

# Standardization of medical devices nomenclature



**Member States information session.**

31 March 2022

# Agenda



1. Standardized nomenclature of medical devices
2. EB150: comments and decision
3. State of play: status quo of 4 major nomenclature systems and WHO work
4. Open discussion on the decision

# Milestones

WHO  
EB 145,  
EB 148,  
WHA74  
May 2022

WHO EB 150  
January 2022

WHA 75  
May 2022



Info session

- 23 Sept 2021
- Mapping process

>40 consultations and mapping of 13,000 terms in collaboration with nomenclature agencies

Information session

- 16 Dec 2021

Information session  
31 Mar 2022

Decision discussion

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

## Naming devices remain the backbone of all processes.



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- Industry production to comply with regulatory bodies and procurement systems



- Regulatory agencies: for premarket registration, tracking, post market surveillance



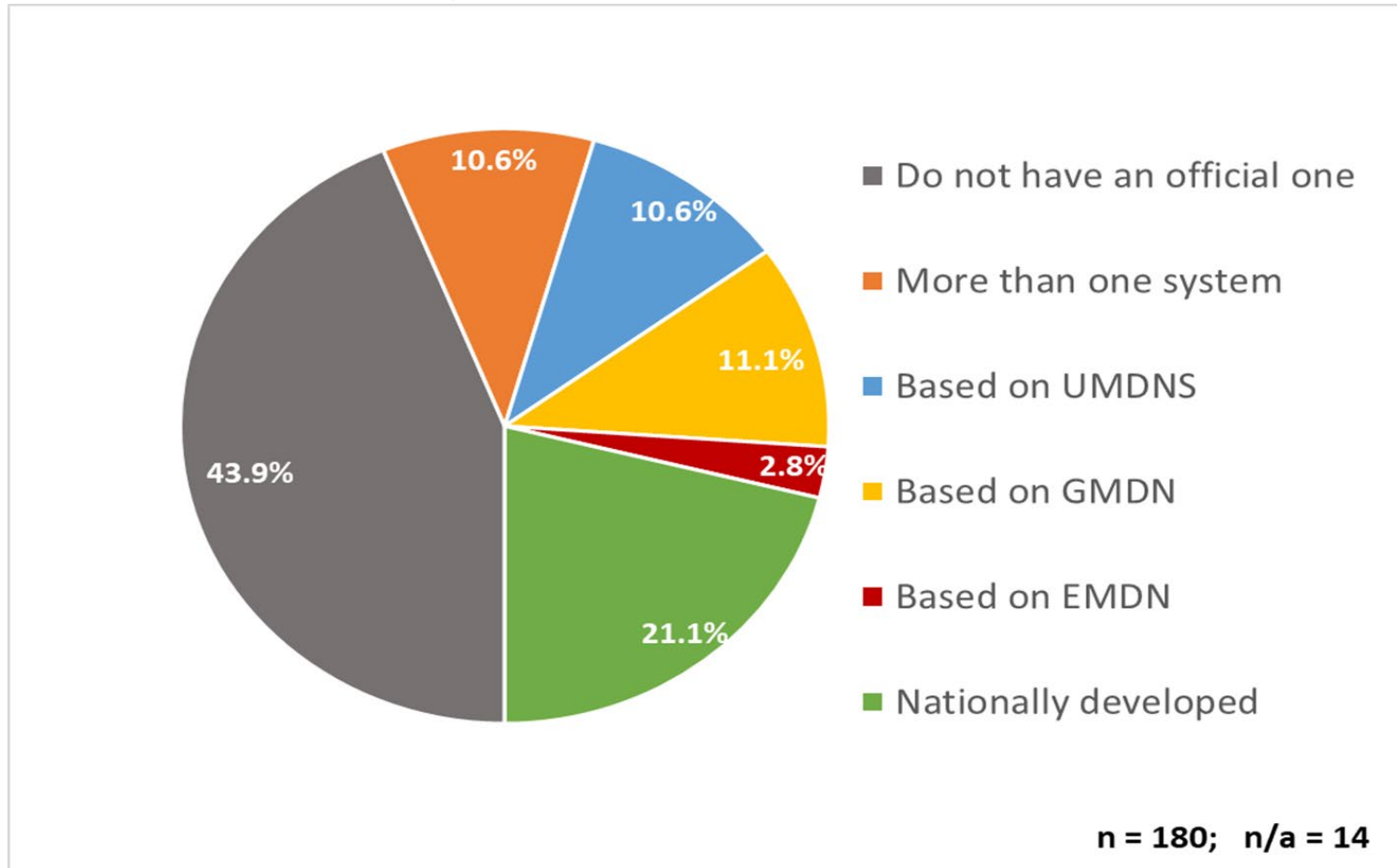
- MOH, national insurance: Selection of medical devices national list for procurement or reimbursement (Essential/ priority/ positive)



- Procurement and supply (trade, customs)
- Inventories, maintenance and training in Health facilities
- Patient safety
- Decommissioning



# Multiple systems co-existing at regional, country, facility levels and by industry and UN agencies, affect health systems and impact patients.



