

WHO Priority medical devices information system,

MEDEVIS is similar to eEML and eEDL, includes 1500 devices. https://medevis.test.evidenceprime.com/

https://medevis.test.evidenceprime.com



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

Seventy-fourth World Health Assembly (who.int)

Requests by Member States

Interventions by 21 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, February 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.

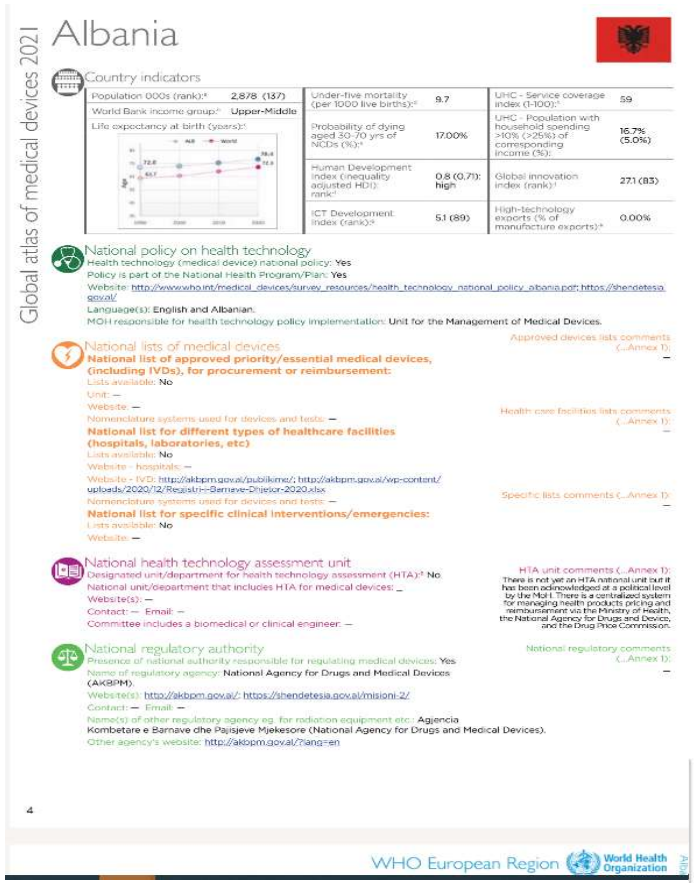
Consultations 2021

World Health Organization

1. **Country data has been received, compiled and posted for review**
2. **Various stakeholder consultations**

Country consultation of Global Atlas of Medical devices. 1 to 30 September

World Health Organization


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	UHC - Service coverage index (1-100):[c]	59
World Bank income group:[a]	Upper-Middle	Probability of dying aged 30-70 yrs of NCDs (%):[d]	17.00%	UHC - Population with household spending >10% (>25%) of corresponding income (%):	16.7% (5.0%)
Life expectancy at birth (years):[c]		Human Development Index (inequality adjusted HDI): rank:[c]	0.8 (0.71): high	Global innovation index (rank):[f]	27.1 (83)
		ICT Development Index (rank):[g]	5.1 (89)	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-Barneve-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 viz 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

A1B2 C3D4

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	Healthcare facility*	Total	Density per 100,000 population
Magnetic Resonance Imaging:[a]	5	1.58	Health posts:	415	13.08
Computerized Tomography Scanner:[a]	17	5.36	Health centres:	n/a	n/a
Positron Emission Tomography Scanner:[a]	0	0	General/district hospitals:	23	0.72
Gamma camera or nuclear medicine:[a]	0	0	Specialized/regional/national hospitals:	9	0.28
Mammograph:[a,b]	18	54.4	Estimation % of health facilities with none or very limited oxygen supply:		n/a
Radiotherapy:[a]	6	2.08			

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

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 (13 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):[a] 16.47
Number of biomedical/clinical engineers professionals in the country:[a] 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

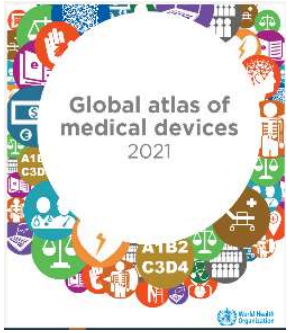
WHO Eastern Mediterranean Region — World Health Organization — Bahrain

Medical device nomenclature system

A1B2 C3D4

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

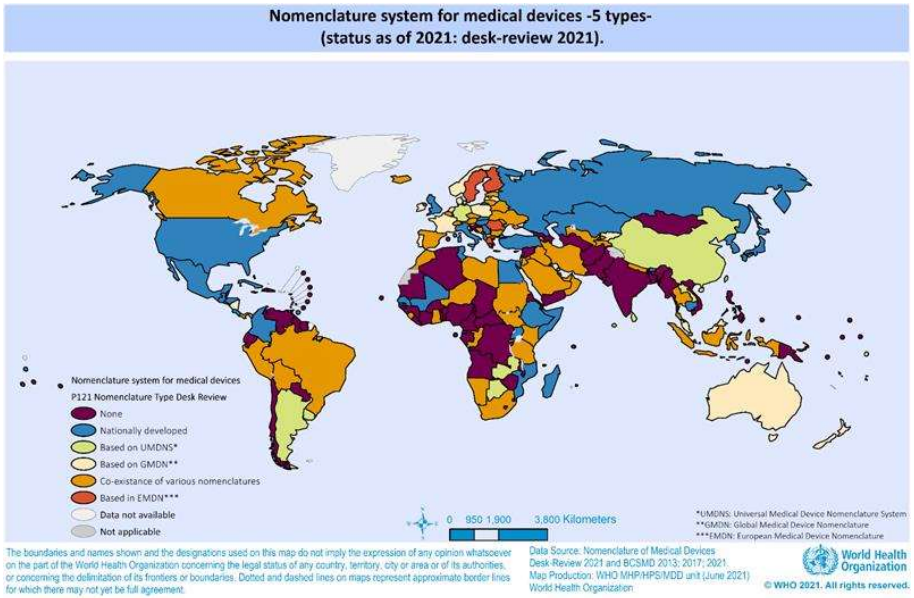
Nomenclature comments (...Annex 1): It is needed the GMDN code for registration of medical devices, as well as the HS code.

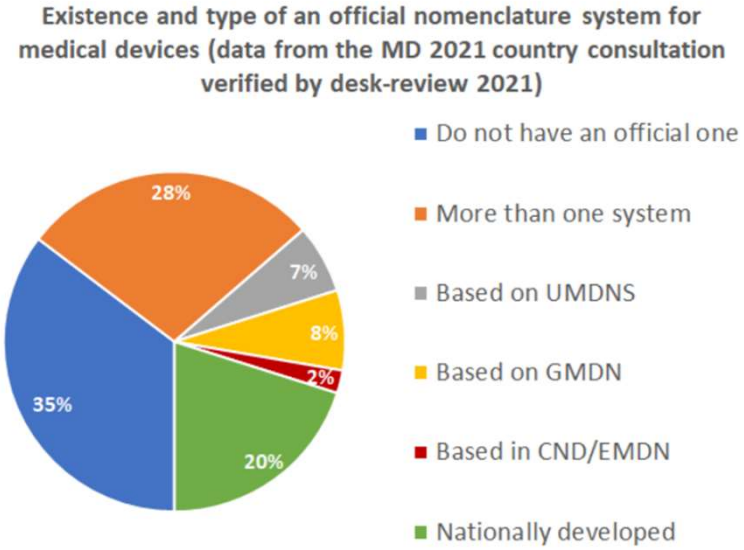


https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/global-atlas-of-medical-devices

Survey and desk review for consultation .

For comments and review by MS DRAFT





Stakeholders consultations July to September 2021

- Several meetings with different stakeholders:
  - WHO Regional Advisors (2 and invited to all nomenclature agencies meetings)
  - Medical devices industry associations (3)
  - Bilateral meetings with Nomenclature Agencies (EMDN, GMDN, UNSPSC, UMDNS) (5)
  - Biomedical & Clinical Engineers association (3)
  - UN Agencies and International NGOs (3)
  - MOH, Regulatory agencies (2 today, 3 next week and will continue)
- 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.

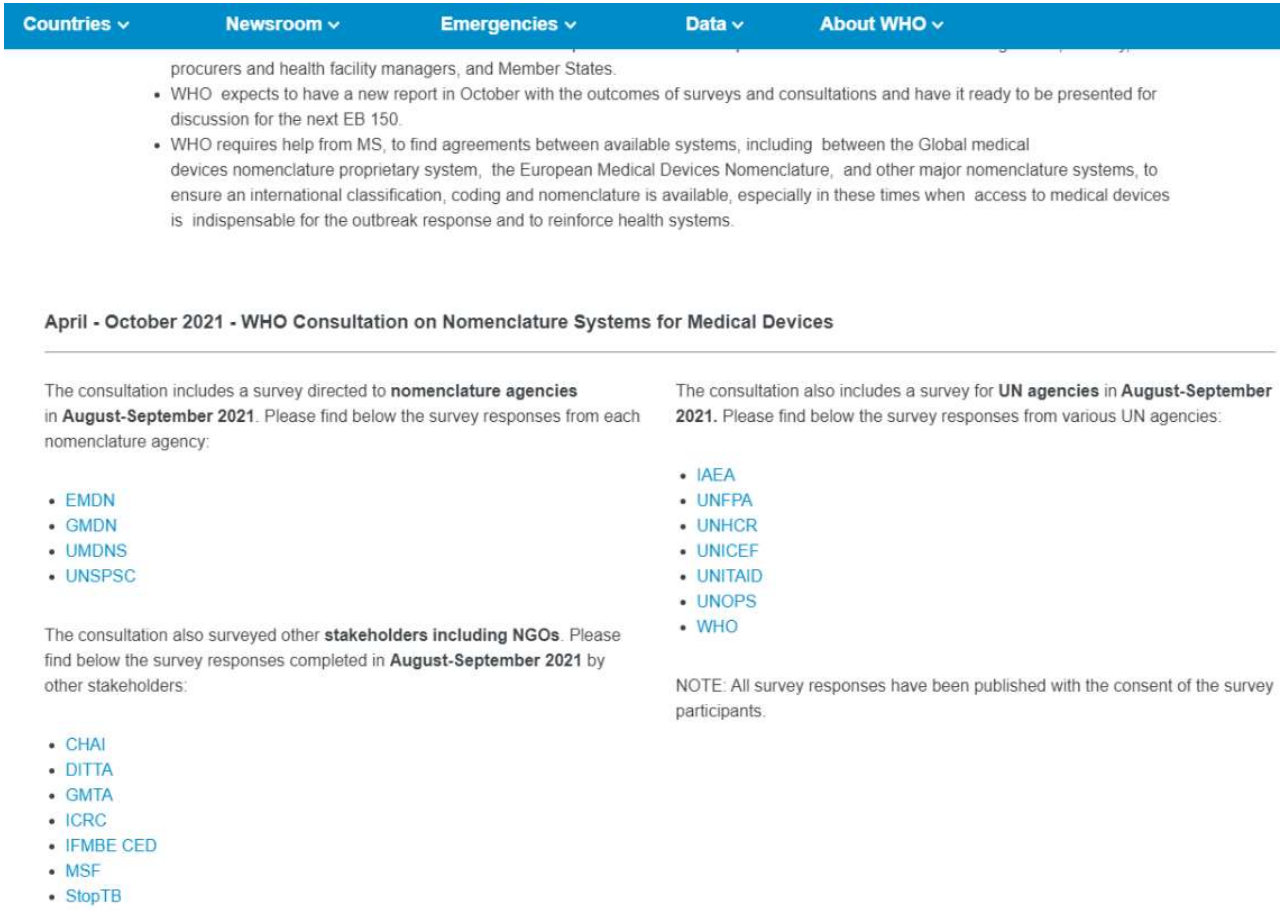
WHO standardization of medical devices nomenclature

Activities towards the 150 Executive Board in February 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, 26 August 21 September	**Medical devices industry** Medical devices industry and Regional WHO Meeting with industry and UN	GMTA, DITTA , Discussion of the outcomes of survey Status, ongoing activities
30 July, 27 August 1 3 September	**UN agencies and NGOs** UN agencies and NGOs and Regional Advisors UNICEF, Global Fund	Nomenclature and tech specs uses Discussion of the outcomes of the survey Nomenclature used, catalogue and codes used, challenges
1st round: 29 and 30 of July, 03 August 2nd round: 24 and 25 August 8 September 3rd round: 15 September	**Nomenclature agencies** Nomenclature agencies and Regional WHO All 4 nomenclature agencies together Nomenclature agencies	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
29 July, 26 August 22 September	**Biomedical and Clinical engineers** Biomedical and Clinical engineers and Regional Advisors	Use of nomenclature in health care facilities 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
1 October	Report for EB150	Report sent for WHO internal clearance
October, November, December	Development of mapping study; Other consultations as needed.	Publish report Consensus and mapping outcomes.
1 February 2022	EB150.	Presentation to the Executive Board

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

- 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**

Analysis Nomenclature agencies

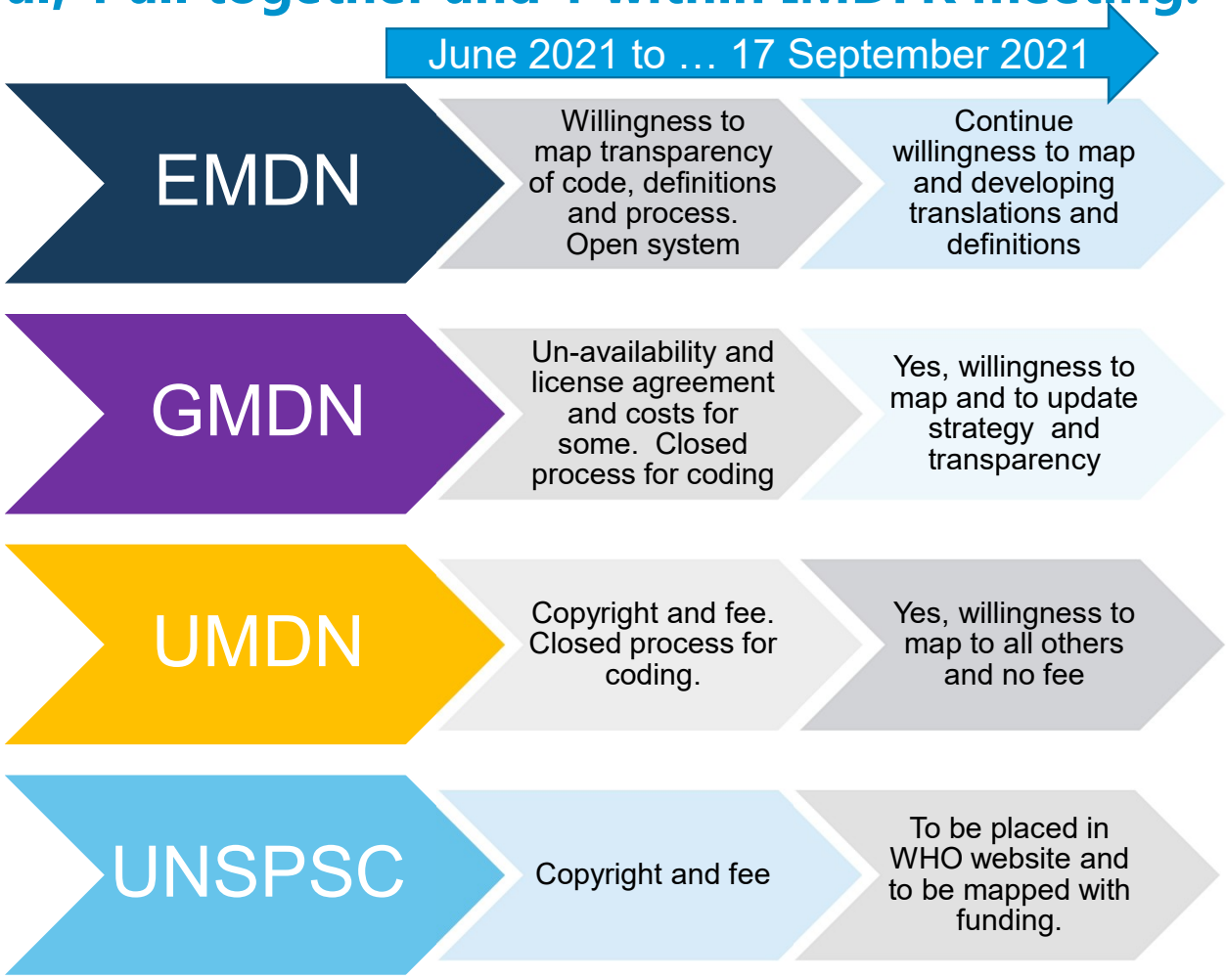
Comparison of characteristics of nomenclature systems

