



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Report from AHWP STG Nomenclature

Yan Liang, Chair
Lindsay Tao, Co- Chair
Nov 4 – 7, 2009
AHWP Annual Conference
HK

Definition and Objective

Based on ISO 15225 Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

Nomenclature:

System of terms which is elaborated according to pre-established naming rules.

The purpose of a medical device nomenclature system is to enable competent authorities, notified body, and manufacturers to meet the requirements of Council Directive on medical device; and facilitate co-operation and exchange of regulatory data on an international level between interested parties such as: regulatory authorities, manufacturers , suppliers, healthcare providers, and end users.

Uses of Nomenclature

Regulatory:

- Product Registration
- Vigilance
- Risk Assignment
- Data Exchange
- Data Element in UDI Data Base

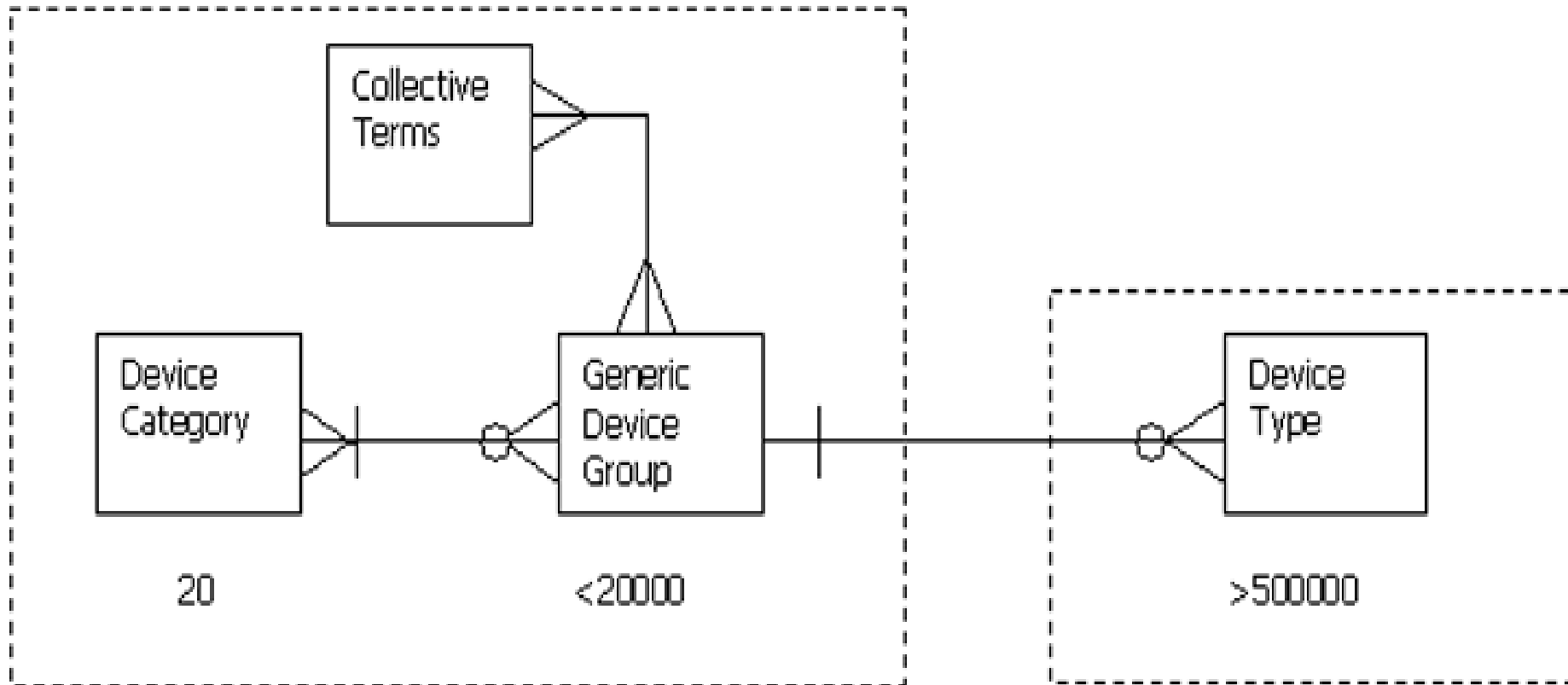
Commercial:

- Procurement
- Tender
- Supply Chain Management
- Medical Facility Inventory and Use Management
- Spend Analysis

Current Well-recognized Nomenclatures

GMDN (Global Medical Device Nomenclature):

- Sources:
 - Universal Medical Device Nomenclature System (UMDNS) ECRI
 - Norwegian Nomenclature (NKKN)
 - Classification Names for Medical Devices and In-Vitro Diagnostic Products (USFDA and Canada)
 - Japanese Medical Device Nomenclature (JFMDA)
 - European Diagnostic Manufacturers Association's In-Vitro Diagnostic Product Classification (EDMA)
 - International Standards Organization for Standardization's Technical Aids for Disabled Persons (ISO 9999)