Data reported in 2021, by 180 MS, in country survey for Global Atlas of Medical Devices

# WHO data principles for medical devices: established in 2018 and published and discussed in EB145/3, EB148 and EB150.



## (a) Governance:

(i) will have structures in place to ensure that **all** stakeholders are able to provide feedback.

## (b) Classification, coding and nomenclature characteristics with:

- (i) a transparent methodology and processes for updates; and
- (ii) terms in other languages.

## (c) Access of information, which:

- (i) can be referenced and used by regulators, procurers, managers and all users;
- (ii) is freely available and considered a global public good;
- (iii) can support the Unique Device Identifier system;
- (iv) facilitates simple and intuitive search; and
- (v) is available for use in all health-related database systems.



**Comments and decision arising from EB150**

## **Standardization of medical devices nomenclature**

The Executive Board, having considered the reports by the Director-General on standardization of medical devices nomenclature and the draft steps towards standardization referred to therein,<sup>1</sup>

Decided to request the Director-General:

- (1) to continue the mapping and use of the four nomenclature systems in WHO platforms and publications, with stakeholder collaboration, [and with the purpose of drafting a plan on the development of a WHO global nomenclature of medical devices];
- (2) to submit a report on progress made on the steps towards the standardization of medical devices nomenclature to the Seventy-sixth World Health Assembly in 2023.

Eleventh meeting, 29 January 2022  
EB150/SR/11



# Comments in EB by MS:

## 1 “transparency of Methodology for mapping ”:

Methods were explained in information sessions and then posted in the WHO website and shared in the consultations

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

## 2. “insufficiency of consultations”.

Between July and December 2021, WHO did multiple consultations, listed in the WHO website, and EB150 report, including:

13 meetings with the nomenclature agencies (EMDN, GMDN, UNDNS, UNSPSC). 3 with medical devices industry (GMTA, DITTA)

5 with UN agencies and NGOs. 3 with Biomedical engineers.

Regulatory networks: AMDF, GHWP, IMDRF; besides regulators in the following regions: PAHO, EURO and SEARO.

2 Member States information sessions: September and December 2021.

## 3. “consultation with the IMDRF”

Participated in 3 meetings invited by IMDRF to explain the process, the status and outcomes.

Information on consultations and mapping methodology: <https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature>

# Why GMDN is not for adoption by WHO?

## Public access

If the RA of the member state has adopted GMDN , can the same system be used freely by the Hospitals ,manufacturer or any related organisation in the said country?

GMDN can be used only by the ones that register in GMDN system and only to use internally, not in public documents. Using copyright claim.

## GMDN agency

Why WHO does not adopt GMDN as International nomenclature?

Because it is owned by a private entity that makes decisions by themselves.

Because it does not comply with open access to everyone as a global public good.

## IMDRF and GMDN

How many IMDRF members have adopted GMDN?

According to MS report for Global Atlas of Medical devices:

3 out of 10 Members, adopted as is.

3 others have based on it but modified it locally with local codes.