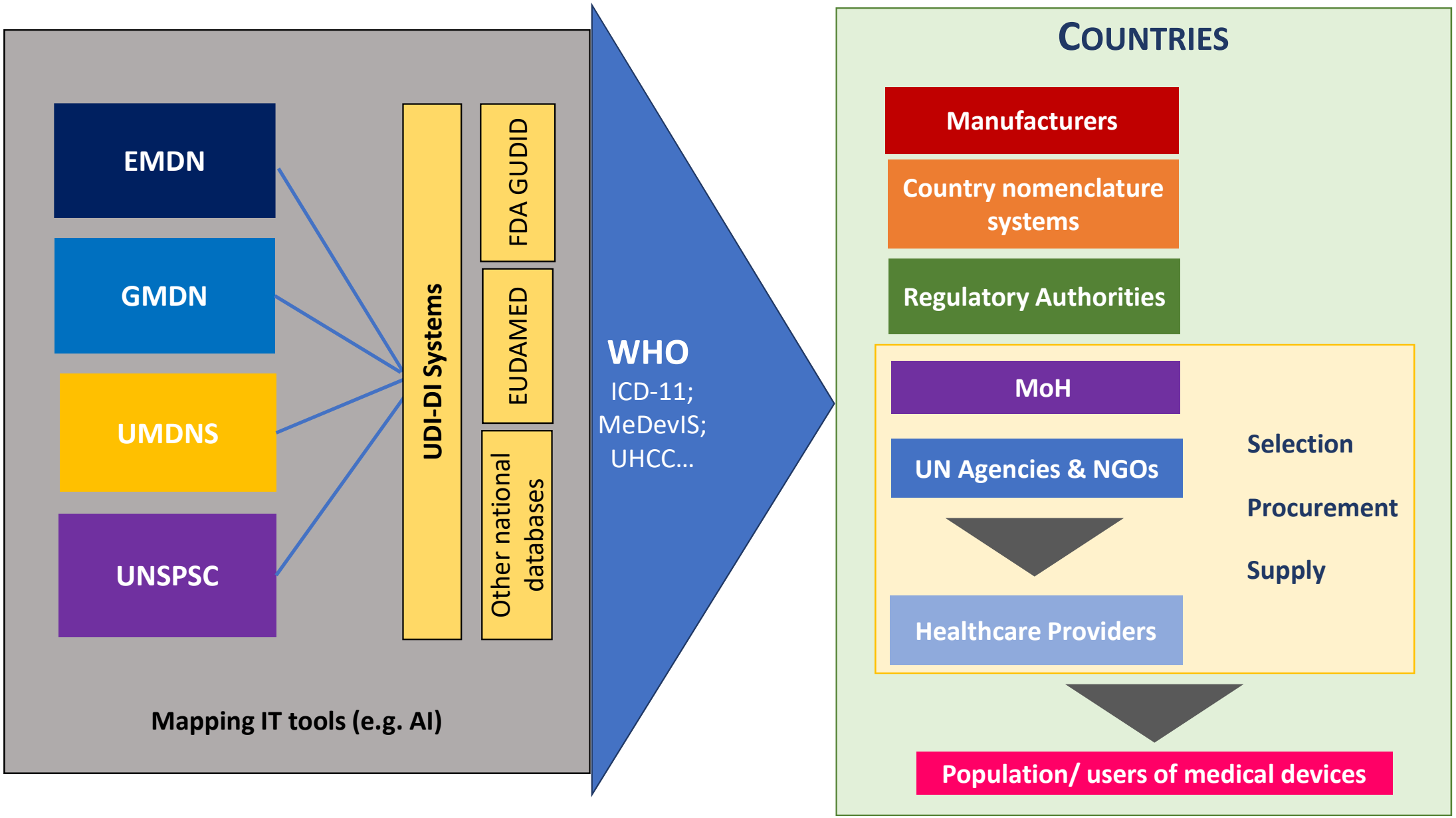
Updated as of **24 June 2021**

	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	✗	✗		✓	✓

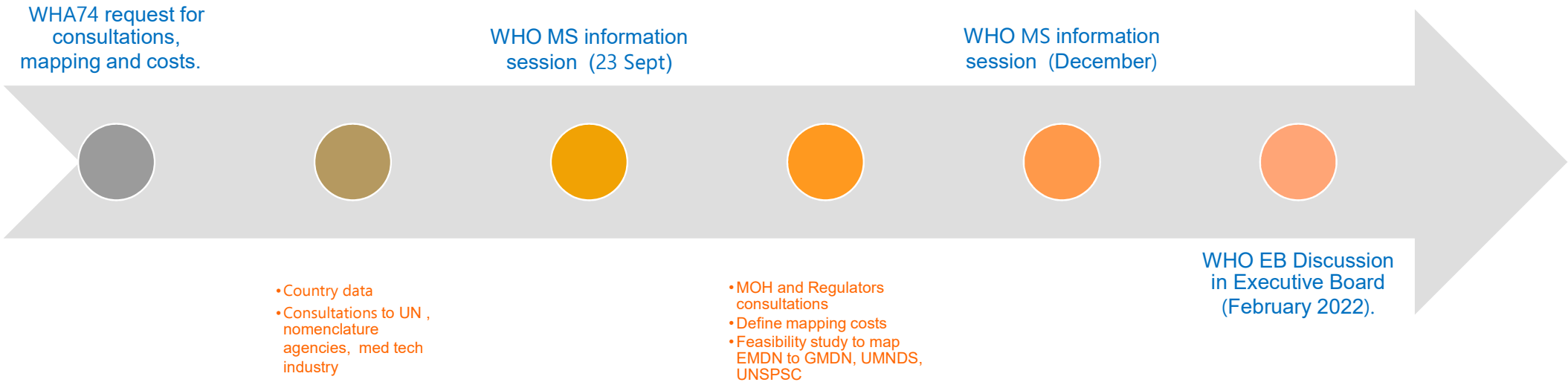
Findings up to 13 sept and presented in IMDRF	EMDN	GMDN	UMDNS	UNSPSC
Information freely available	yes	Yes, for all registered users	Yes, for non-commercial users	Yes, fully downloadable after registration
Processes used for: code development and maintenance,	Managed by the Medical Device Coordination 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

4 rounds of meetings with nomenclature agencies: 3 bilateral, 1 all together and 1 within IMDFR meeting.

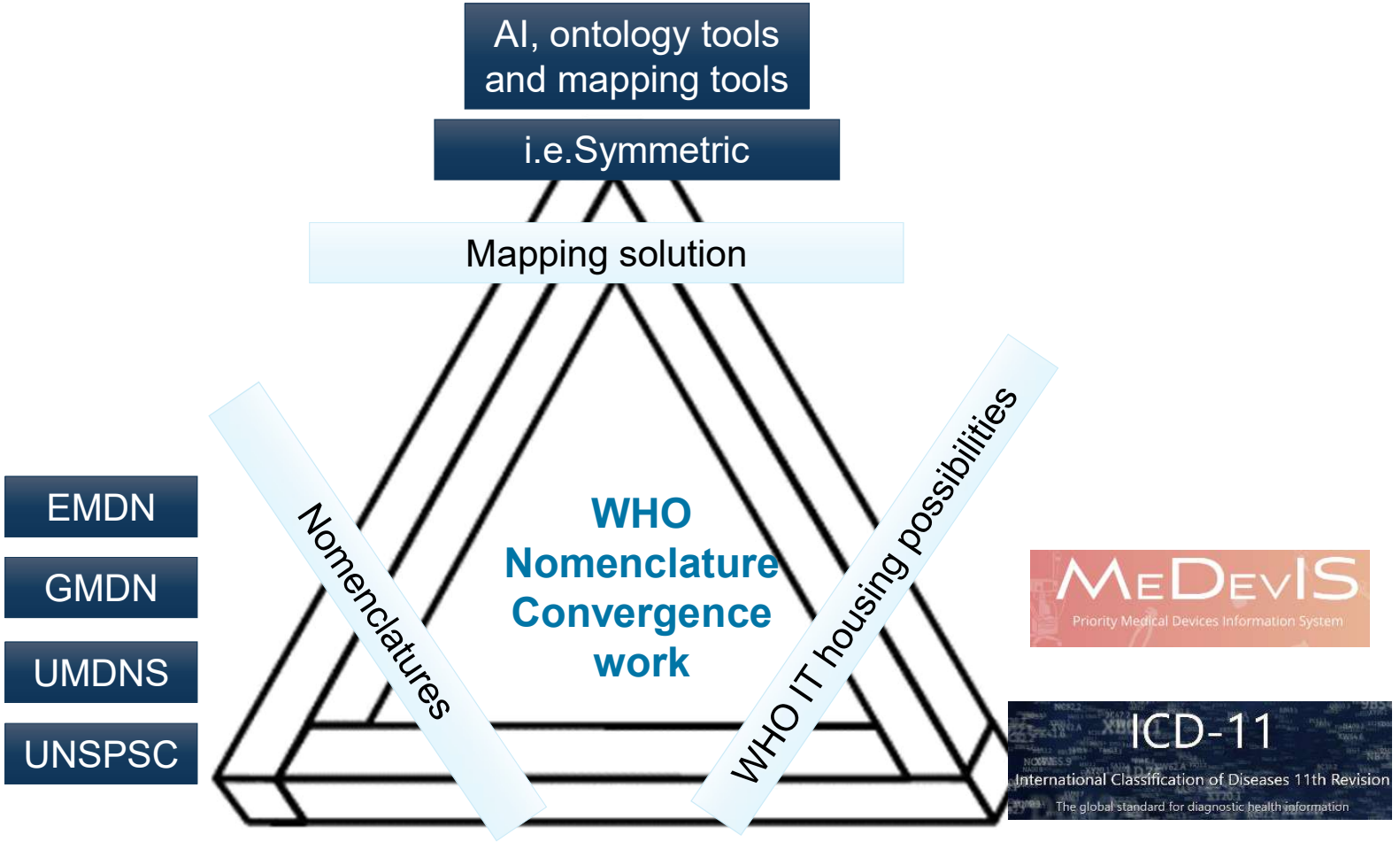



EMDN
GMDN
UMDNS
UNSPSC
UDI-DI Systems
FDA GUDID
EUDAMED
Other national databases
Mapping IT tools (e.g. AI)
WHO
ICD-11;
MeDevIS;
UHCC…
COUNTRIES
Manufacturers
Country nomenclature systems
Regulatory Authorities
MoH
UN Agencies & NGOs
Healthcare Providers
Selection
Procurement
Supply
Population/ users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

Road map towards the EB Feb 2022.



Towards a Global Public Good, mapping feasibility study



Medical devices purchased and supplied by UN agencies and NGOs , undergo QA, delivery to LMIC.

Ideally to have harmonized naming and coding to simplify transactions and traceability.
Interested in being part of the pilot?

Medical devices
Nomenclature standardization

WHO

20, Avenue Appia
1211 Geneva

Switzerland

Medical devices

Email: medicaldevices@who.int

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

World Health Organization

Four Nomenclature Agencies presentation

European Medical Device Nomenclature

SANTE B6 Medical Devices and HTA -
Nada Alkhayat

Background

The road towards the EMDN

2017

The two new regulations published in May

2018-2019

MDCG deliberation on choice of Nomenclature and Commission notice on choosing CND as basis for future EMDN

2019

Extra-ordinary revision of the CND

2020

COVID-19

A one year postponement of the MDR was announced in April

2021

Publication of IT and EN EMDN and DOA of MDR in May

2021

September UDI module go-live

European Commission

Key EMDN principles

- The EMDN is based on fundamental key principles jointly set out by the European Commission and EU regulators. These principles include but are not limited to:
- **(a) Regulators-led**: regulators play a key role in managing, validating, updating and advising on the nomenclature.
- **(b) Structured:** the nomenclature has transparent hierarchies by which terms and codes could be meaningfully clustered into groups and types.
- **(c) Predictable:** the structure and content remains sufficiently stable to allow various regulatory uses of the nomenclature, in a manner which still allows for the accommodation of technological innovation.

European Commission

EMDN key principles continued.

- **d) Transparent:** the policies for updates of the nomenclature terms and descriptions are sound and reflect the needs of regulators and the wider healthcare community.
- **(e) Inclusive:** the periodic reviews are open to all, based on real-world use and demonstrable needs.
- **(f) Available:** the terms, descriptions and codes are available, in full, to all users.
- **(g) Accessible:** no manufacturer or natural/legal person should be subject to fee or suffer from any discrimination, compared to other operators, in relation to the use of the nomenclature.
- **(h) International:** internationally recognised at the time of the date of application of the MDR/IVDR.

European Commission

European Medical Device Nomenclature

- Serves as terms associated to the UDI-DI
- Supports work related to market surveillance and vigilance.
- Used for sampling basis for Class II A & B as well as Class B & C.
- Used in the implant card*
- Used on certificates*
- Used in the clinical investigation application form
- Used in the SAE reporting form

Beyond the medical device regulation (non-exhaustive):

- Can be used by hospitals and clinics internally in their systems
- Empowers the patient in gaining more information regarding their device, and other devices falling within the same code.
- Can play a role in other healthcare related frameworks
- Data analysis and research

European Commission

Categories

- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- C - CARDIOCIRCULATORY SYSTEM DEVICES
- D - DISINFECTANTS, ANTISEPTICS, STERILISING
- F - DIALYSIS DEVICES
- G - GASTROINTESTINAL DEVICES
- H - SUTURE DEVICES
- J - ACTIVE-IMPLANTABLE DEVICES
- K - ENDOTHERAPY AND ELECTROSURGICAL DEVICES
- L - REUSABLE SURGICAL INSTRUMENTS
- M - DEVICES FOR GENERAL AND SPECIALIST DRESSINGS
- N - NERVOUS AND MEDULLARY SYSTEMS DEVICES
- P - IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES
- Q - DENTAL, OPHTHALMOLOGIC AND ENT DEVICES
- R - RESPIRATORY AND ANAESTHESIA DEVICES
- S - STERILISATION DEVICES (EXCLUDING CAT. D - Z)
- T - PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS
- U - DEVICES FOR UROGENITAL SYSTEM
- V - VARIOUS MEDICAL DEVICES
- W - IN VITRO DIAGNOSTIC MEDICAL DEVICES
- Y - DEVICES FOR PERSONS WITH DISABILITIES NOT INCLUDED IN OTHER CATEGORIES
- Z - MEDICAL EQUIPMENTS AND RELATED ACCESSORIES, SOFTWARE AND CONSUMABLES

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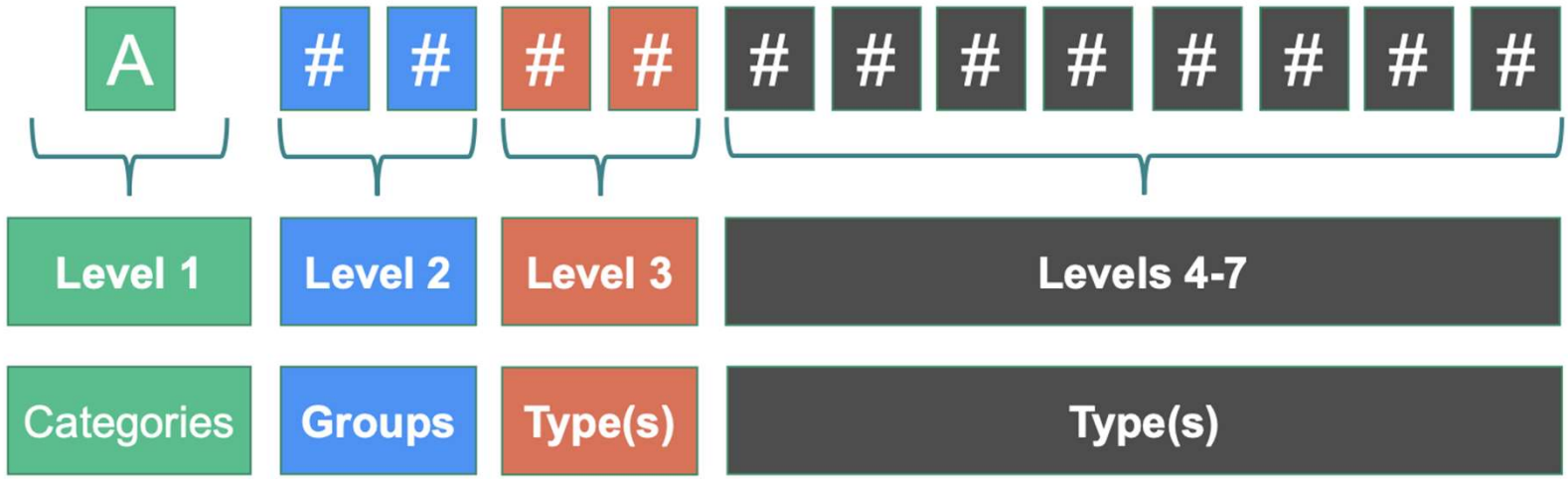
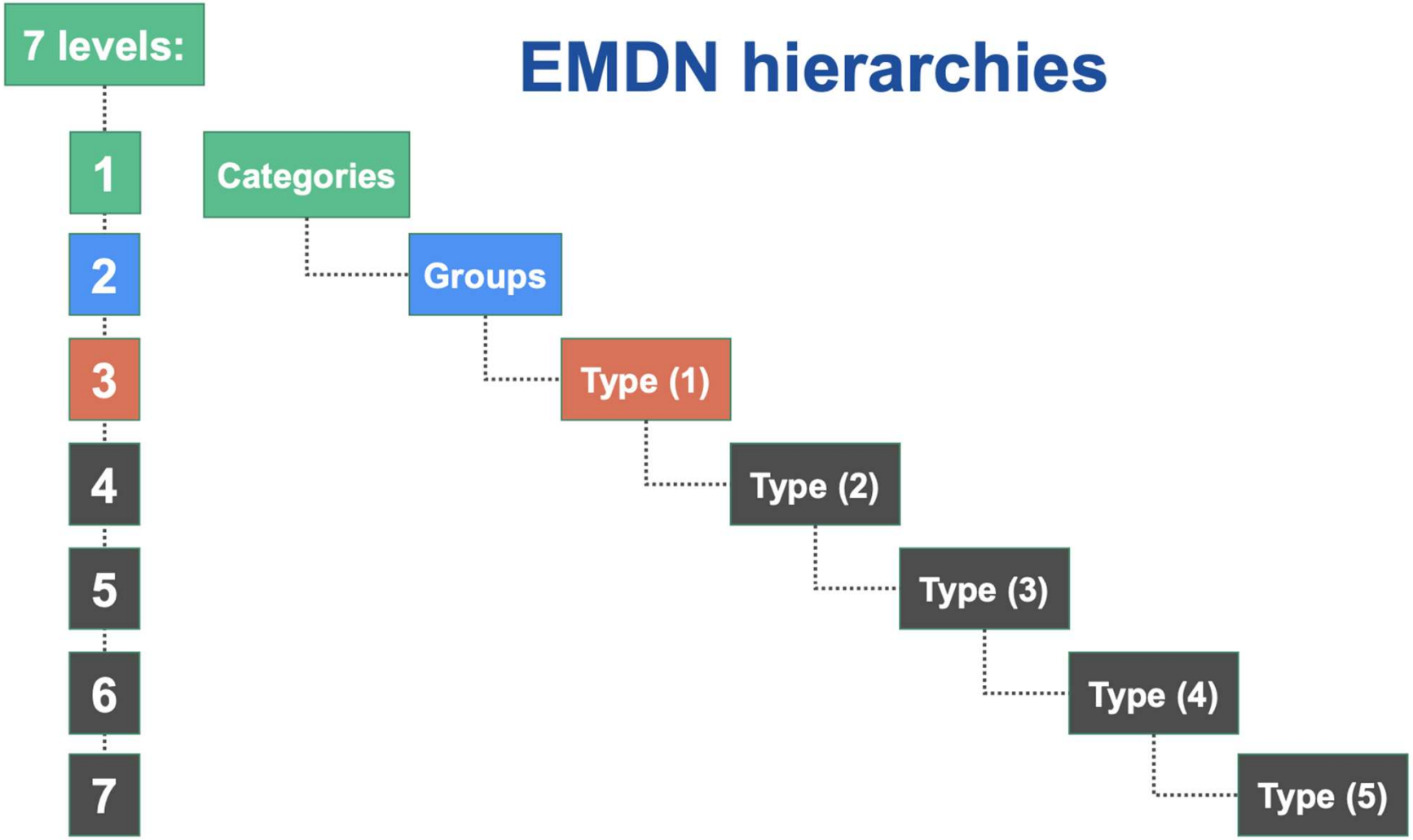
EMDN structure