**Status quo of 4 nomenclatures and WHO work up to 16 March 2022**

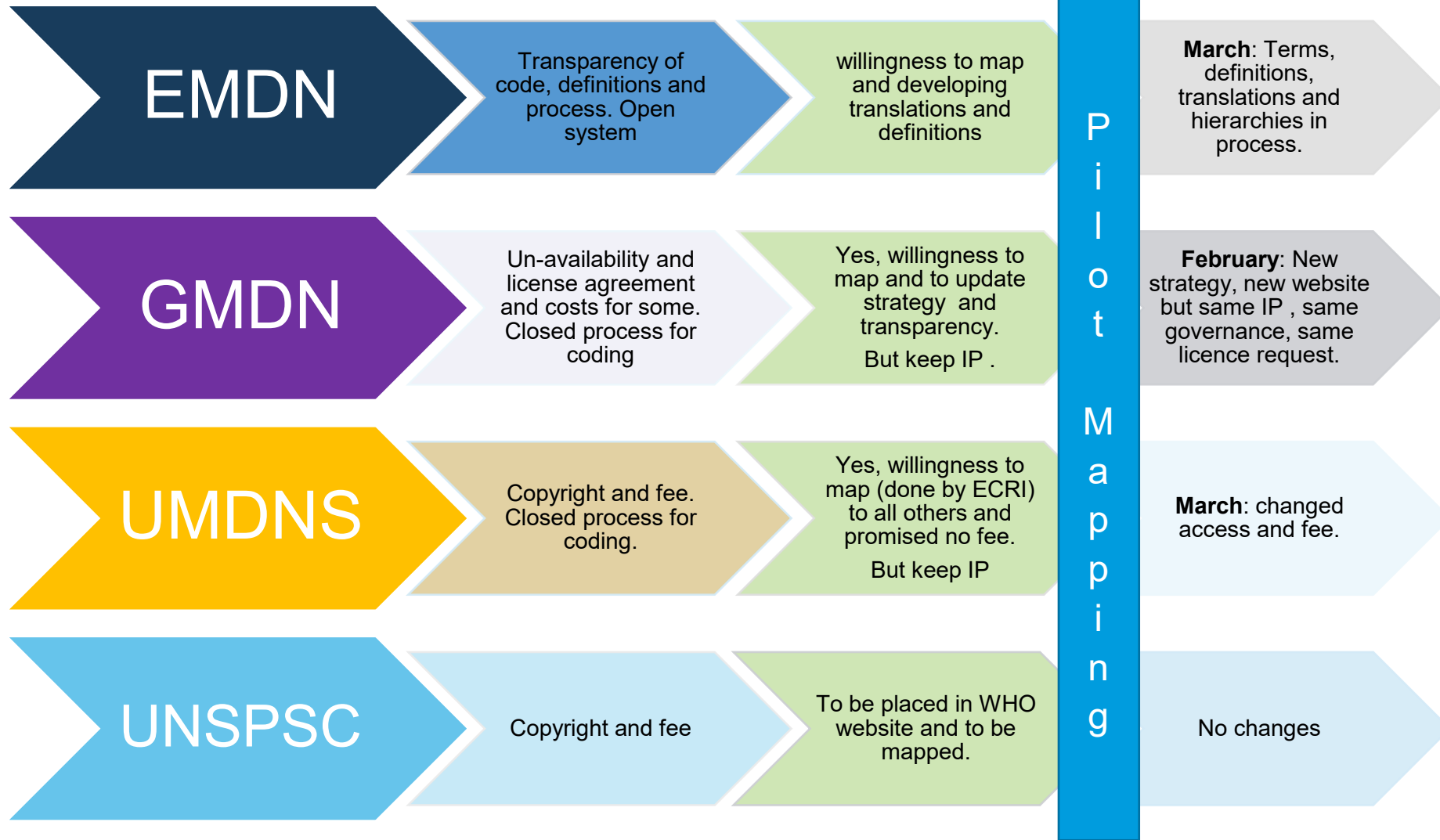
# Comparison against WHO principles

Updated as of 16 March 2022



|   | Universal Medical Device Nomenclature System (UMDNS) | Global Medical Device Nomenclature (GMDN)                      | United Nations Standard Products and Services Code (UNSPSC) | European Medical Devices nomenclature (EMDN) May 2021 |
|---|--|--|---|---|
| Organization owner  | ECRI Institute                                       | GMDN Agency  | GS1 US  | European Commission                                   |
| Governance  | Private  | Private  | Private   | Public  |
| Transparent methodology to define terms.                            | Defined by agency, without input from industry.      | Defined by agency with input from members, including industry. | Defined by agency   | Defined by MDCG, with open input                      |
| Hierarchical organization   | Multiple   | Multiple   | Single  | Single  |
| Free available as global public good                                | In process   | No   | No  | Yes   |
| Translations (available languages)                                  | 2  | 25   | 1   | 3   |
| Supports Unique Device Identifier (UDI)                             | No   | Yes  | No  | Yes   |
| Available for use in all health-related databases (public systems). | X  | X  | X   | Yes   |

June 2021 to ... September .....December.. 16 March 2021



# WHO Advances till 16 March

Pilot project mapping done using UDI and public data, and machine learning

(sample: 13,129 devices from 510 manufacturers)

Agreement from nomenclature agencies to use code, term in WHO tools.

Text and flow chart for selection of nomenclature for the Global Model Regulatory Framework was discussed for final approval

Pilot test using MEDEVIS and ICD, WHO platforms to be freely available, single code linked to the different nomenclature systems.



| 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 conta | 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 |



Foundation URI : <http://id.who.int/icd/entity/93666629>

### XD2N29 Dialyzers - UHF < 18 ml/h/mmHg, cellulose membranes

All ancestors up to top

- X Extension Codes
- Health Devices, Equipment and Supplies
- Dialysis devices
- XD8V84 Dialysis filters
- XD8DD4 Haemodialysis, hemofiltration, haemodiafiltration filters
  - XD2KJ5 Dialyzers - UHF < 18 ml/h/mmHg
  - XD2N29 Dialyzers - UHF < 18 ml/h/mmHg, cellulose membranes

Foundation URI : <http://id.who.int/icd/entity/1483205780>

### ICD-11 for Mortality and Morbidity Statistics

Search:

- Histopathology
- Dimensions of injury
- Dimensions of external causes
- Consciousness
- Substances
- Diagnosis code descriptors
- Capacity or context
- Health Devices, Equipment and Supplies
  - Devices for administration, collecting and picking
- Hematology and hemotransfusion devices

**XD4ZY0 Stethoscopes**

Parent: **Cardiocirculatory devices**

All Index Terms: **Stethoscopes**

<https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2fcd%2fentity%2f822324204>

<https://medevis.who-healthtechnologies.org/>

# Open discussion on the decision



**EXECUTIVE BOARD  
150th session  
Agenda item 14**

**EB150(10)  
29 January 2022**

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## **Standardization of medical devices nomenclature**

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Eleventh meeting, 29 January 2022  
EB150/SR/11

**Gracias  
Thank you  
Merci  
Shokran  
Xie xie  
Spasiva**



**World Health  
Organization**

**WHO**

20, Avenue Appia  
1211 Geneva

Switzerland

Medical devices

Email: [medicaldevices@who.int](mailto:medicaldevices@who.int)

website: [https://www.who.int/health-topics/medical-devices#tab=tab\\_1](https://www.who.int/health-topics/medical-devices#tab=tab_1)





**More information: References and links in extra slides**

# Links to WHO links, references

1. Nomenclature of medical devices, description of activities, consultations, methodologies and discussions in EB and WHA.

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

2. Standardization of medical devices nomenclature EB150(10) 1150th session 29 January 2022 Decisions.

[https://apps.who.int/gb/ebwha/pdf\\_files/EB150/B150\(10\)-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB150/B150(10)-en.pdf)

3. Extension codes of International Classification of diseases that include medical devices

<https://icd.who.int/browse11/l-m/en#/http%3a%2f%2fid.who.int%2fid%2fentity%2f822324204>

2. Example of external references to EMDN for one medical device in ICD-11 maintenance platform

3. [ICD-11 for Mortality and Morbidity Statistics \(who.int\)](#)

4. Medical Devices information system, MEDEVIS, <https://medevis.who-healthtechnologies.org/>

5. MEDEVIS, test mapping: [\(proof of concept\) https://medevis-nomenclaturemapping.test.evidenceprime.com/](https://medevis-nomenclaturemapping.test.evidenceprime.com/):

## Links to 4 agencies information updated as of (16- 03- 2022)

| Considerations                      | EMDN  | GMDN   | UNSPSC  | UMDNS  |
|-------------------------------------|---|--|---|--|
| Webpage                             | <a href="https://webgate.ec.europa.eu/dyna2/emdn/">https://webgate.ec.europa.eu/dyna2/emdn/</a>   | <a href="https://www.gmdnagency.org/">https://www.gmdnagency.org/</a>  | <a href="https://www.unspsc.org/">https://www.unspsc.org/</a>   | <a href="https://www.ecri.org/solutions/umdns">https://www.ecri.org/solutions/umdns</a>  |
| Governance                          | Medical Device Coordination Group from EU Members States.<br><a href="https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en">https://ec.europa.eu/health/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en</a>  | GMDN agency, nonprofit private organization.<br>Board of Trustees:<br><a href="https://www.gmdnagency.org/About/Board">https://www.gmdnagency.org/About/Board</a><br><br>(no government representation in the Board)   | Community managed, hosted by GS1 US<br>“The United Nations Standard Products and Services Code® (UNSPSC®), managed by GS1 US® for the UN Development Programme (UNDP)”  | ECRI, non-profit, independent organization<br><a href="https://www.ecri.org/about/">https://www.ecri.org/about/</a>  |
| Licence requirements <sup>2</sup>   | No requirement's  | Requires registration GMDN and copyright;<br><a href="https://www.gmdnagency.org/Legal/License">https://www.gmdnagency.org/Legal/License</a>   | No requirements to download PDF but requirements for use<br>“Copyright (c) United Nations Development Programme 2013 All rights reserved.”<br><a href="https://www.unspsc.org/terms-of-use">https://www.unspsc.org/terms-of-use</a> | (ECRI required fee and copyright before 16 March, but modified requirements for access of UMDNS).<br><a href="https://www.ecri.org/solutions/umdns">https://www.ecri.org/solutions/umdns</a> |
| Number of total terms               | 7,000   | 24,800 GMDN terms, in addition about 2,000 high level terms.   | 3,800 for Medical Devices   | UMDNS March 2022 includes More than 43, 000 terms 30, 608 Entry terms and 13,025 Preferred Concepts  |
| Translations available <sup>3</sup> | <b>Already publicly available:</b> English, French (currently available only on EUDAMED: <a href="https://webgate.ec.europa.eu/eudamed/landing-page#/">https://webgate.ec.europa.eu/eudamed/landing-page#/</a> ), Italian<br><b>Under expert peer-review (2022):</b> Bulgarian, Croatian, Czech, Danish, Dutch, Estonian, Finnish, German, Greek, Hungarian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish | <b>UN Languages</b><br>Chinese (Simplified), English, French, Spanish, Russian<br><b>Other Languages</b><br>Bulgarian, Czech, Danish, Dutch, Estonian, Finnish, German, Greek, Hungarian, Italian, Japanese, Latvian, Lithuanian, Norwegian, Polish, Portuguese (Brazilian and European), Romanian, Slovak, Slovenian, Swedish | All version in English, some versions in different languages (Arabic, Chinese, Danish, Dutch, Finnish, French, German, Hungarian, Italian, Japanese, Norwegian, Portuguese, Spanish, and Swedish).                                  | English<br>Spanish (last version 2014)   |