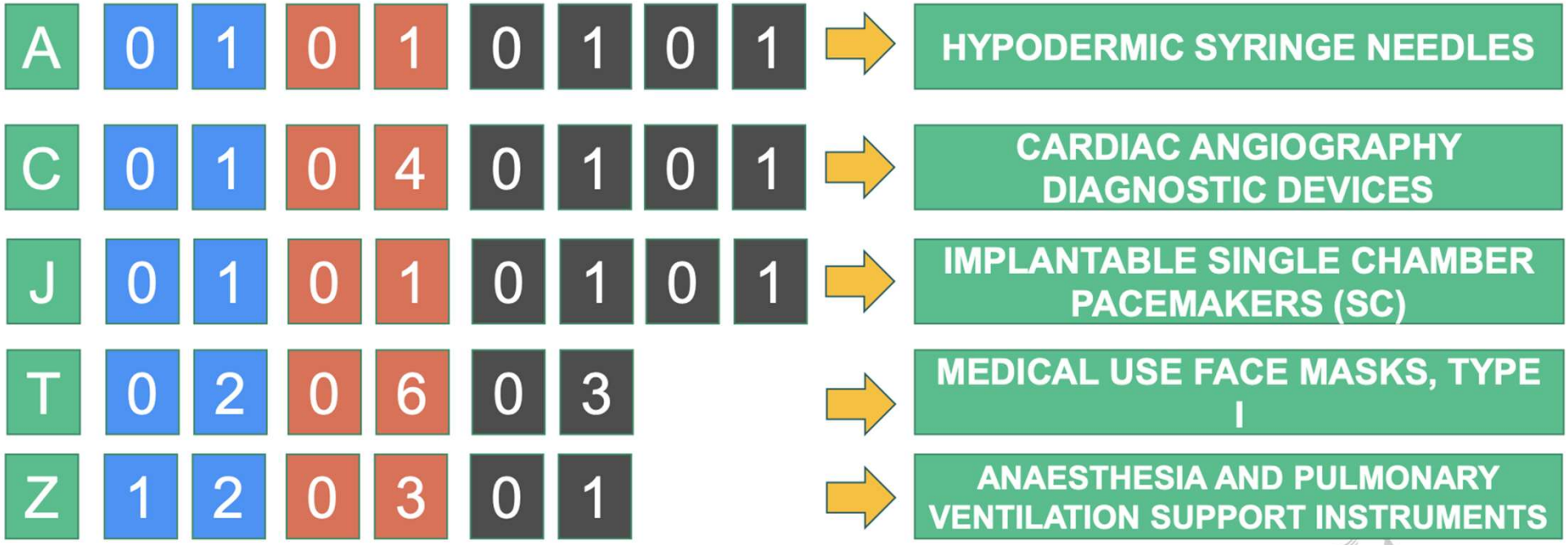
European Commission

EMDN hierarchies



EMDN structure in practice

- Alphanumeric structure → Device description



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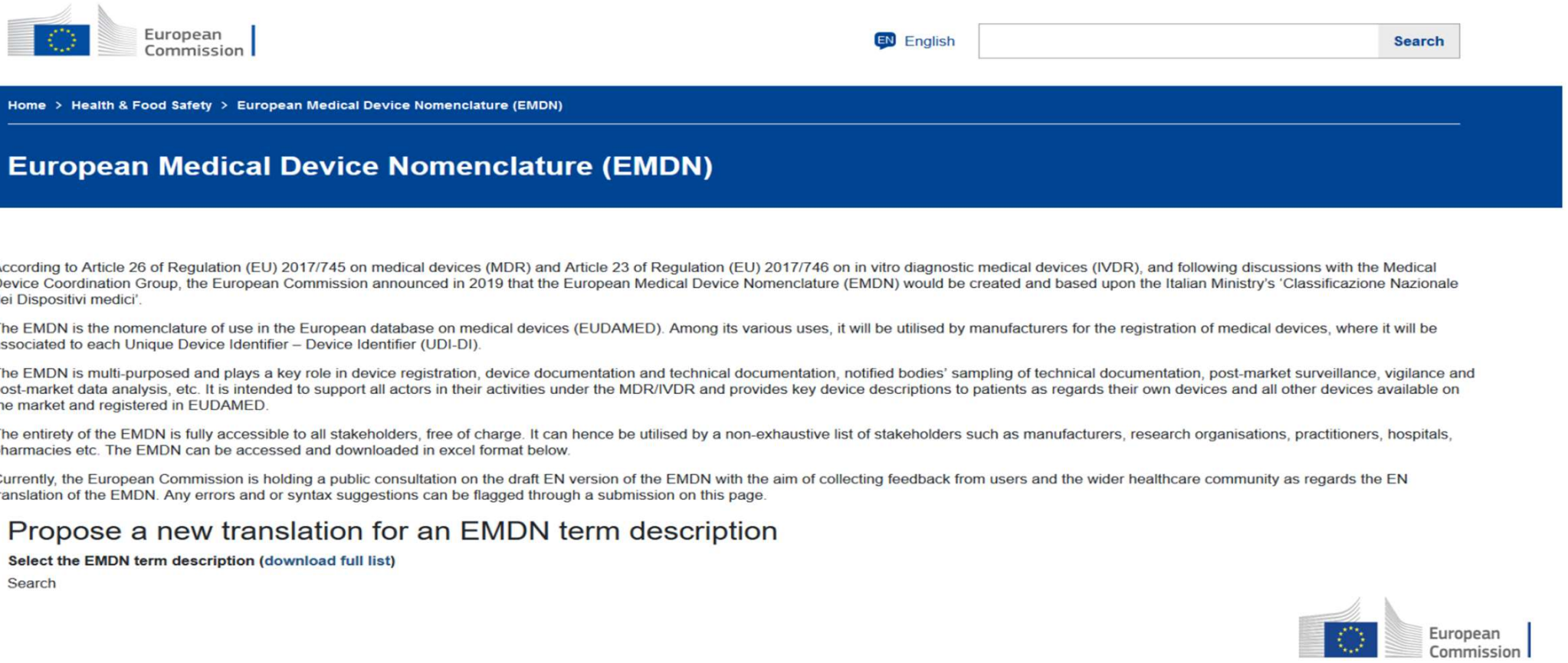
EMDN public access portal



The EMDN browser

Propose a new translation for an EMDN term description

Select the EMDN term description (download full list)

Search

- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
- B - HAEMATOLOGY AND HAEMOTRANSFUSION DEVICES
- C - CARDIOCIRCULATORY SYSTEM DEVICES
- D - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES
- F - DIALYSIS DEVICES
- G - GASTROINTESTINAL DEVICES
- H - SUTURE DEVICES
- J - ACTIVE-IMPLANTABLE DEVICES
- K - ENDOTHERAPY AND ELECTROSURGICAL DEVICES
- L - REUSABLE SURGICAL INSTRUMENTS
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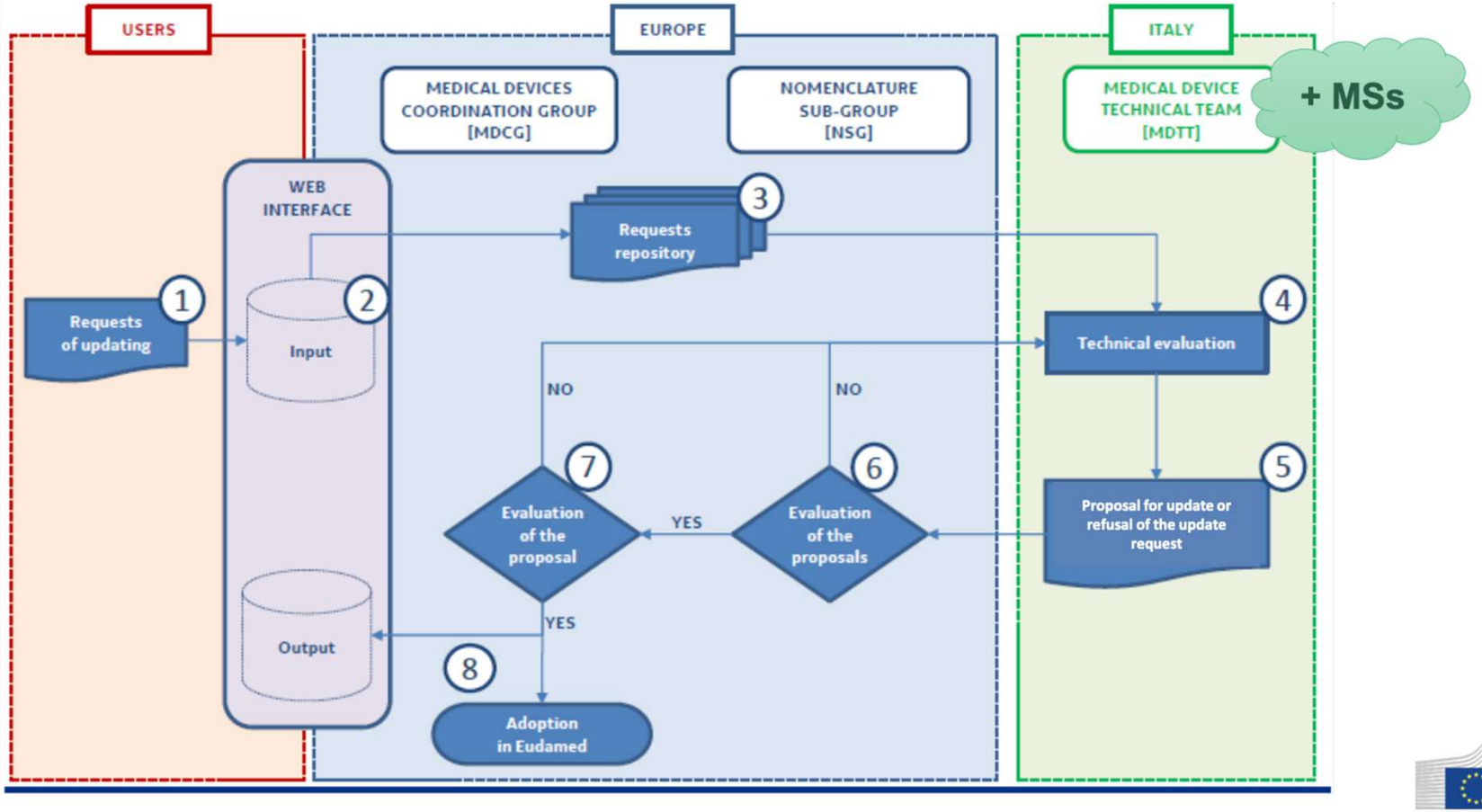
- R - RESPIRATORY AND ANAESTHESIA DEVICES
- S - STERILISATION DEVICES (EXCLUDING CAT. D - Z)
- T - PATIENT PROTECTIVE EQUIPMENT AND INCONTINENCE AIDS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)

- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
  - A01 - NEEDLES
  - A02 - SYRINGES
  - A03 - TUBULAR DEVICES
  - A04 - SOLUTION FILTERS
  - A05 - MECHANICAL INFUSION SYSTEMS, SINGLE-USE
  - A06 - DRAINAGE AND FLUID COLLECTION DEVICES
  - A07 - ADAPTERS, CONNECTORS, RAMPS, STOPCOCKS, CAPS
  - A08 - NUTRITION AND INFUSION BAGS AND CONTAINERS, SINGLE-USE
  - A09 - ORGAN CONTAINERS
  - A10 - ABDOMINAL OSTOMY DEVICES
  - A11 - SAMPLE COLLECTION SWABS
  - A12 - SAMPLE COLLECTION SPATULAS
  - A99 - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION - OTHER

- A - DEVICES FOR ADMINISTRATION, WITHDRAWAL AND COLLECTION
  - A01 - NEEDLES
  - A02 - SYRINGES
    - A0201 - SINGLE-USE SYRINGES
    - A0202 - REUSABLE SYRINGES
      - A020201 - REUSABLE INFUSION SYRINGES
      - A020202 - REUSABLE IRRIGATION SYRINGES
      - A020203 - CARTRIDGE SYRINGES
      - A020299 - REUSABLE SYRINGES - OTHER

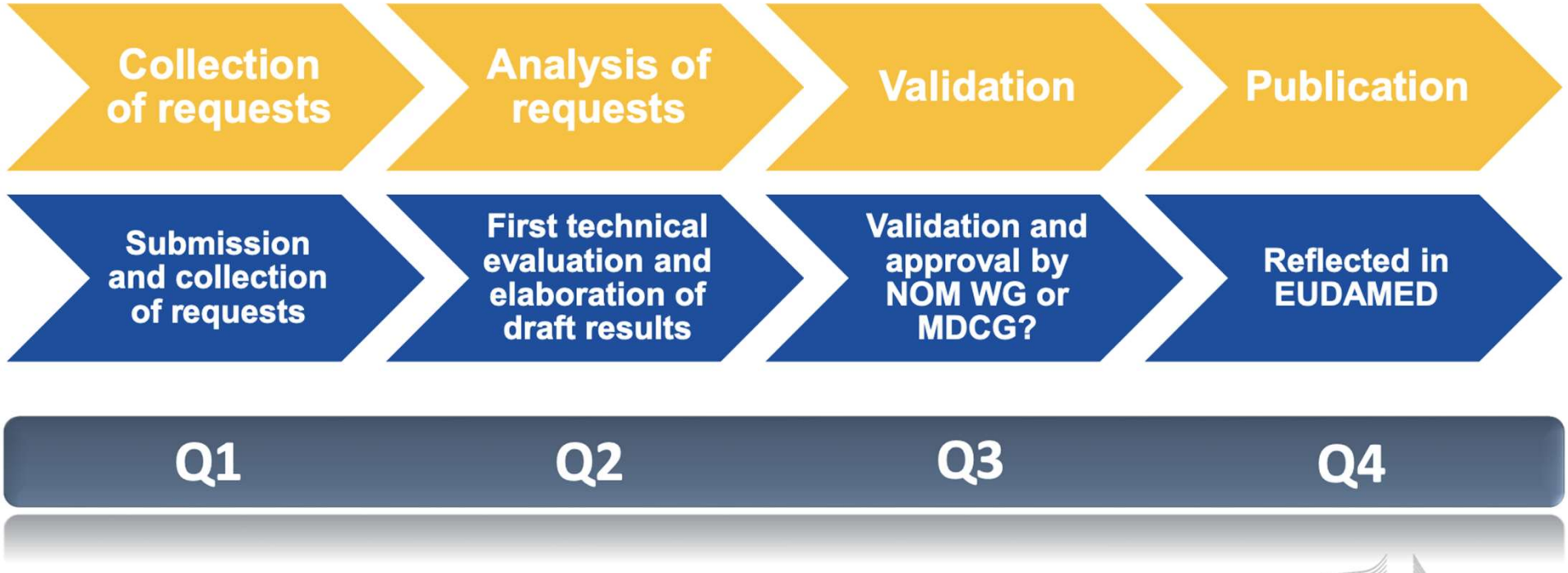
European Commission

Open update procedures for EMDN accessible to all



European Commission

Annual EMDN updates procedures



European Commission

Ad-hoc EMDN updates procedures

Procedures for the updates of the European Medical Device Nomenclature

European Commission

Thank you

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Slide xx: element concerned, source: e.g. Fotolia.com; Slide xx: element concerned, source: e.g. iStock.com