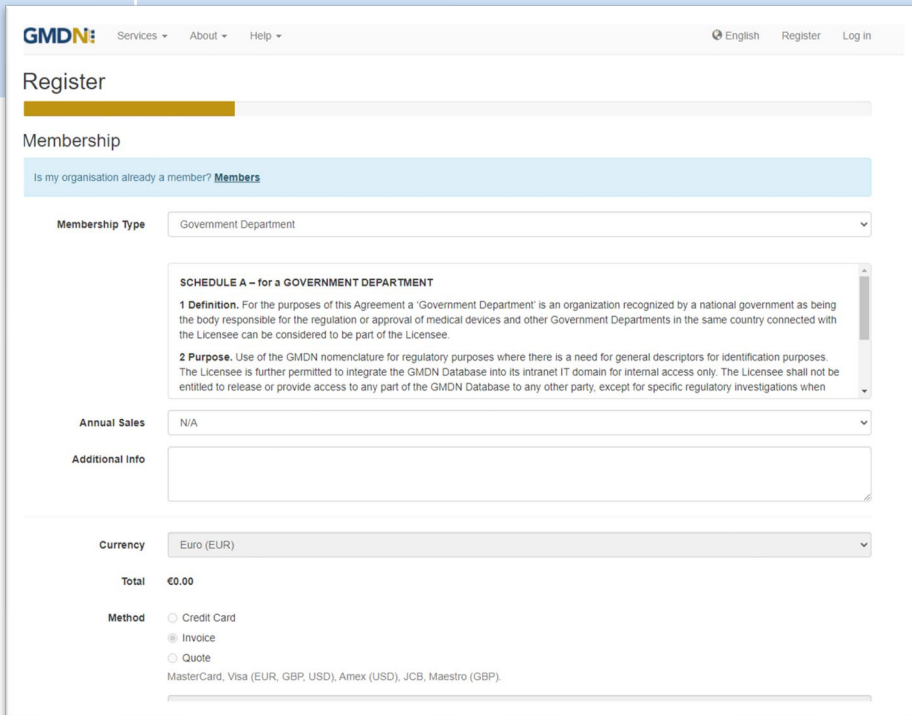
# Availability vs access and copyright

3 of the nomenclatures: UMNDS, GMDN and UNSPSC require that the user registers to have a licence, to have full access to the information.

|                    | GMDN                                   | UMDNS   | UNSPSC  |
|--------------------|--|---|---|
| Website reference. | <a href="#">Register - GMDN Agency</a> | <a href="https://www.ecri.org/solutions/umdns">https://www.ecri.org/solutions/umdns</a> | <a href="https://www.unspsc.org/subscribe">https://www.unspsc.org/subscribe</a> |

The GMDN Agency may in such circumstances grant an extension to this Licensee to allow the Licensee to allow public access to single GMDN term, but not GMDN Codes. |

Changed copyright 16 March!



**GMDN: Register**

Services - About - Help - English Register Log In

Register

Membership

Is my organisation already a member? [Members](#)

Membership Type: Government Department

**SCHEDULE A – for a GOVERNMENT DEPARTMENT**

**1 Definition.** For the purposes of this Agreement a 'Government Department' is an organization recognized by a national government as being the body responsible for the regulation or approval of medical devices and other Government Departments in the same country connected with the Licensee can be considered to be part of the Licensee.

**2 Purpose.** Use of the GMDN nomenclature for regulatory purposes where there is a need for general descriptors for identification purposes. The Licensee is further permitted to integrate the GMDN Database into its intranet IT domain for internal access only. The Licensee shall not be entitled to release or provide access to any part of the GMDN Database to any other party, except for specific regulatory investigations when

Annual Sales: N/A

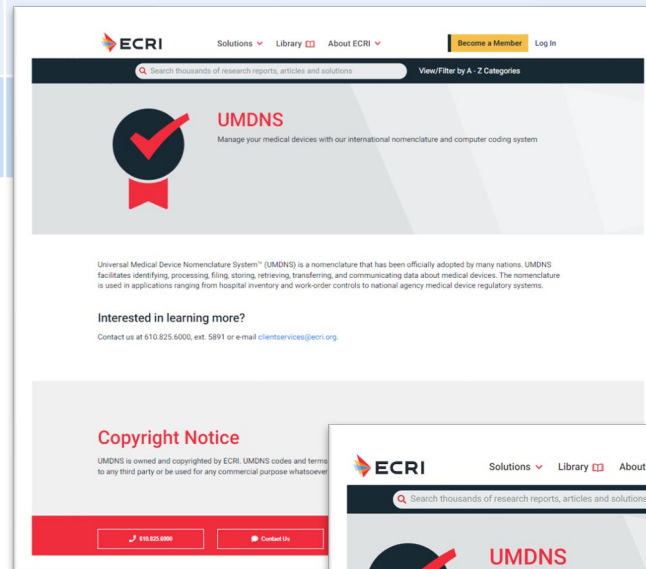
Additional Info:

Currency: Euro (EUR)

Total: €0.00

Method:  Credit Card  Invoice  Quote

MasterCard, Visa (EUR, GBP, USD), Amex (USD), JCB, Maestro (GBP)