European Commission

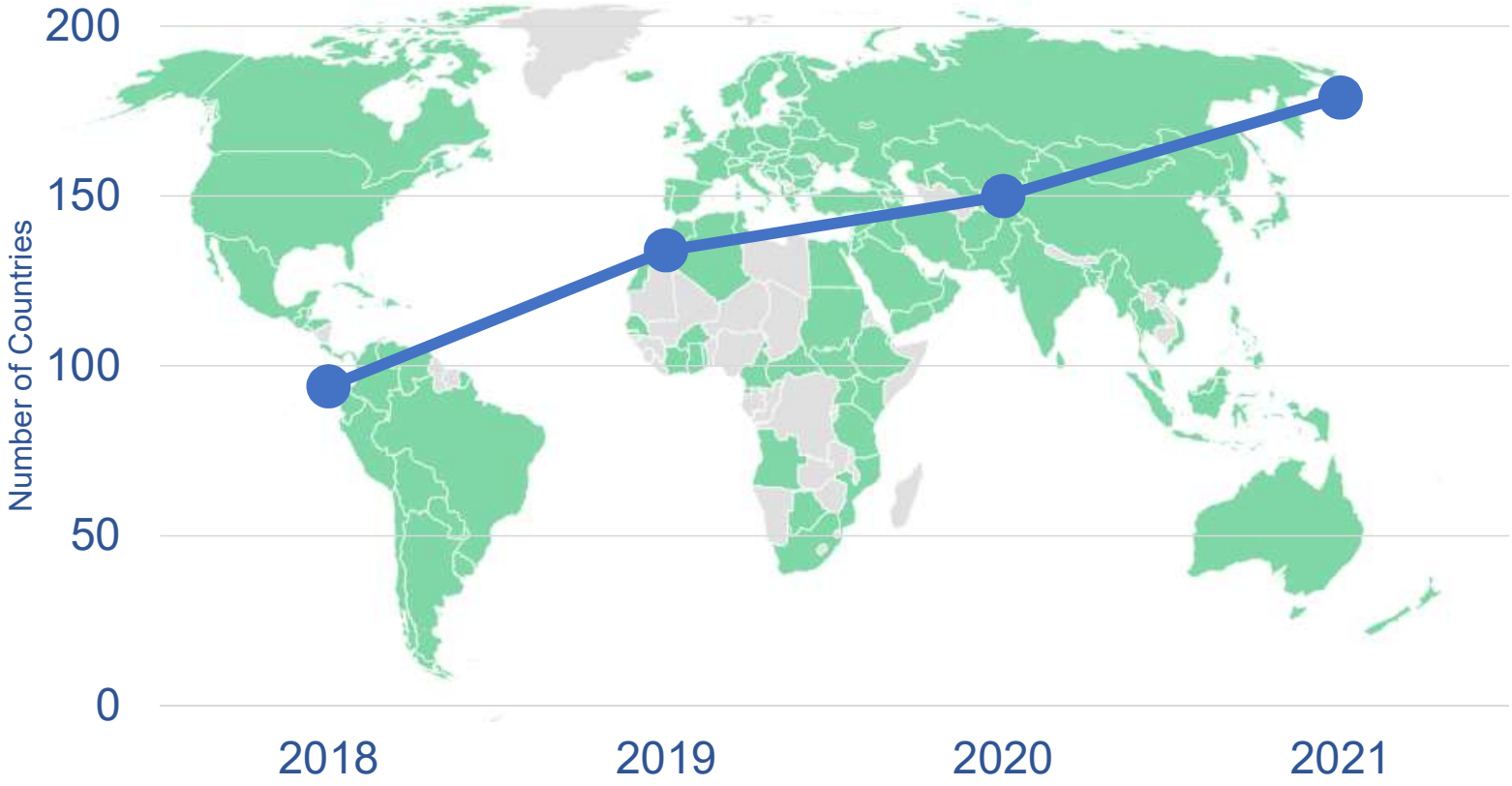
Meeting the needs of WHO Member States

Mark Wasmuth – CEO, GMDN Agency

GMDN has grown consistently over the last year:

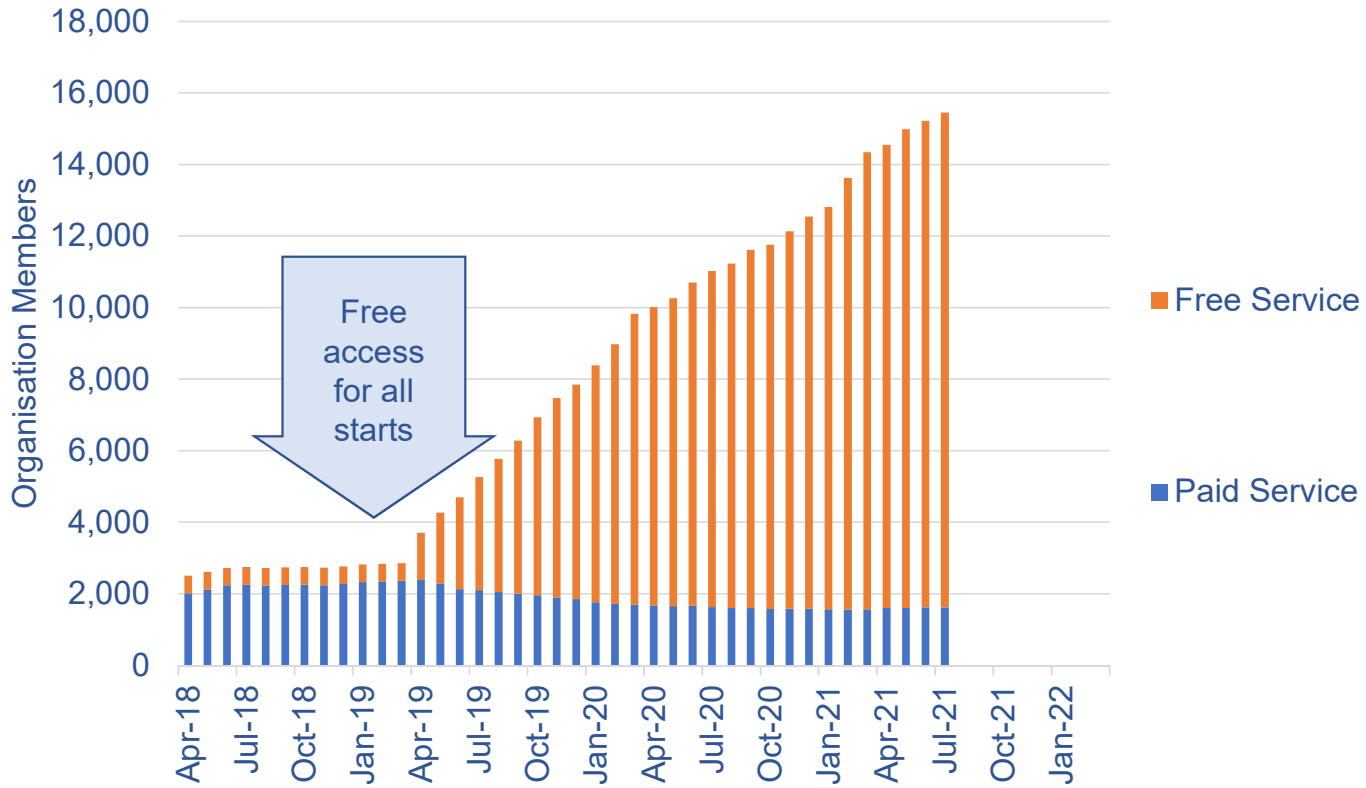
- **No barriers to access**
- **Global demand for GMDN**
- **Free membership continues to drive growth**

Global use of GMDN

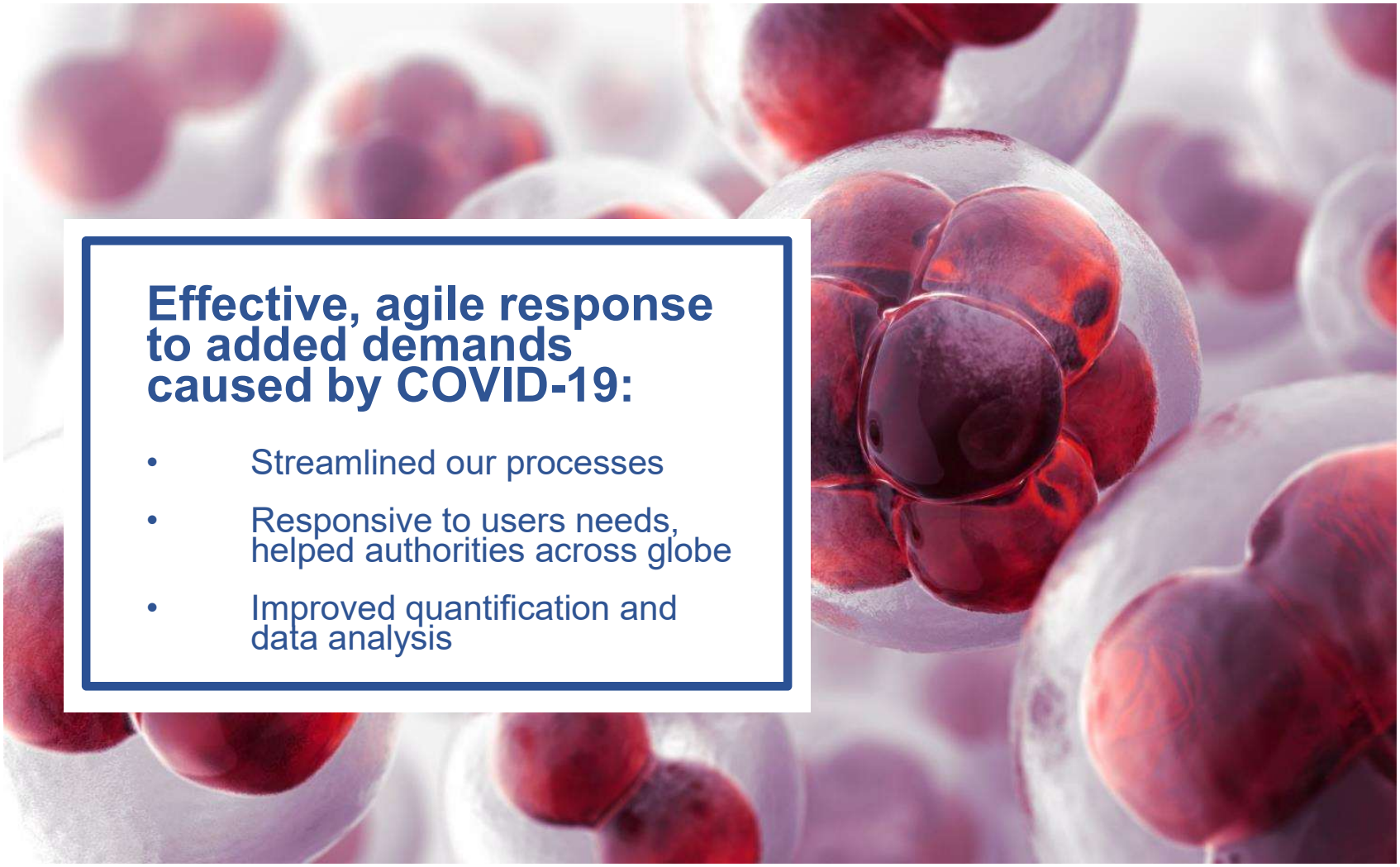


GMDN membership by country

Free GMDN access for all



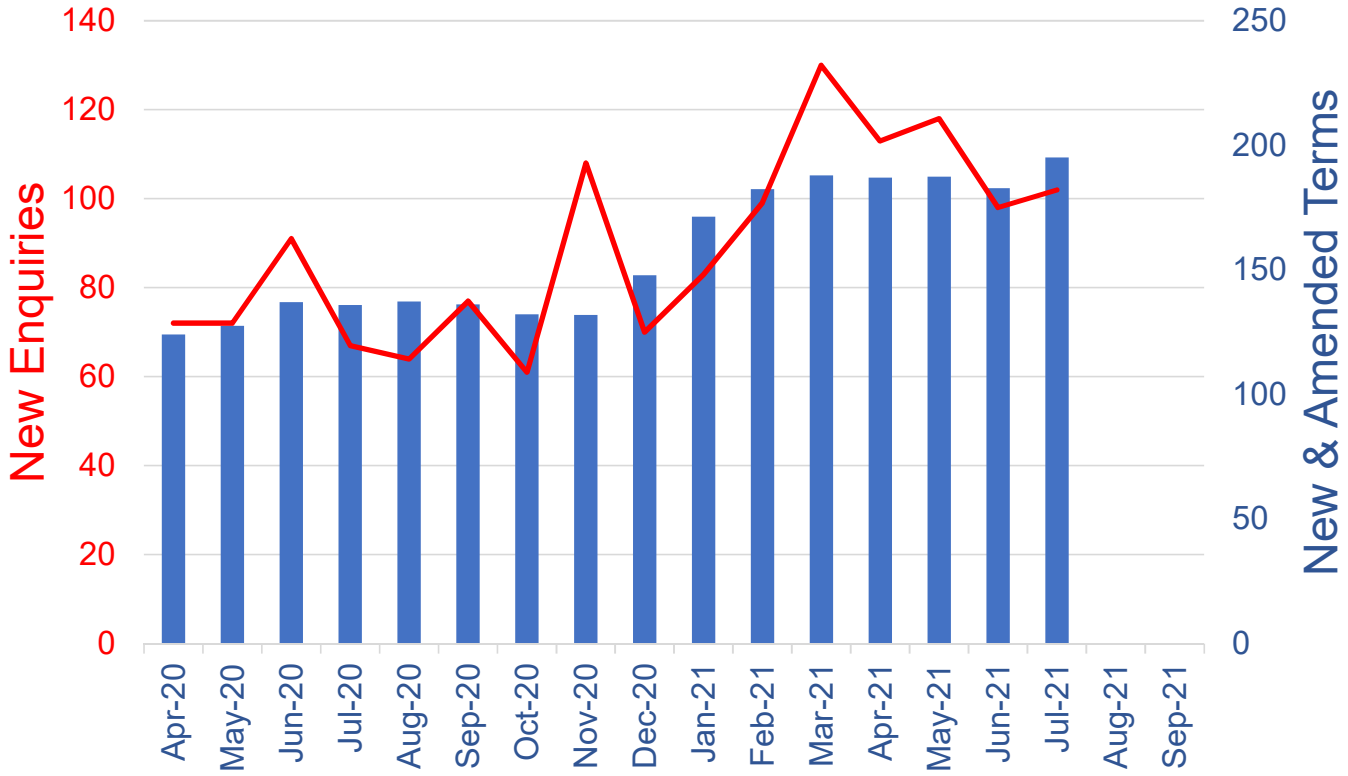
GMDN membership grown since ‘free access for all’ introduced



Effective, agile response to added demands caused by COVID-19:

- Streamlined our processes
- Responsive to users needs, helped authorities across globe
- Improved quantification and data analysis

Active through the Covid-19 pandemic



"Our sector files one new European patent every 50 minutes" – MedTech Europe

Most active areas

Most active in the last year:

Covid-19 IVDs

Respirators, Masks and PPE

Ventilators, Oxygenators

New issues:

Personalised MDs - Custom / Patient-matched / Adaptive

AI, SAMD, etc

Launching our 2021-2025 Strategy

To be launched later this year, the strategy will outline how we intend to:

Be more transparent (operational and strategic)	**Increase dialogue and engagement with stakeholders**	**Be ambitious for future 'how can we enhance our value to stakeholders'**	**Promote greater global harmonisation**

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www.gmdnagency.org

Better data, better decisions

ECRI

The Most Trusted Voice in Healthcare

UMDNS

Universal Medical Device Nomenclature System

51 Years of Safe and Effective Healthcare

SERVING TENS OF THOUSANDS OF MEMBERS GLOBALLY

Hospitals, Health Systems, Government Agencies, Payers, Insurers

INDEPENDENT TESTING & EVALUATION LAB

The only independent medical device testing and evaluation lab in North America and Asia Pacific

PATIENT SAFETY ORGANIZATION

Listed by the U.S. Department of Health & Human Services and now one of the largest in the U.S

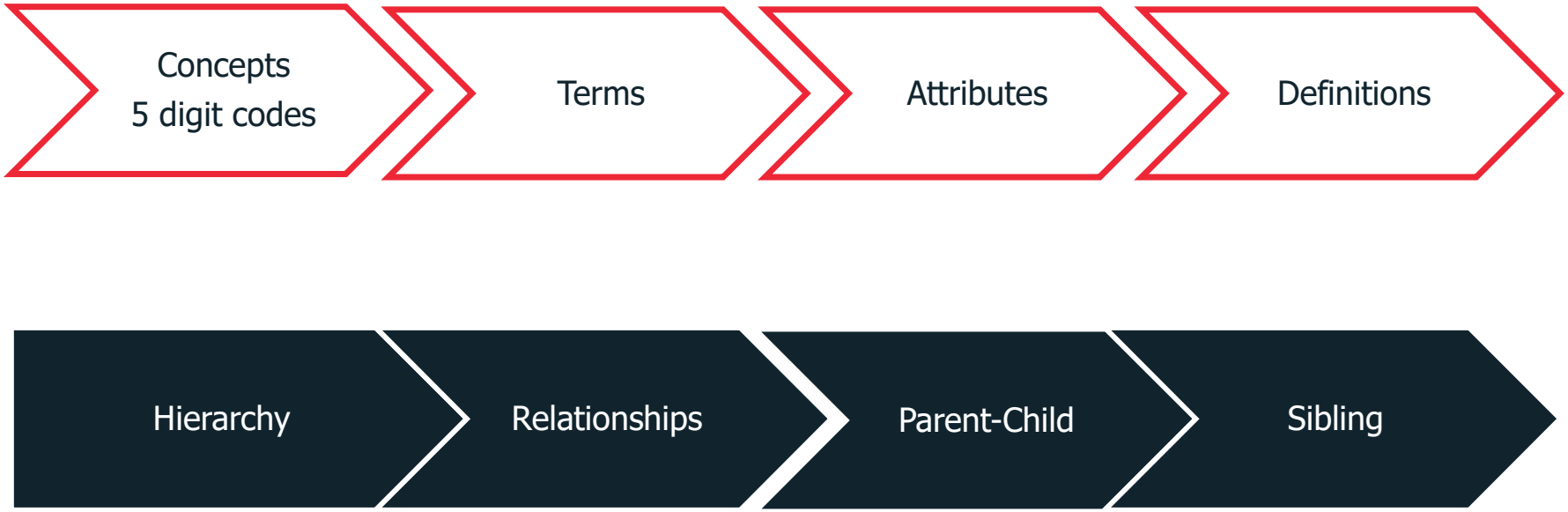
EVIDENCE-BASED PRACTICE CENTER

Designated as an Evidence-Based Practice Center by the U.S. Agency for Healthcare Research & Quality

"The country's most respected independent laboratory for testing medical products"

The New York Times

UMDNS Components



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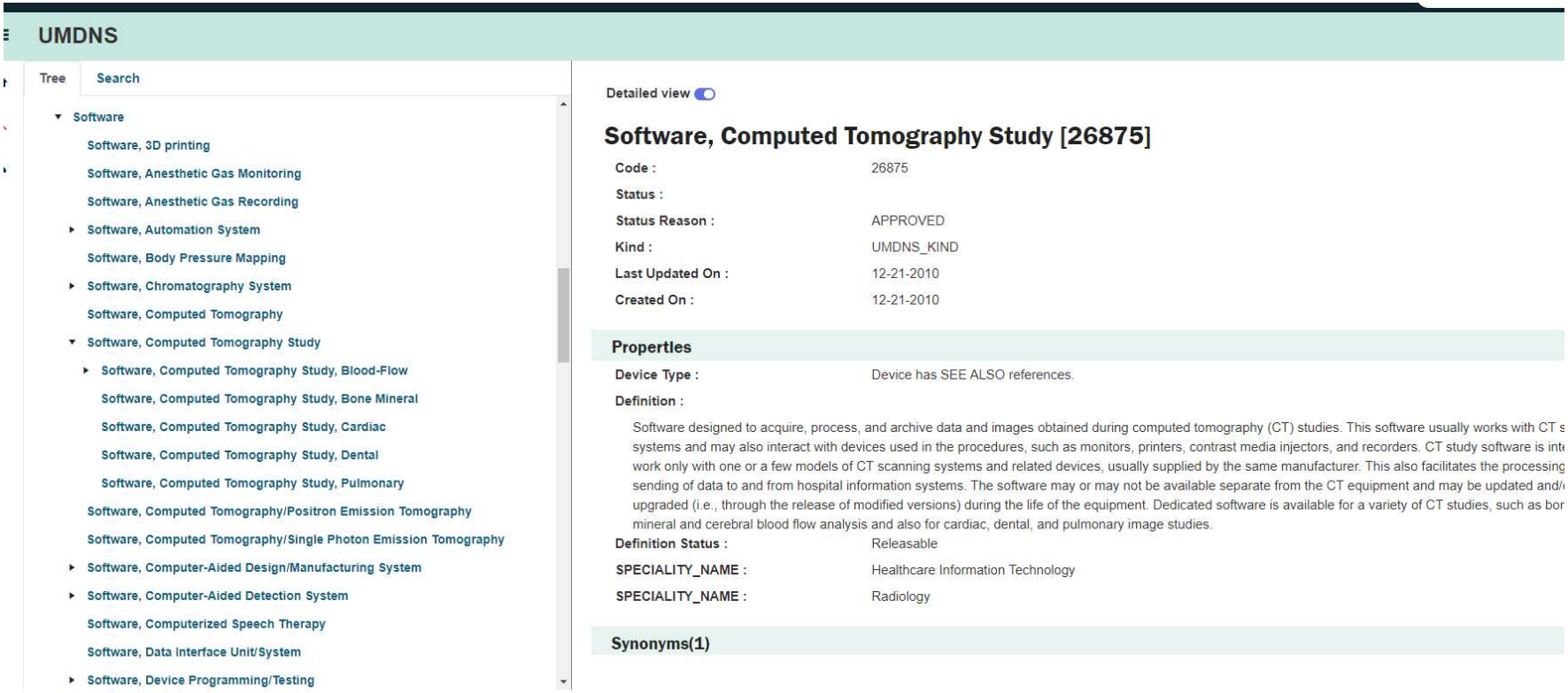
UMDNS Licensing

UMDNS LOOKUP TOOL

- Currently for internal ECRI use only: https://umdns.ecri.org



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Types of Relationships Between Terms

- Entry terms point to preferred terms
  - One-to-many (Use More Specific Term, SEE)
    - Example: Breast cancer gene

Breast Cancer Gene Mutation Detection Reagents
Use More Specific Term See:
IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA1 [24-319]
IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA2 [24-321]

Early-onset Breast Cancer Gene Mutation Detection Reagents
Use More Specific Term See:
IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA1 [24-319]
IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA2 [24-321]

Familial Breast Cancer Gene Mutation Detection Reagents
Use More Specific Term See:
IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA1 [24-319]
IVD Test Reagent/Kits, Molecular Assay, Gene Anomaly, Mutation, BRCA2 [24-321]

Attributes

- Way of assigning general properties to UMDNS concepts
  - Implantable
  - Reusable/disposable
  - Capital equipment
  - Clinical specialty
  - Trackable device
- These provide another method of classifying and sorting concepts
- Properties apply to multiple concepts
- Concepts can have multiple properties applied to them

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Recent strategic initiatives

- Expansion of in vitro diagnostics category to include genetic tests (including multigene panels for cancer genomics, proteomic, epigenetic, mitochondrial, whole exome, whole genome, whole transcriptome tests)
- Expansion of UMDNS scope to meet stakeholder needs:
  - Devices used in laboratory and animal research
  - Devices used in telehealth (e.g. mobile medical apps, wearables, home monitoring devices)
  - Expansion of non-traditional device coverage to accommodate equipment planning in healthcare facilities

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What makes UMDNS unique?

- Used world-wide
- UMDNS has been continuously maintained for more than 40 years
- UMDNS is a constituent of the Unified Medical Language System. This provides linkages with more than 100 other medical controlled vocabularies (SNOMED CT, ICD-9, ICD-10, LOINC, MeSH, HCPCS, etc.)
- Continuous quality improvement and R&D
- Emerging technologies – barometer of technology evolution world-wide

Introduction and Overview UNSPSC®

United Nations Standard Products and Services Code®

Hussam El-Leithy, Global Standards Director, GS1 US

23. September 2021

Agenda

- What is UNSPSC?
- UNSPSC Design
- Access to the UNSPSC Codeset

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What is the UNSPSC?

- United Nations Standard Products and Services Code® (UNSPSC®)
  - A free open standard
  - A taxonomy of materials, products, and services
  - A practical business tool

- Owned by **The United Nations Development Program (UNDP)**

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UNSPSC: Timeline & Provenance

- Started by Dun & Bradstreet as the Standard Product and Services Code (SPSC)
  - First generation spend analytics derived from DUNS numbers as a (“from whom”) entity identifier.
- 1998: Merged with UNCCS
  - Owned and operated by The United Nations Development Program (UNDP)
  - Became the United Nations Standards and Products Code (UNSPSC)
- 2003: UNDP contracted GS1 US to operate UNSPSC. The codeset development and maintenance must be self funded.
- 2019: Addition of over 65,000 ICD-10 diagnostic codes to the codeset
- 2021: UNSPSC Codeset covers all materials, goods, and services
  - About 160,000 Codeset entries
  - Over 11,000 downloads per year from every continent

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UNSPSC Design

- Hierarchical 4-level tree structure:
  - Segment, Family, Class and Commodity
    - Note: “Commodity” is not defined as bulk materials, e.g. futures contracts on soybeans, but in the broader sense as any article of commerce including capital equipment, high-value products, and professional services.
- Category titles are unambiguous and mutually exclusive
- Products appear in only one category; categories each have only have one parent
- Products are grouped according to dominate usage in world market

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Example of UNSPSC

"root" = All Products and Services (implied)

- **Segment** 44 Office equipment and accessories and supplies
  - **Family** 10 Office machines and their supplies and accessories
    - **Class** 15 Duplicating machines
      - **Commodity** 01 Photocopiers
    - Class 31 Printer and facsimile and photocopier supplies
      - Commodity 03 Printer or facsimile toner

44101501 **Photocopiers**

44103103 **Toner**

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UNSPSC Components

- UNSPSC Code: 8 digits, e.g. 44103103
- Title: natural language text up to 400 characters long, e.g. “Toner”
- Definition: free form text gives concise explanation
- Key/Unique ID: sequential, arbitrary code used to semi-automate version updates (optional to use)
- Synonyms: where applicable, these will provide other terms for the Commodity

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How to access to UNSPSC

- The UNSPSC codes can be used royalty free.
- UNSPSC codeset can searched free of charge on the UNSPSC web page.
- A PDF version with all information can be downloaded free of charge.
- A tabular version can be obtained for a fee.
- Changes to the codeset can only be requested by subscribers. Subscribers need to pay a fee.
- The codeset can be used free of charge in software product and online services.

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World Health Organization

WHO IT data platforms: classification system and clearinghouse

International Classification of Diseases 11th Revision Medical devices perspective

Dr Robert Jakob, WHO

Unit Lead

Classifications and Terminologies

International Classification of Diseases (ICD)

- Legally mandated health data standard* – in effect from January 2022 (mortality and morbidity)
- Conceptual framework independent of language and culture
- Integration of terminology and classification
- End-to-end digital solution (API, tools, online and offline)
- Up-to-date scientific knowledge
- Comparable statistics – semantic interoperability - for 150 years
- Free: Creative Commons Attribution-NoDerivs 3.0 IGO license (CC BY-ND 3.0 IGO)

*WHO Nomenclature Regulations 1967, WHO constitution, World Health Assembly (WHA 72 2019)

WHO core classifications

ICD

International Statistical Classification of Diseases
and related health problems – diagnoses, injuries, findings, primary care

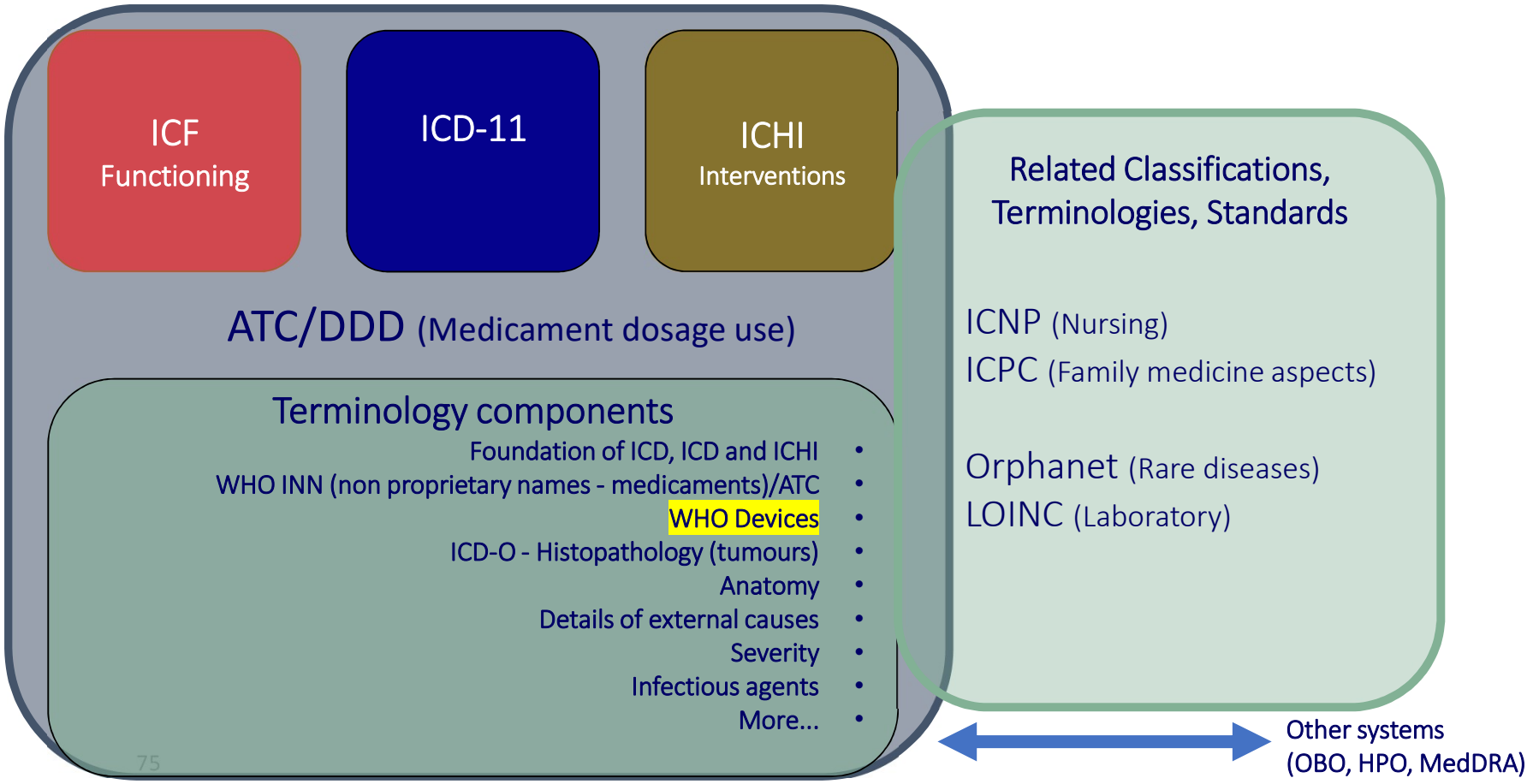
ICF

International Classification of Functioning, Disability and Health:
Describes functional health status and social impact (bio-psycho-social model).

ICHI

Interventions for treatment, prevention and diagnostics:
Medical, nursing, rehabilitation, laboratory, imaging, ultrasound, public health...

The WHO Family of International Classifications and Terminologies (WHO-FIC)



WHO-FIC
Information and Interoperability

Health Records
Surveillance
Death certificates

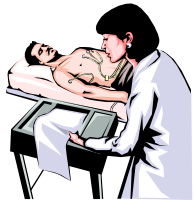
ICD
ICF
ICHI

Diseases, health related conditions

Functioning, Disability

Health interventions (individual and public health)