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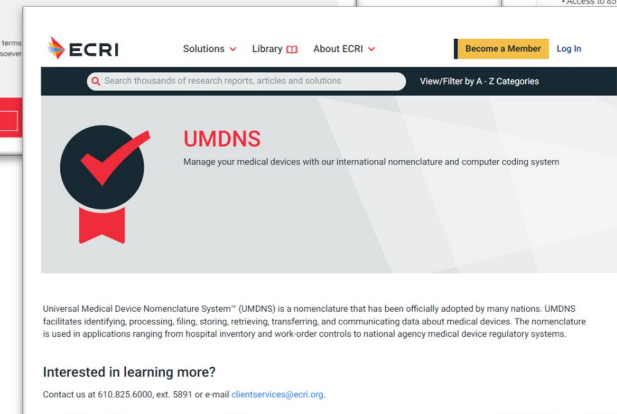
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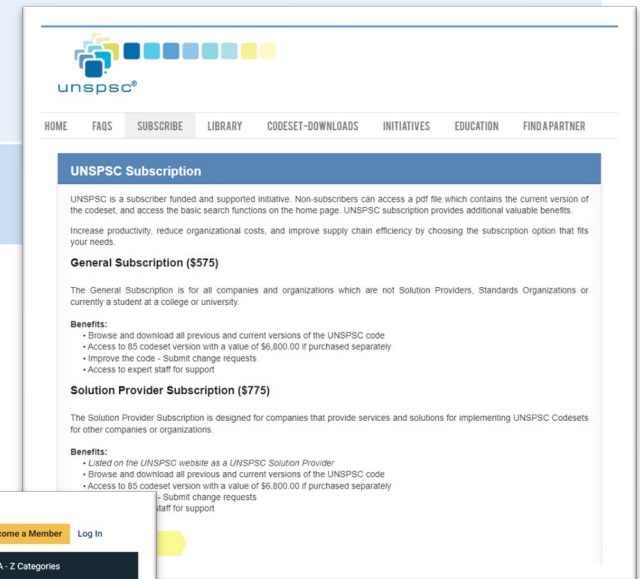
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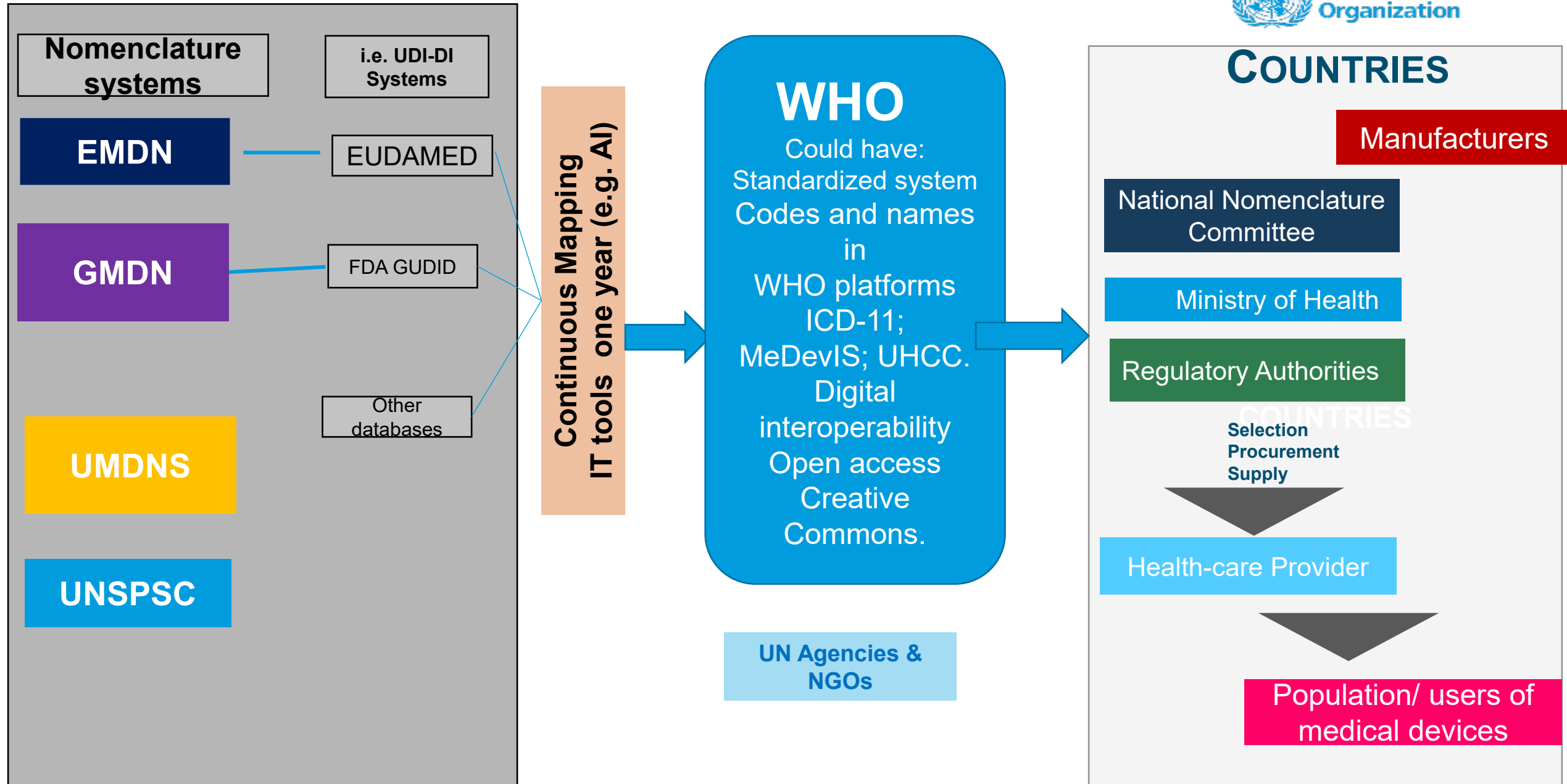
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# Mapping strategy to make information available to all



# Questions/ comments in EB 150

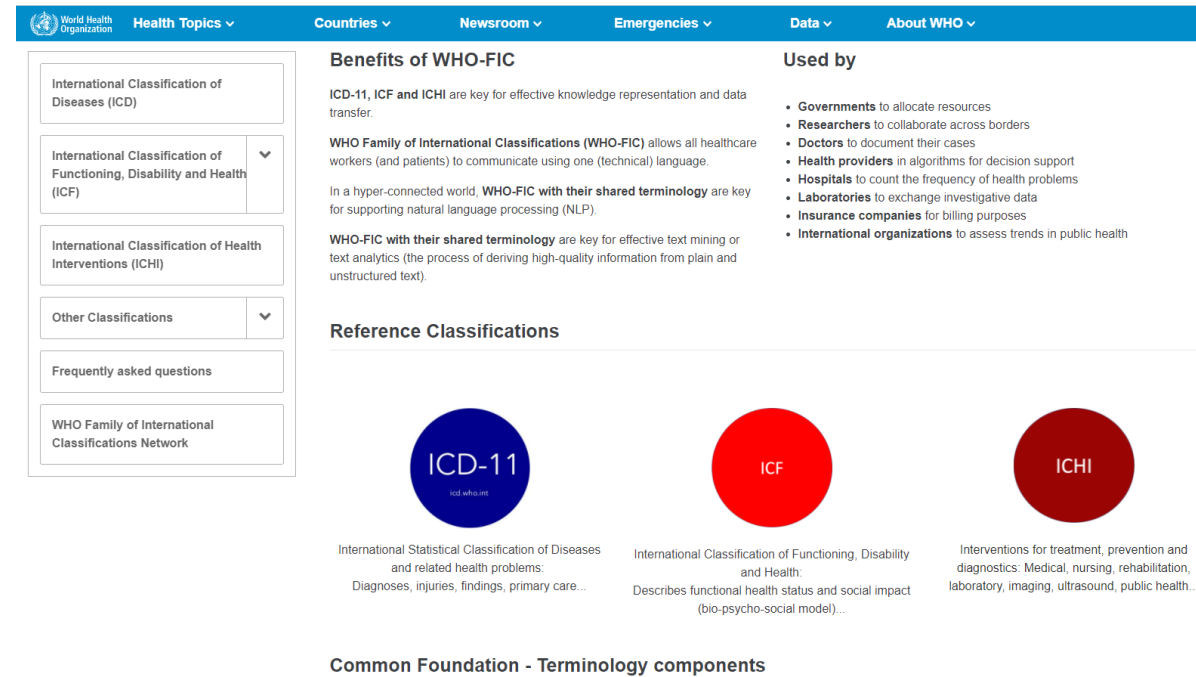
Standardized International Nomenclature:

Was proposed as the one managed by WHO, in alignment with the International Non Proprietary names of medicines, and International Classification of diseases and other WHO classifications.

Issues(EB143,148,150):

1. Some EB members required WHO to develop/make available a WHO nomenclature.
2. Other EB members required WHO not to develop a new one and consider one of the existing ones
3. WHO does not “own” any of the 4 nomenclatures that were mapped in the pilot project in 2021. 1 belong so European States, the other 3 are private entities.
4. In order to have a WHO one, proposal is to list the mapped devices and present in WHO tools with a code/ name that can be used by all and link to all of them.