Population Health
- Births
- Deaths
- Diseases
- Disability
- Risk factors
- SDG

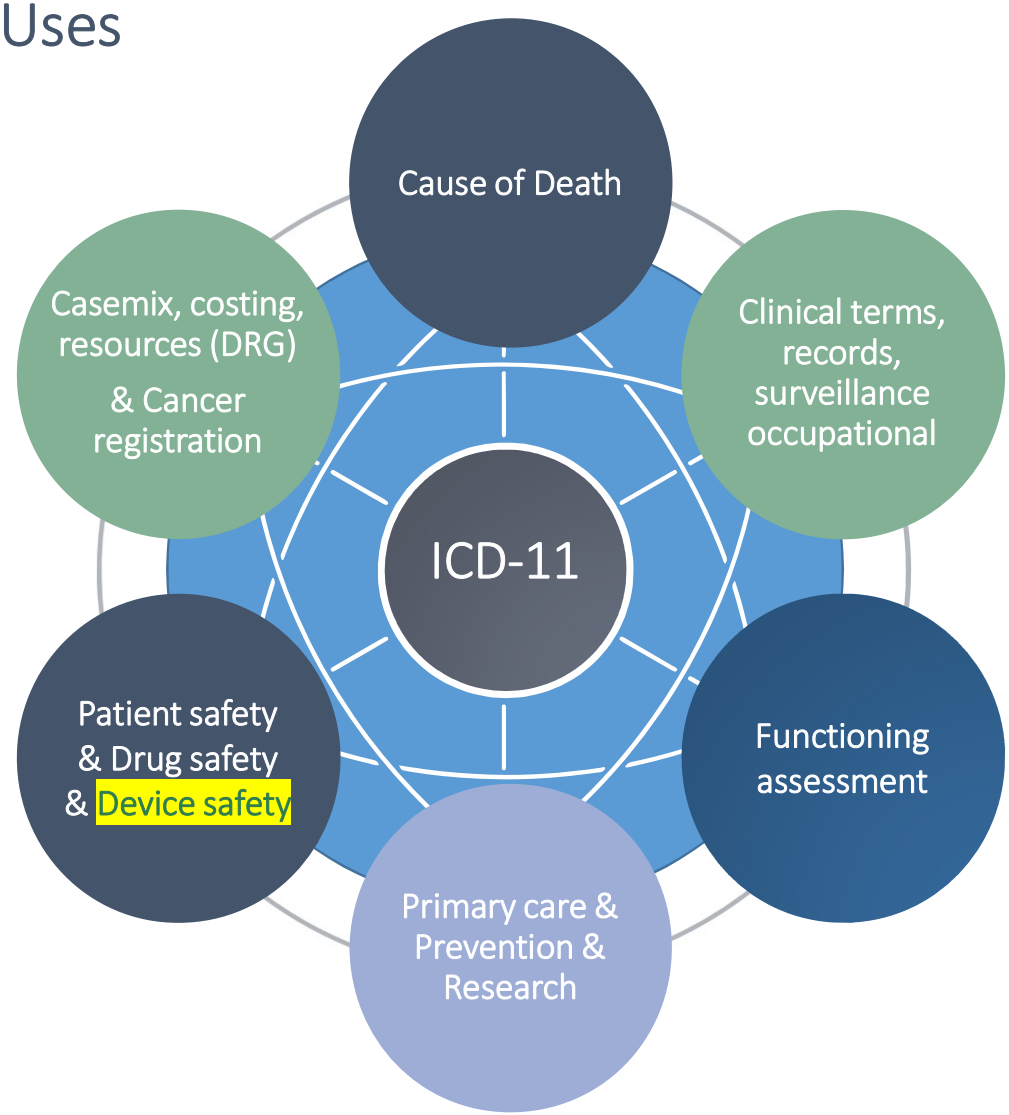


Clinical
- Decision Support
- Integration of care
- Outcome
- Guidelines

Administration
- Scheduling
- Resources
- Billing

Reporting
- Cost
- Needs
- Outcome
- Epidemiology
- Research

Designed for Multiple Uses



ICD-11 – more than diagnoses

Traditional Classes and Terminology

- Diagnoses
- Injuries
- Signs
- Symptoms
- Findings

- Reasons for encounter or health status
- External causes of illness & death

- Traditional medicine conditions
- Functioning assessment – WHO-DAS2

Extension codes - Terminology

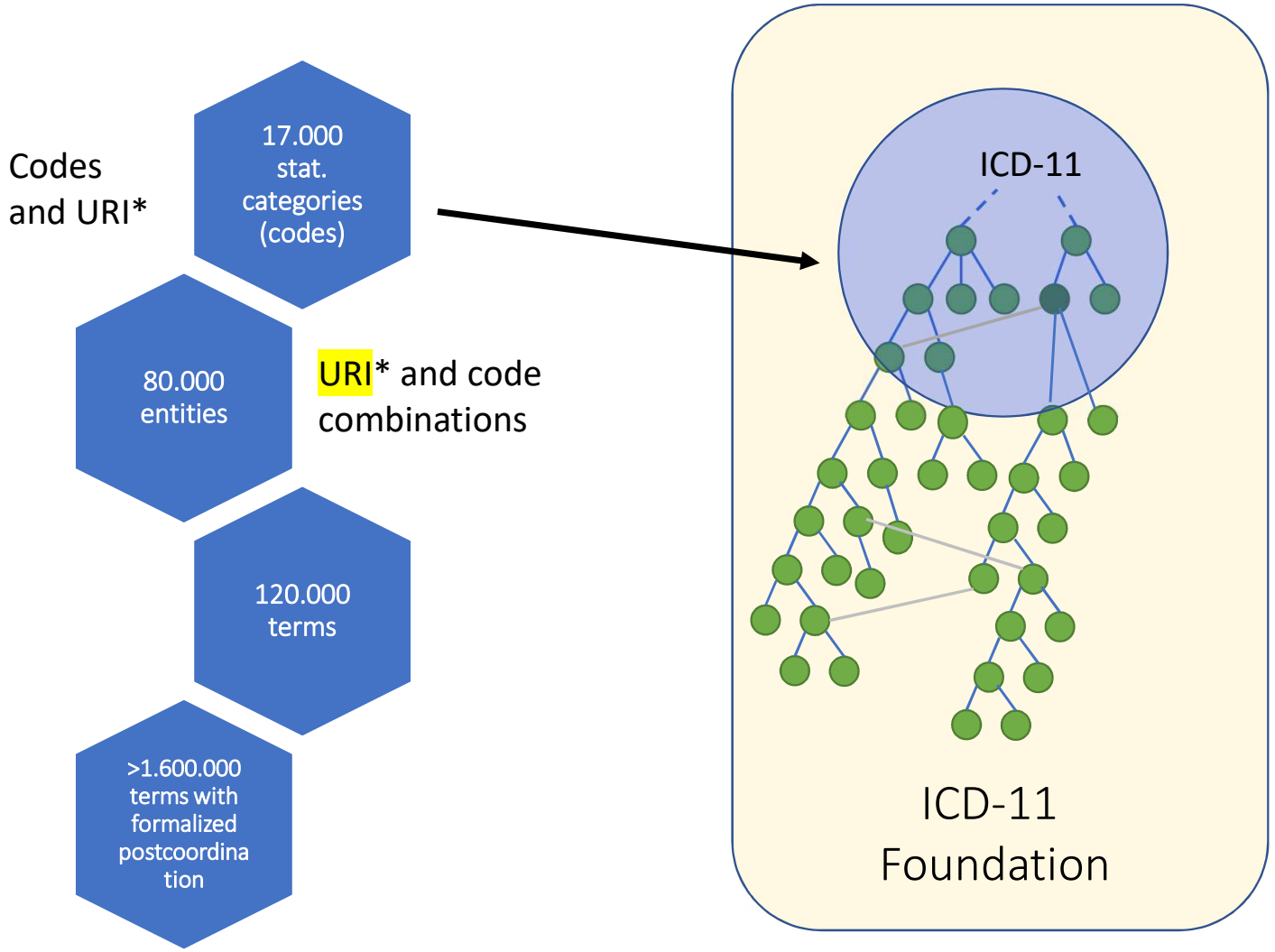
- Anatomy
- Laterality
- Infectious agents and AMR

- Histopathology (ICD-O)
- Chemicals and Medicaments (INN)
- Devices

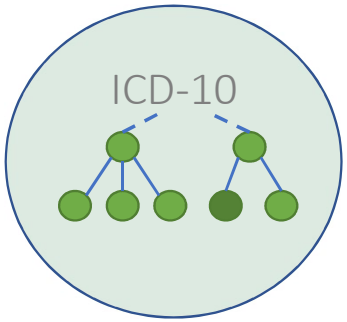
- Mechanisms of harm (Safety)
- Activities
- Places
- Objects

e.g. devices: EMDN classification embedded

ICD-11 – Clinical system



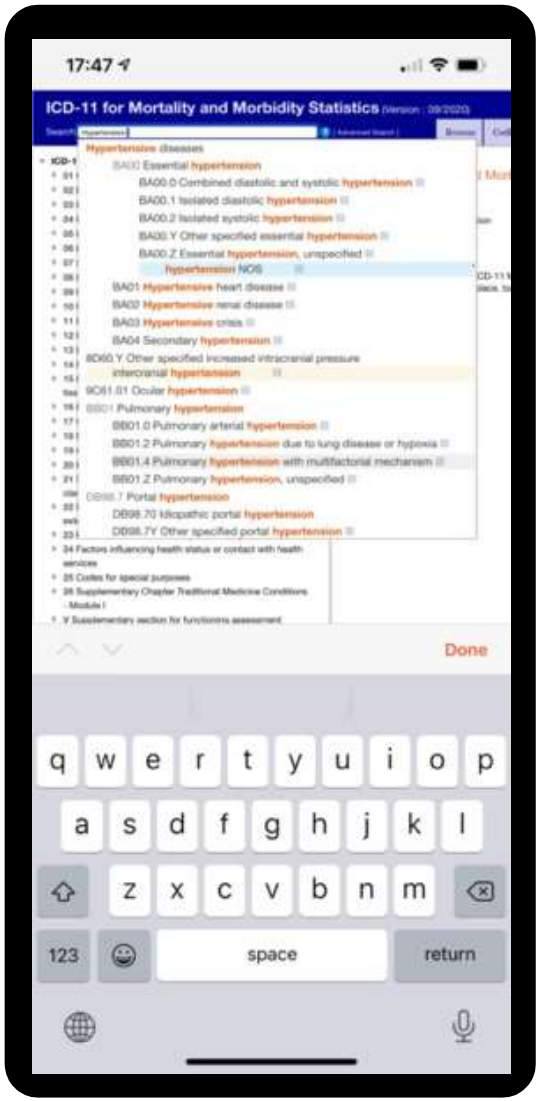
*URI: Uniform Resource Identifier - IT



14000 categories
Separate text index
Separate rule base
Need terminology link
Outdated content

Statistical system
used in
clinical setting

ICD-11 Digital



Tooling for use by humans

Modern ontology

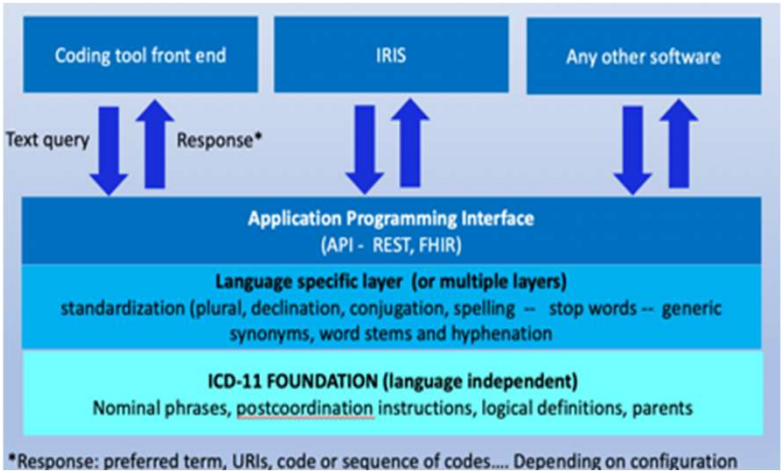
Fully digital

Portable: offline & online

Tools for use by software

Application Programming Interface (API)

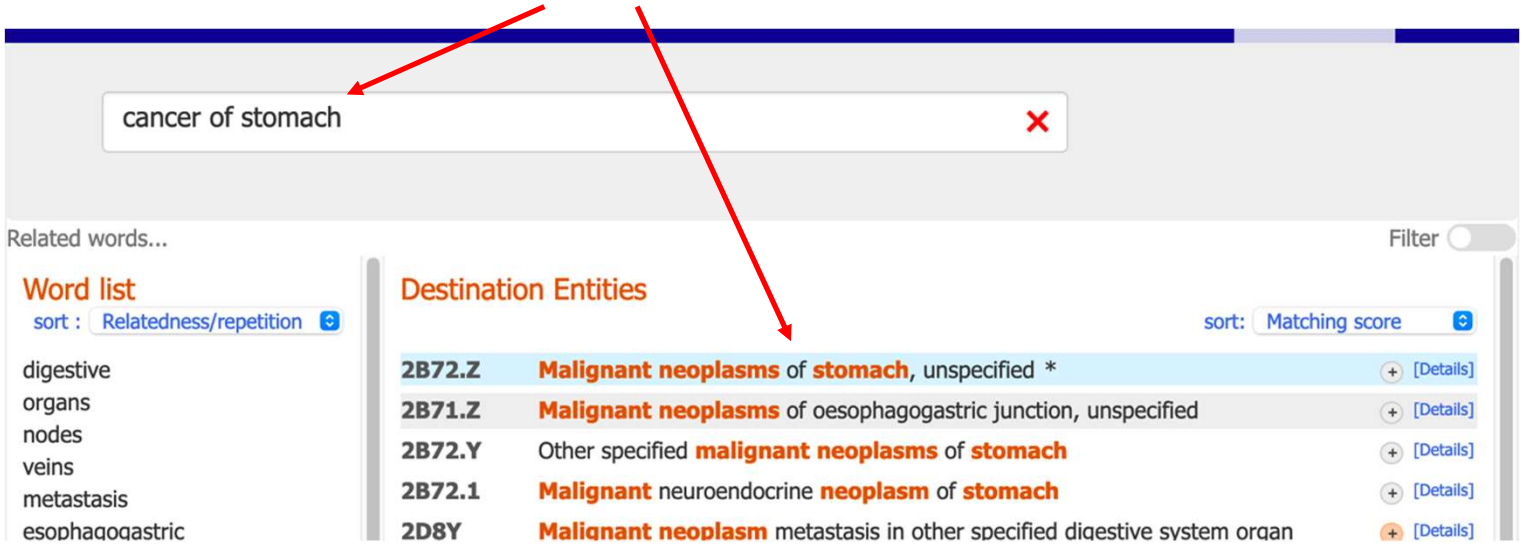
Software applications on all devices and OS



Easy to use

Type a diagnostic statement into the Coding Tool

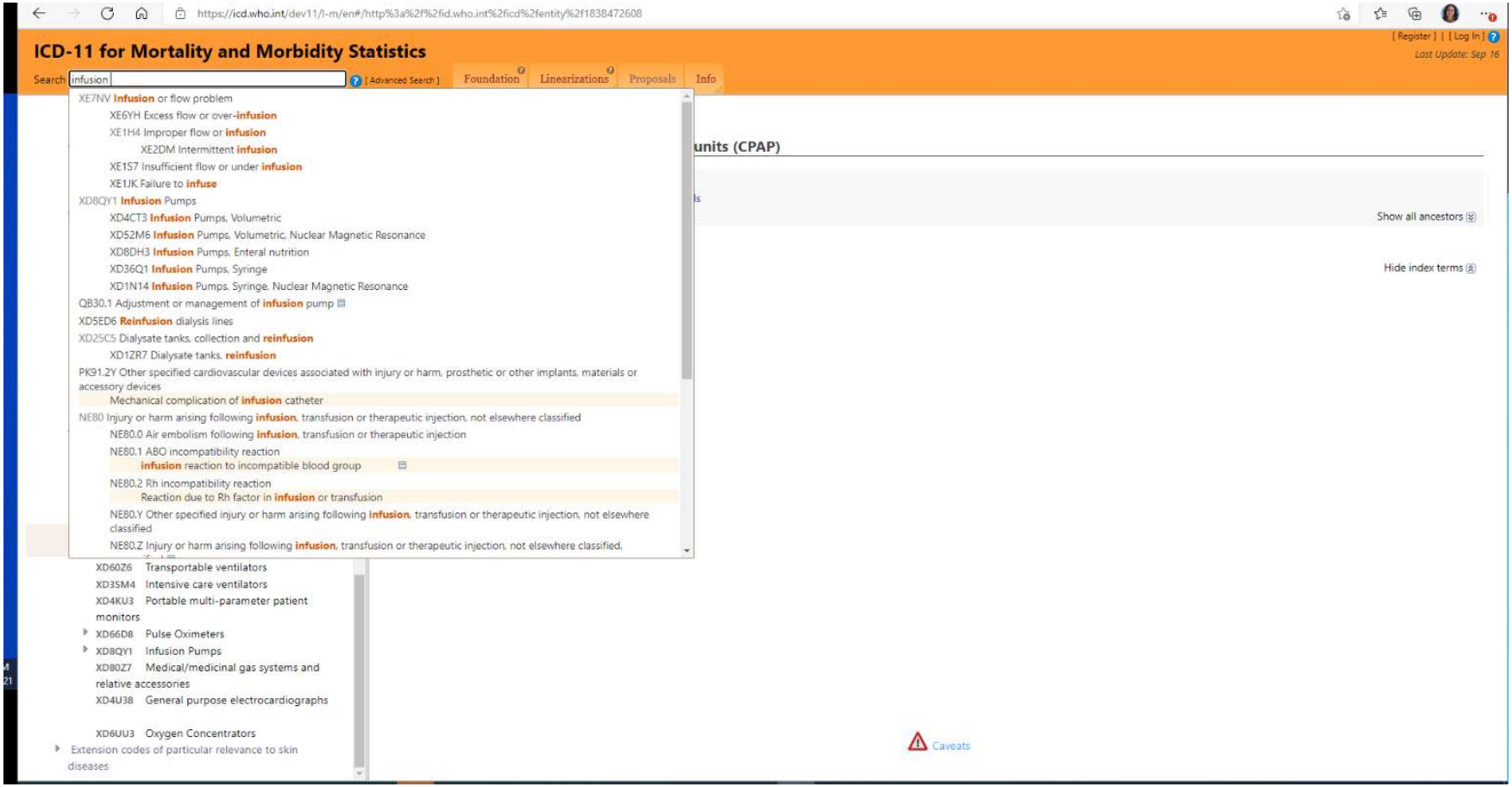
e.g. ***cancer of stomach***



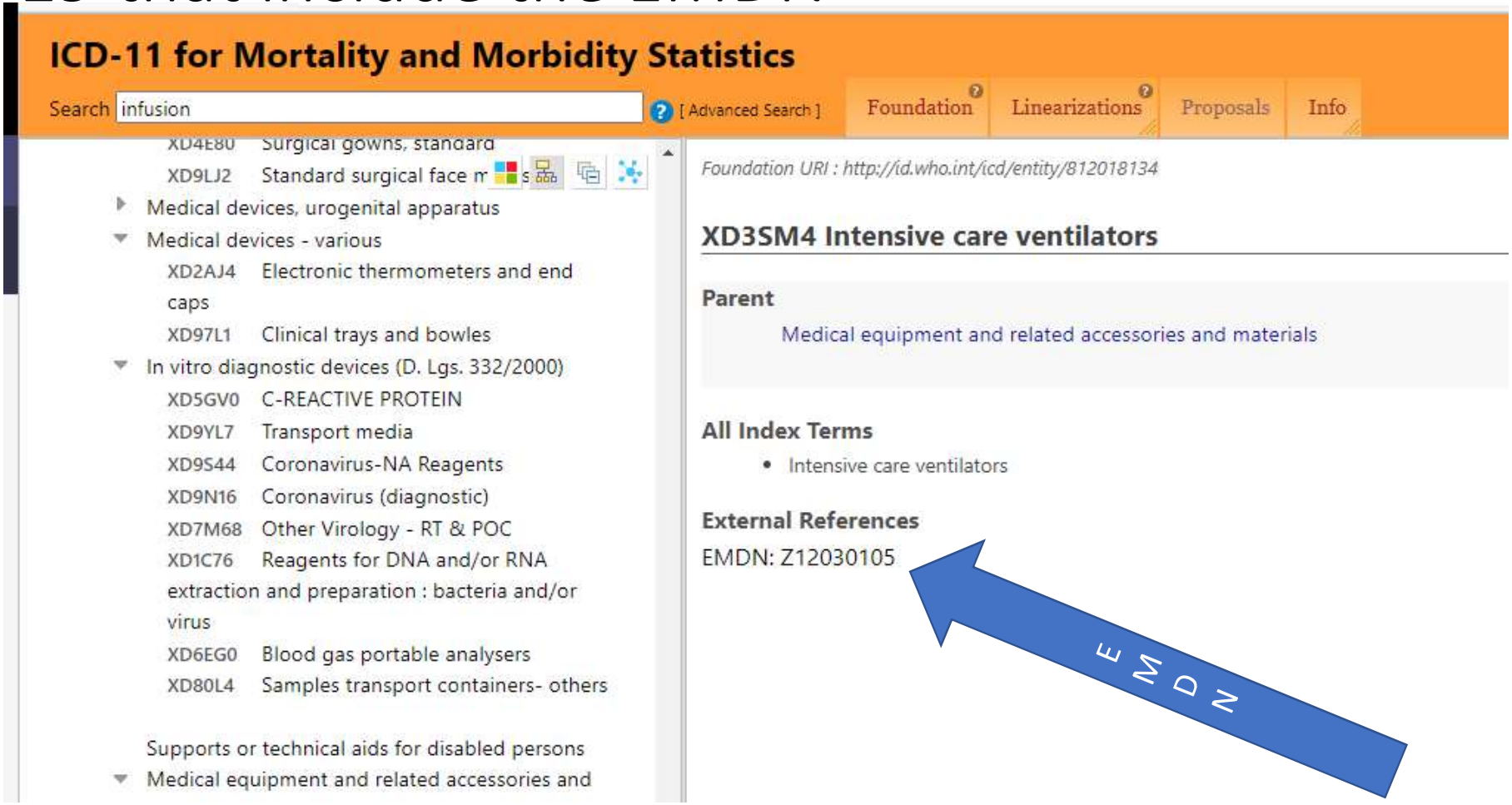
The Coding Tool will find the best match