<https://www.who.int/standards/classifications>

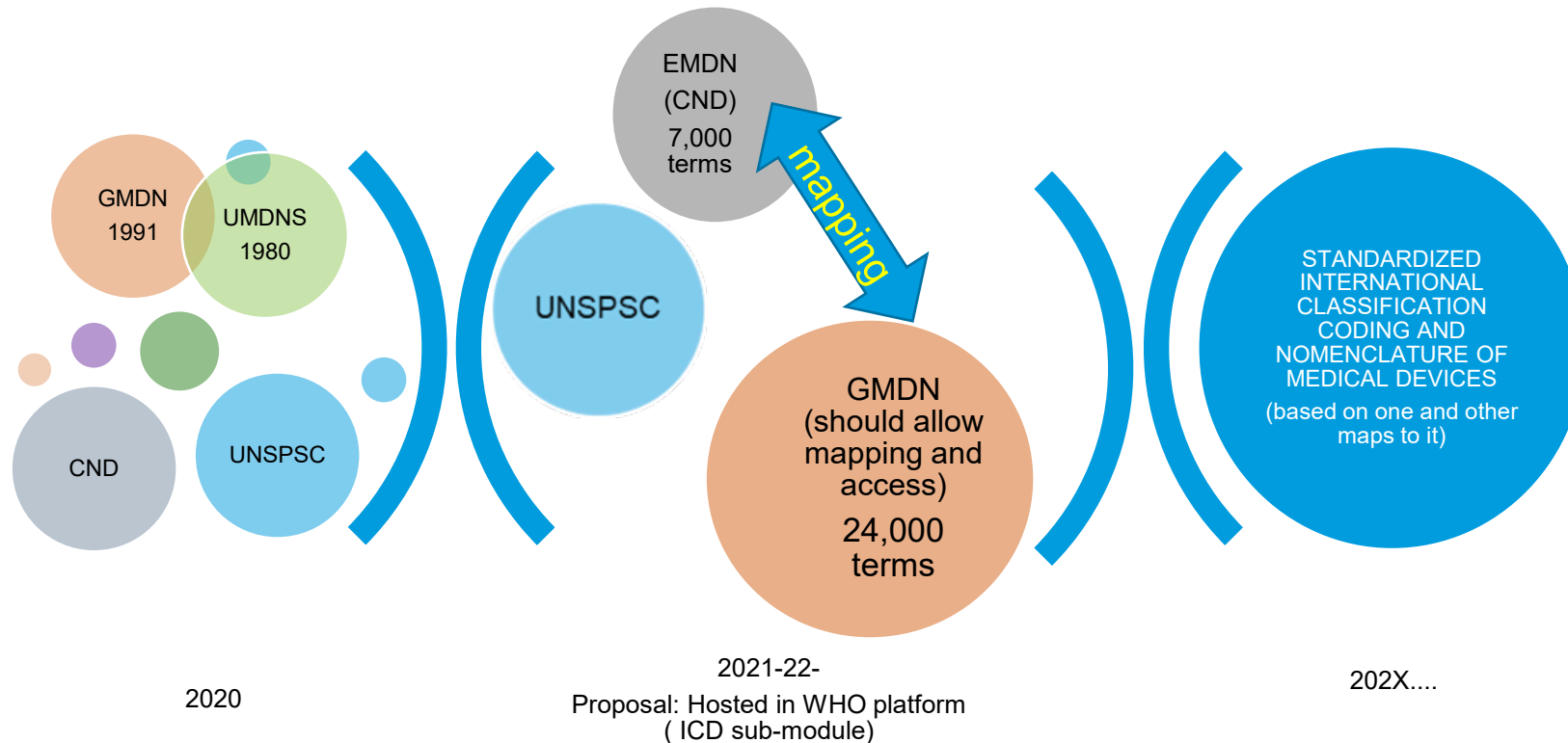


The screenshot shows a WHO website page titled "Benefits of WHO-FIC". The page features a navigation bar with "Health Topics", "Countries", "Newsroom", "Emergencies", "Data", and "About WHO". The main content is divided into three columns. The left column contains a list of classification types: "International Classification of Diseases (ICD)", "International Classification of Functioning, Disability and Health (ICF)", "International Classification of Health Interventions (ICHI)", "Other Classifications", "Frequently asked questions", and "WHO Family of International Classifications Network". The middle column, titled "Benefits of WHO-FIC", explains that ICD-11, ICF, and ICHI are key for effective knowledge representation and data transfer. It states that WHO-FIC allows all healthcare workers to communicate using one technical language and that shared terminology is key for supporting natural language processing (NLP). It also notes that WHO-FIC with shared terminology is key for effective text mining or text analytics. The right column, titled "Used by", lists several groups: Governments, Researchers, Doctors, Health providers, Hospitals, Laboratories, Insurance companies, and International organizations, each with a brief description of their use. Below this is a "Reference Classifications" section with three circular icons: a blue circle for "ICD-11" (International Statistical Classification of Diseases and related health problems), a red circle for "ICF" (International Classification of Functioning, Disability and Health), and a dark red circle for "ICHI" (Interventions for treatment, prevention and diagnostics). Each icon is accompanied by a short description of its scope. At the bottom, there is a section for "Common Foundation - Terminology components".

# Proposal of co-existence: WHO to be a converging platform with global governance and mapping.

Slide from 2020. Now 2022 got mapping and collaboration from agencies.

Note: Mapping will only be possible if non-restrictive access and collaboration



# Consensus needs to be made by all stakeholders in country