Training 30 minutes = 88% correct coding

In ICD-11 diseases, interventions and medical devices i.e. “infusion”

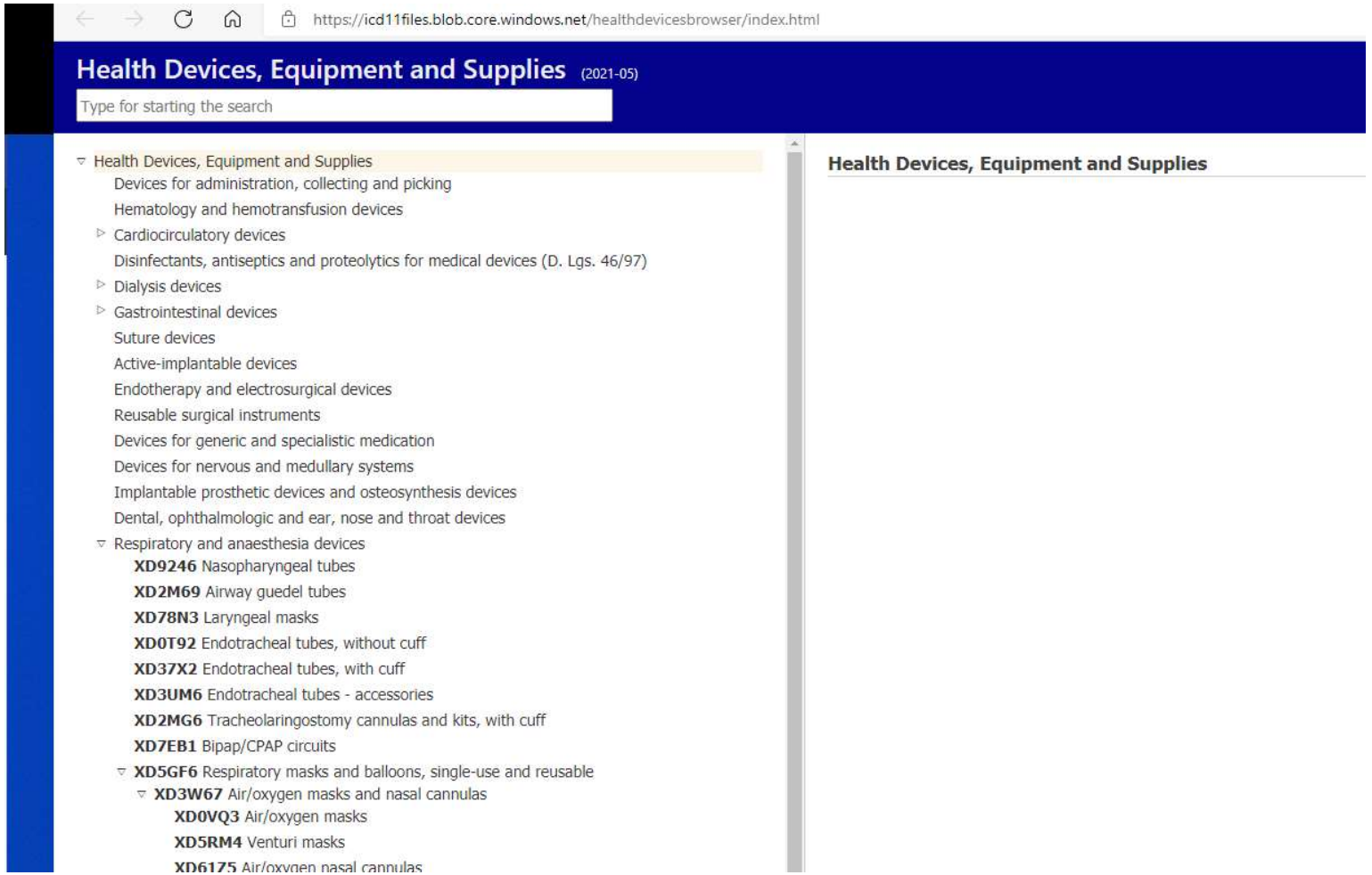


Sample of medical devices for COVID-19 that include the EMDN



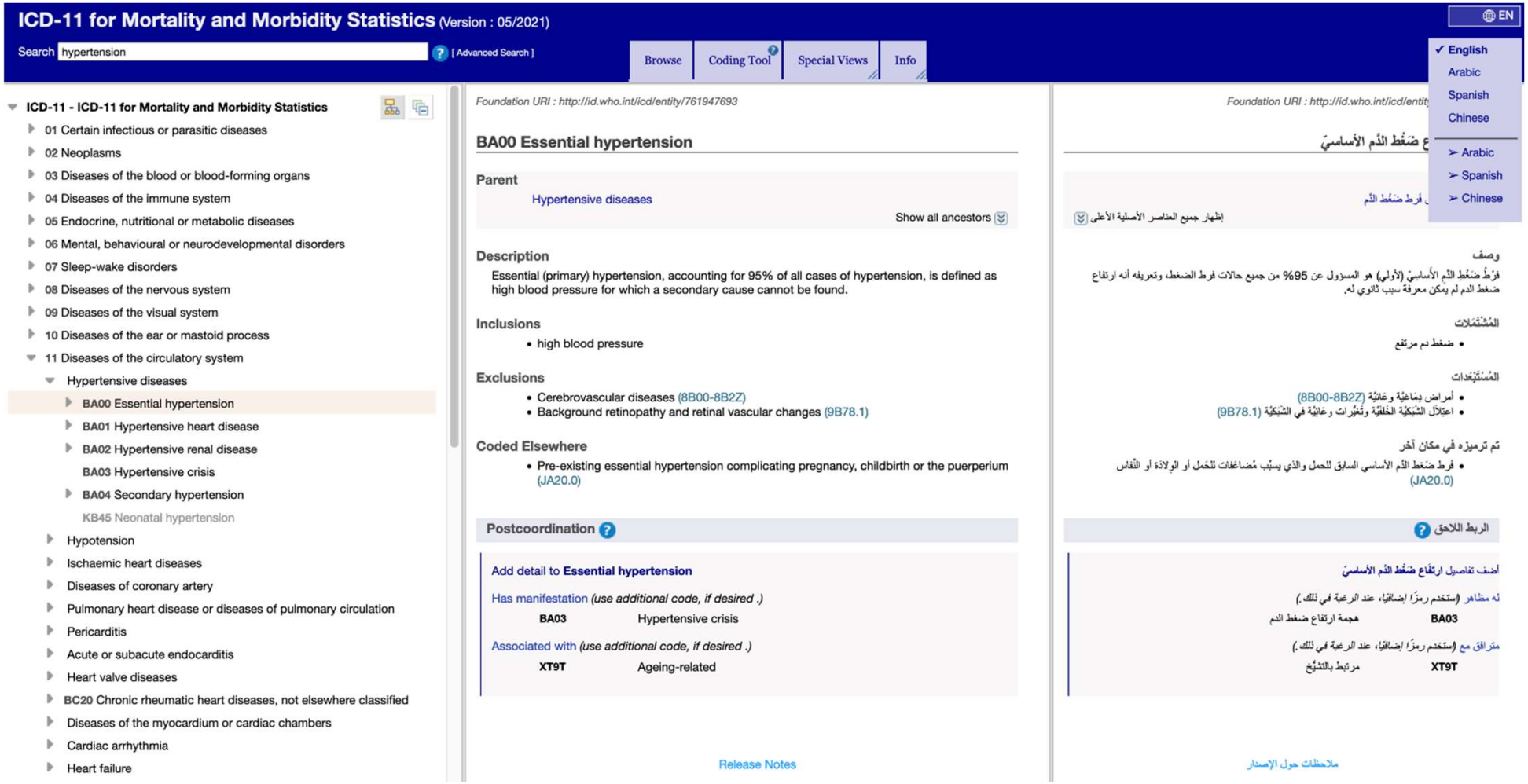
WHO willing to describe the different nomenclatures, codes and terms if agreement from the nomenclature organizations.

ICD-11 ontological platform has created a page specific for devices having URI, using EMDN structure open to add other systems for mapping



Multilingual (23 more languages in translation)

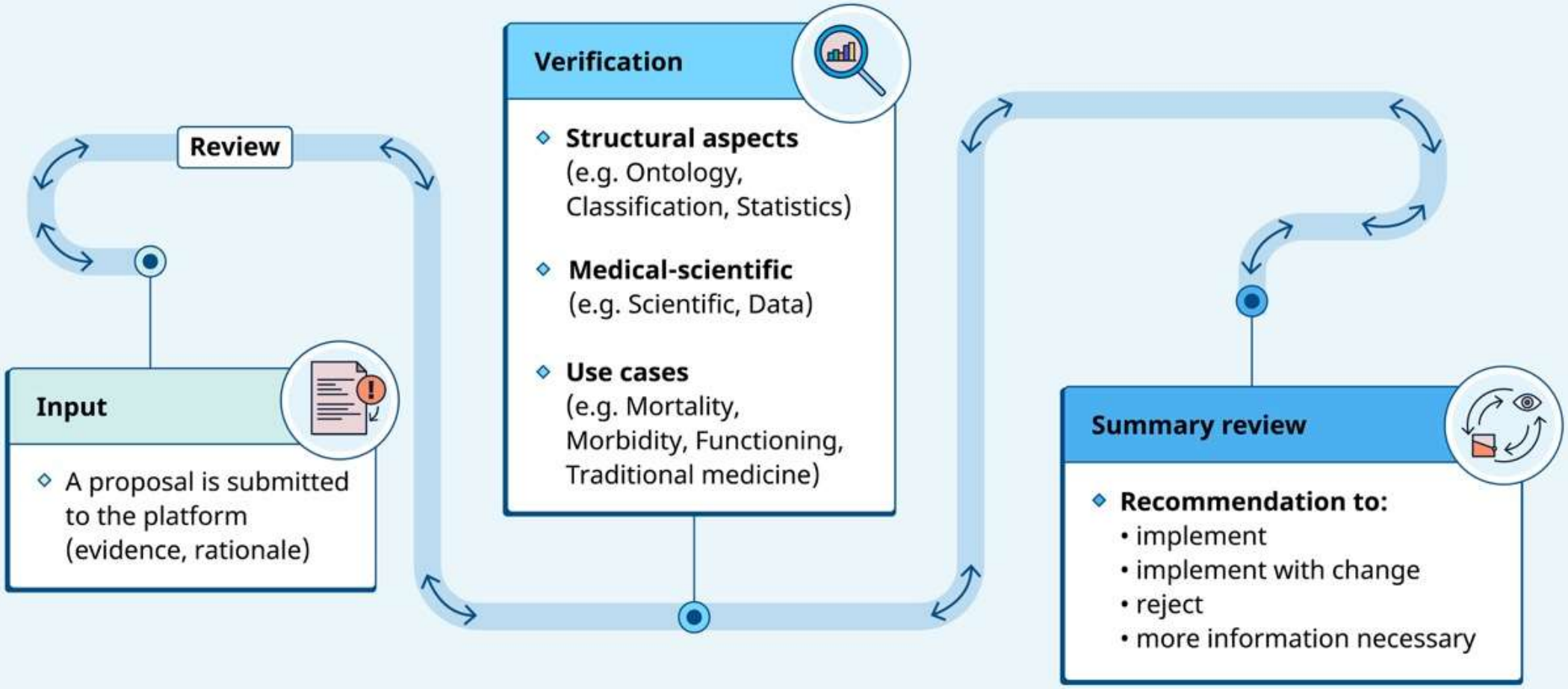
Select languages

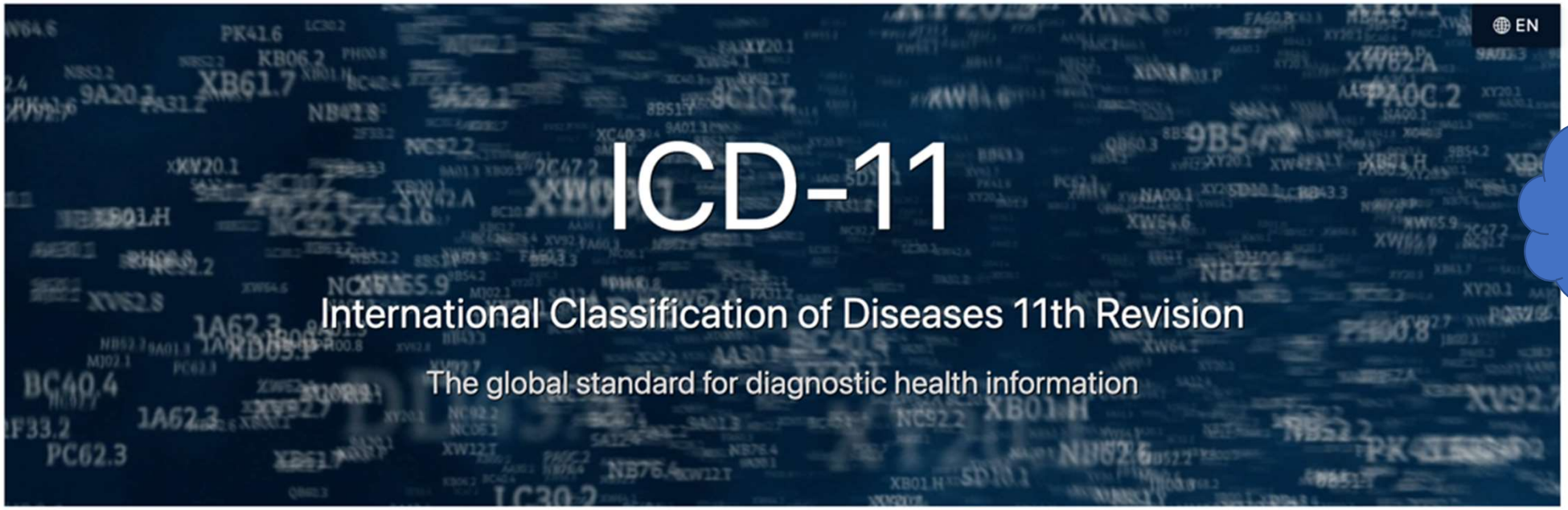


Tools for Users

Coding	API- Integration with IT	Training (WHO-FIT)	Guides for implementation and use
Mappings to ICD-10	Causes of death	Casemix (development started)	ANACOD 3 – quality assessment of cause of death statistics
Software assisted selection cause of death (testing prototype)	Proposals	Translation	…

ICD-11 maintenance is a transparent public process





Select language

Use ICD-11

ICD-11 Browser
for seeing the content
ICD-11 Coding Tool
for coding with ICD-11
ICD-API
web services to get programmatic access to ICD-11
ICD-11 Implementation or Transition Guide

Learn More

ICD Home Page
ICD-11 Reference Guide
ICD-11 Fact Sheet
ICD Video

Older versions
ICD-10 Browser

Be Involved

Our maintenance platform provides various ways to contribute

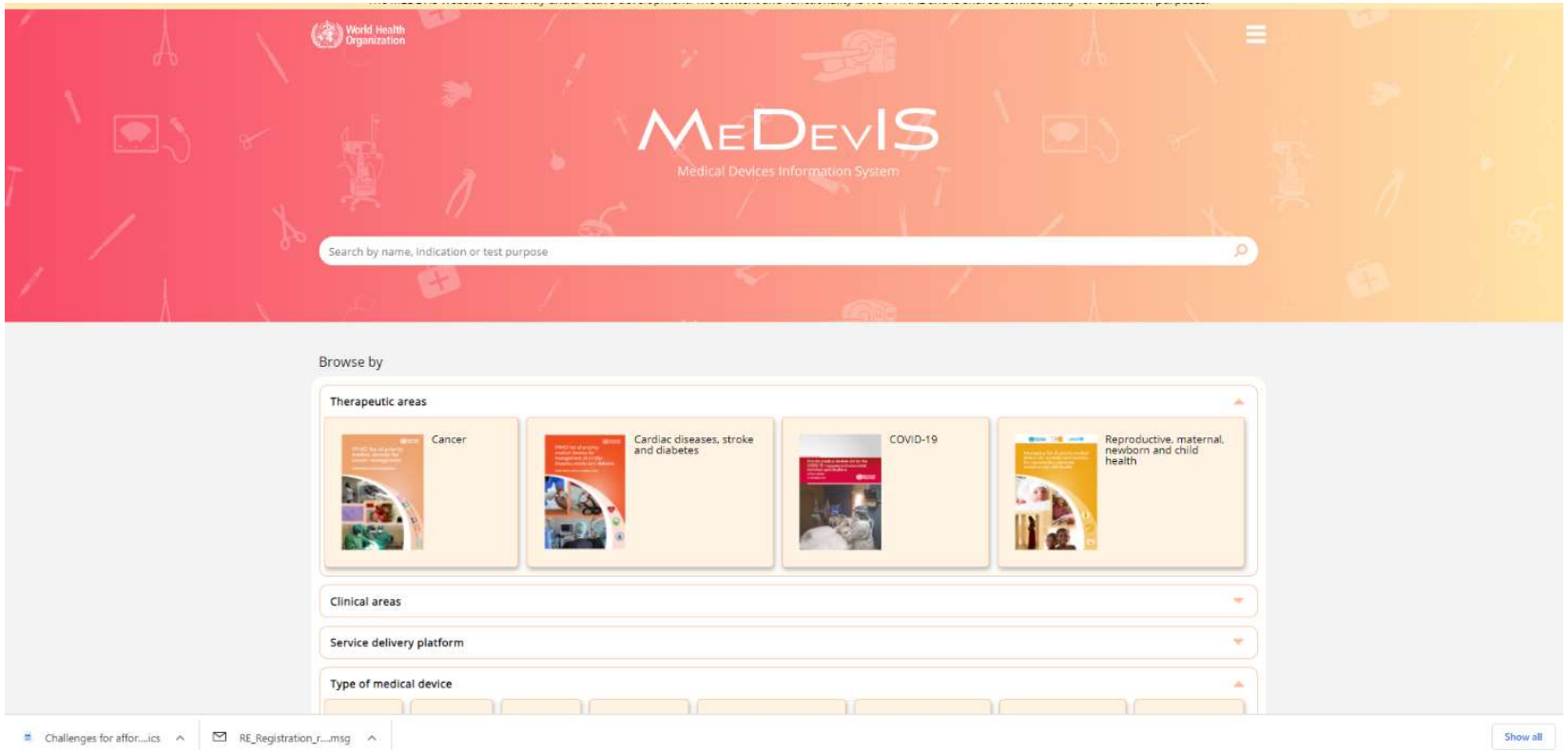
Comments
Proposals
Translations

Register, submit proposal

Information and files online : http://icd.who.int

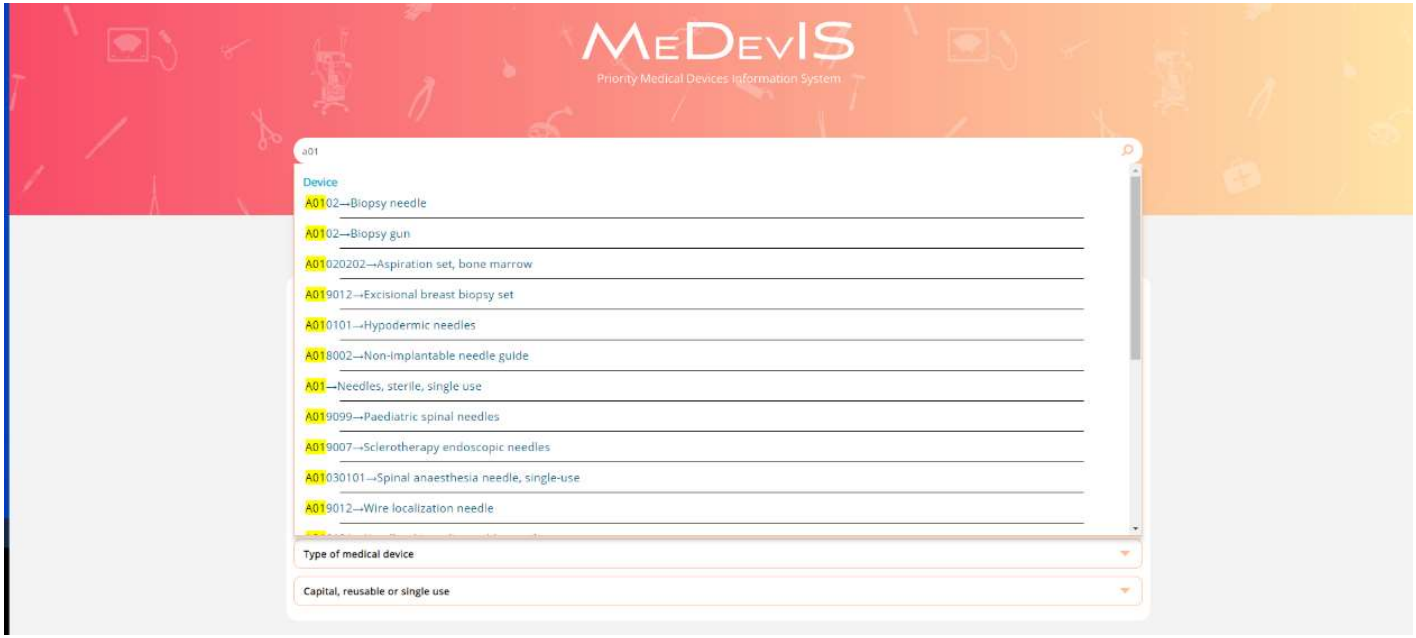
- Global Goods
- Mandated by International Regulations
- Improved and refined by
- Global support, contributions and feedback
- For comparable data, reliable easy use and interoperability
- Webinars for introduction
- **icd@who.int**

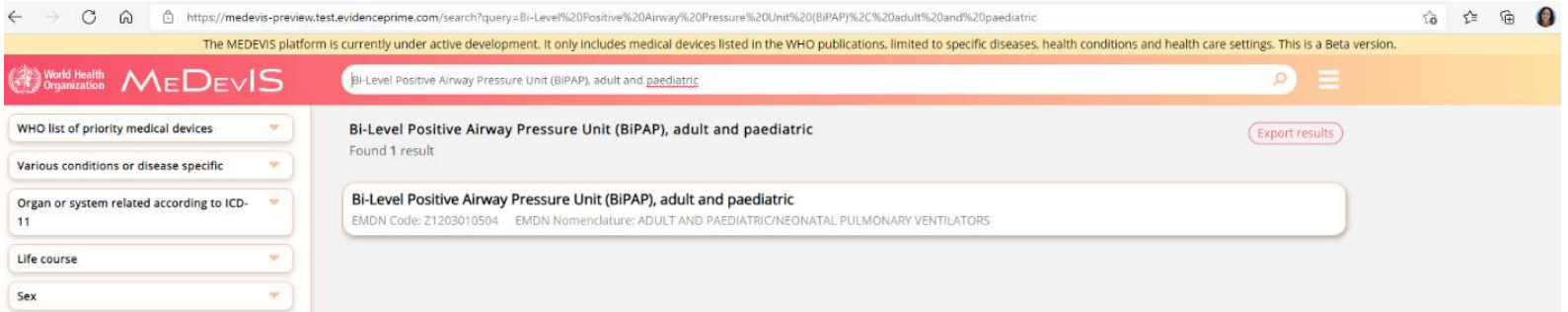
WHO Priority medical devices information system “MEDEVIS” clearing house of WHO documents to support decision making



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

MEDEVIS includes EMDN in pilot project and can add GMDN, UMNDS, UNSPSC codes and terms.





World Health Organization

Feasibility study

Nomenclature Mapping Proposal

Terrie L. Reed
WHO Nomenclature Consultant
Symmetric Health Solutions LLC

Nomenclature Mapping Project

By 1 October 2021

- Understand mapping requirements
- Educate nomenclature stakeholders on innovative tools for using UDI-DI to map nomenclatures
- Offer technical options for integration of UDI-DI with multiple nomenclatures in existing WHO and UN platforms (UHCC, MEDEVIS, ICD-11)
- Provide estimate of costs of feasibility study including technical options

Communicating Product Information: Unique Device Identification

1974 - UPC

1976 - NDC

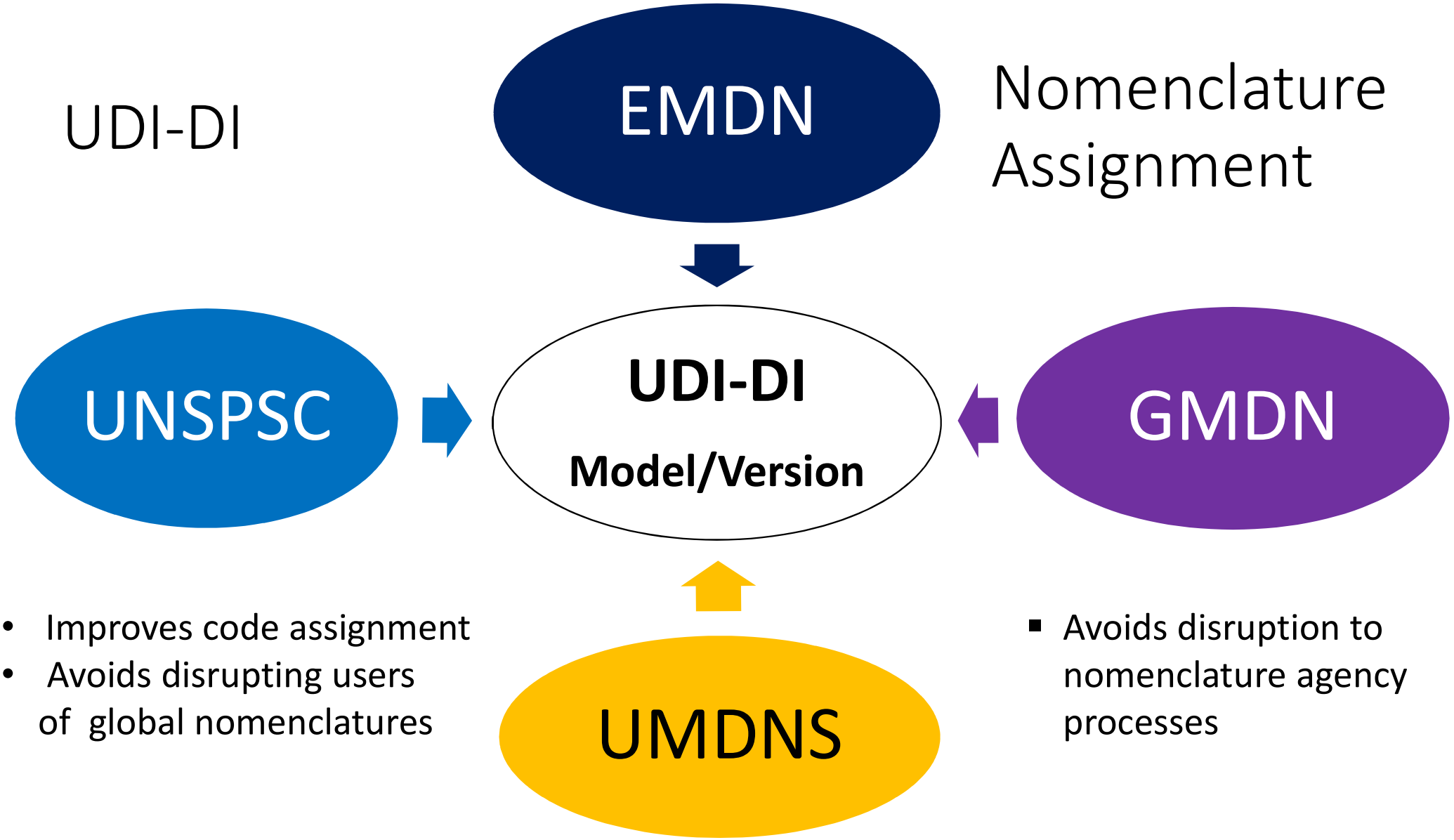
2013 - UDI

Scan UDI to unlock device information

01: Device Identifier (UDI-DI) = 00606959026605

21 – Serial Number = J18062750CED

UDI-DI



Nomenclature Assignment

- Improves code assignment
- Avoids disrupting users of global nomenclatures

- Avoids disruption to nomenclature agency processes

UDI-DI
00606959026605

Mapping across Nomenclatures

EMDN	GMDN	UMDNS	UNSPSC
Z12030102	60711	11001	42272202
Continuous positive pressure equipment	Home CPAP Unit	Positive Airway Pressure Units, Continuous	Non-invasive continuous positive air pressure machines

Mapping across Nomenclatures

Device Type – COVID-19

UDI-DI	Manufacturer Description	EMDN Code	EMDN Name	GMDN Code	GMDN Preferred Term	UMDNS Code	UMDNS Term	UNSPSC	UNSPSC Title
10711234160015	Avoximeter Whole Blood Oximeter Optical QC Filters	W0201069002	BLOOD GAS PORTABLE ANALYSERS	56673	Co-oximetry analyser IVD, point-of-care	18635	Oximeters, In Vitro, Point-of-Care	41116203	Monitor or meter accessories
00849686073782	WristOx2 Wearable Pulse Oximeter with Bluetooth	Z1203020408	PULSE OXIMETERS	36118	Pulse oximetry telemetric monitoring system	22855	Monitors, Physiologic, Pulse Oximetry, Personal	42181801	Pulse oximeter units
00874750005703	E1 MASK & HG LARGE HRI LABEL	R03010201	AIR/OXYGEN MASKS	35171	Rebreathing oxygen face mask	39680	Masks, Air-Oxygen, Positive Airway Pressure Unit, Oronasal	42272213	Continuous positive airway pressure CPAP masks or straps
00606959032590	EverFlo w/Oxygen Percentage Indicator, 230V Italy Chile	Z12159004	OXYGEN CONCENTRATORS	12873	Stationary oxygen concentrator	12873	Oxygen Concentrators	42271702	Oxygen concentrators

Mapping across Nomenclatures

Device Type – Cardiovascular Devices

UDI-DI	Manufacturer Description	EMDN Code	EMDN Name	GMDN Code	GMDN Preferred Term	UMDNS Code	UMDNS Term	UNSPSC	UNSPSC Title
10846835007978	CATHETER ELECTROPHYSIOLOGY BLACK 115CM 6FR 5MM SPACE F CURVE FIX QUADRAPOLAR AUTO ID 1MM	C020103	ARRHYTHMOLOGY TETRAPOLAR ELECTROCATHETERS	46355	Cardiac mapping catheter, percutaneous, single-use	41923	Catheters, Cardiac, Electrophysiology, Mapping	42203430	Electrophysiology catheters
00811806010717	Guidewire	C0499	CARDIOVASCULAR GUIDEWIRES - OTHER	35094	Cardiac/peripheral vascular guidewire, single-use	36599	Guide Wires, Cardiovascular	42203404	Vascular imaging guidewires

Mapping across Nomenclatures

Device Type – Orthopedic Devices

EMDN Code	EMDN Name	GMDN Code	GMDN Preferred Term	UMDNS Code	UMDNS Term	UNSPSC	UNSPSC Title
P09120699	BONE FIXATION SCREWS, TENDON AND LIGAMENT SYNTHESIS SCREWS - OTHER	45062	Tendon/ligament bone anchor, non-bioabsorbable	32734	Screws, Bone/Graft	42322201	Interference screws
P09088099	HIP PROSTHESES - OTHER ACCESSORIES	43167	Acetabulum prosthesis hole plug	16126	Restrictors, Orthopedic Cement	42322601	Orthopedic hole eliminators or plugs
P09120501	OSTEOSYNTHESIS COMPRESSION PLATES	46642	Craniofacial fixation plate, non-bioabsorbable	15749	Cover Implants, Bur Hole	42296104	Cranial plate or bur hole covers

Nomenclature Convergence Roadmap

- Conduct landscape analysis of Global Nomenclature issues
- Propose a technical solution to address nomenclature mapping
- Obtain agreement from WHO member states and key stakeholders on feasibility study proposal
- Conduct feasibility study and report results and recommendations to Member States and key stakeholder groups

Nomenclature Feasibility Study

Purpose:

To demonstrate and evaluate the technical and cost challenges and benefits of using item level data to map/establish a crosswalk across multiple globally used nomenclatures and integrate the study results into WHO platforms.

Nomenclature Feasibility Study
Draft Proposal

- **Timeline**: October to December 2021
- **Participants**: Regulators, Nomenclature Agencies, Industry, Hospitals, UN agencies, WHO, IT Consultants
- **Scope**: Subset of EDL and Priority medical devices (e.g. COVID, CVD, and Infectious Diseases)
- **Methodology**:
  - Using UDI-DI and other IT tools to retrieve, compare and analyze nomenclature codes and terms
  - Periodic engagement of participants
  - Monthly update to all stakeholders
- **Estimated Cost**
  - $150,000-$200,000 (or in-kind)
  - Resources: WHO Subject Matter and IT Consultants , Nomenclature Agencies

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Stakeholders statements:

- **UN Agencies and NGOs**
- **MD Industry**
- **Biomedical and Clinical Engineers**

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Open discussion from Members States

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Conclusions