Records 1-33 from 33

Term	GMDN Code	Source Code	Definition
1. Angiographic catheter, single-use	P 10688	ECRI 10688	A thin, flexible tube designed to inject a contrast medium into select blood vessels of the cerebral, visceral, or peripheral vasculature during an angiographic procedure in order to facilitate the clear visualization of the vascular system of a targeted organ or area of the body. It is introduced percutaneously and has radiopaque bands spaced along its distal working end to indicate its position within the body and to make anatomical measurements. It may also be used for simultaneous pressure measurements to determine the transvalvular, intravascular and intraventricular pressure gradients. This is a single-use device. See also Intravascular microflow catheter ; Microflow infusion system
2. Angioplasty catheter, balloon dilatation, coronary, cutting/scoring	P 44088		A flexible tube designed for used in percutaneous transluminal coronary angioplasty (PTCA) that dilates a stenotic coronary artery, to increase myocardial perfusion, by controlled inflation of a distensible balloon at its distal tip with peripheral cutting/scoring elements (e.g., microsurgical atherotomes) intended to remove stenotic material. The device is typically placed using a guidewire and guiding catheter, and its balloon is

Current Well-recognized Nomenclatures

UMDN (Universal Medical Device Nomenclature)

Used long before medical device regulatory system is established, and widely in hospital and inventory management;

Maintained by US. ECRI (Emergency Care Research Institute)

Some points from comparisons

1. Establish on different purpose. Purchase or Surveillance.
2. Different on hierarchical directory structure
3. Same words, but not same on the definition of terms base on risk
4. Different on term code system
5. Hundred-percent mapping between GMDN and UMDN is nearly impossible

AHWP STG Nomenclature History



- **Issues raised regarding GMDN by some AHWP members (HK, Singapore): license fees, transparency, copy right, and etc.**

- **March 2008:**

ECRI and GMND Agency **invited to present UMDN and GMDN systems** respectively during AHWP meetings at Kuala Lumpur. (GHTF, WHO participating)

- **April 2008:**

Participated in **the GHTF Ad Hoc Working Group on GMDN Governance**

- a model with 13 trustees including 2 AHWP representatives in an International Board of Trustees proposed
- comments from AHWP members consolidated including charging mechanism

STG Nomenclature History



- **May 2008:**

AHWP Chair Dr. Pillay wrote to GMDN agency on behalf of AHWP, raising concerns about license fees and corporate governance structure

- **December 2008**

New GMDN corporate governance structure proposed, with leadership from GHTF, and invite participation from AHWP

- Board of Trustee comprising the 2 existing trustee, 2 GHTF, 1 AHWP, and 1 industry
- Policy Advisory Group comprising 5 GHTF, 5 AHWP, 5 industry and 1 WHO

STG Nomenclature Progress



- **Three telecoms and one face-to-face meeting : Feb, April, May, Sept, 2009**
- **Topics discussed at these meetings:**
 - Global views on nomenclature (BSI, WHO, HK, GHTF)
 - Progress at GMDN since new governance model adoption (GMDN board of trustee)
 - AHWP nomination to GMDN
 - Discussing AHWP statement on nomenclature
- **Progress so far:**
 - Nomination of Alfred Kwek, Singapore HAS to Board of Trustee of GMDN representing AHWP
 - STG statement

- All the GHTF regulators and the industry members are strongly in support of the GMDN.
- Australia is fully supportive of the GMDN and has embedded the requirement for GMDN terminology in their new device regulations.
- GMDN is in the process of being adopted by both the USFDA and the EU.
- Canada is also moving to adopt the GMDN through policy as this is a simpler process than putting the requirement in regulation.
- Japan: JMDN

News on the First Page of GMDN Website

REDUCED MEMBERSHIP COST FOR SMALLER MANUFACTURERS

GMDN Agency is pleased to introduce a reduced level of Annual Contribution for smaller manufacturers with only few generic products, and with annual sales below 1 million Euros. This reduces the base annual cost to 100 Euros, allowing full internet access to all terms (up to 20,000), and the versatile search mechanism, plus identification of a number of codes for selected generic terms (see details for Schedule 'B' Members).

15/08/2009

TRUSTEES SUPPORT - COMMITMENT TO PURSUE FUTURE FREE ACCESS

It has, for many years, been the preferred wish of GMDN Agency to be able to provide access to GMDN, free at the point of use (e.g. free to manufacturers, hospitals, etc). It is thus necessary to obtain a guarantee of annual funding, to cover the continuing costs of developing and managing the large data file. The enlarged Board of Trustees at its first meeting confirmed its commitment to achieve this goal of "Free Access", by means of appropriate world-wide funding, (e.g. - by means of shared annual costs between Global Regulatory Bodies). Footnote:-- GMDN is working in cooperation with the Global Harmonisation Task Force (GHTF), The Asian Harmonisation Working Party and others, to enhance the governance structure of GMDN, and to provide appropriate input from its many stakeholders.

15/08/2009



News

- [REDUCED MEMBERSHIP COST FOR SMALLER MANUFACTURERS](#)
- [TRUSTEES SUPPORT - COMMITMENT TO PURSUE FUTURE FREE ACCESS](#)

I am a GMDN member

Login

Password

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[Forgotten your password?](#)

GMDN Agency Service

Services provided by the GMDN Agency are:

- Access to the GMDN data file and codes via this Internet site through a licence agreement and/or by direct credit card purchase.
- A link from the GMDN database to the user's in-house data system through a licence agreement and a specialised software link.
- Application form for new terms or modification of existing terms/definitions for the identification of the user's product.
- Access to GMDN terminology and information.
- Guidance on how to use the GMDN.
- Access to Collective Terms and codes.
- GMDN translation software tool.

Actions

- [I would like to become a member of GMDN](#) [Continue](#)
- [I would like to submit a proposal for a GMDN term](#) [Continue](#)
- [I would like to learn about the GMDN](#) [Continue](#)
- [I would like to contact the GMDN Agency](#) [Continue](#)
- [I would like a free copy of the GMDN User Guidance](#) [Continue](#)

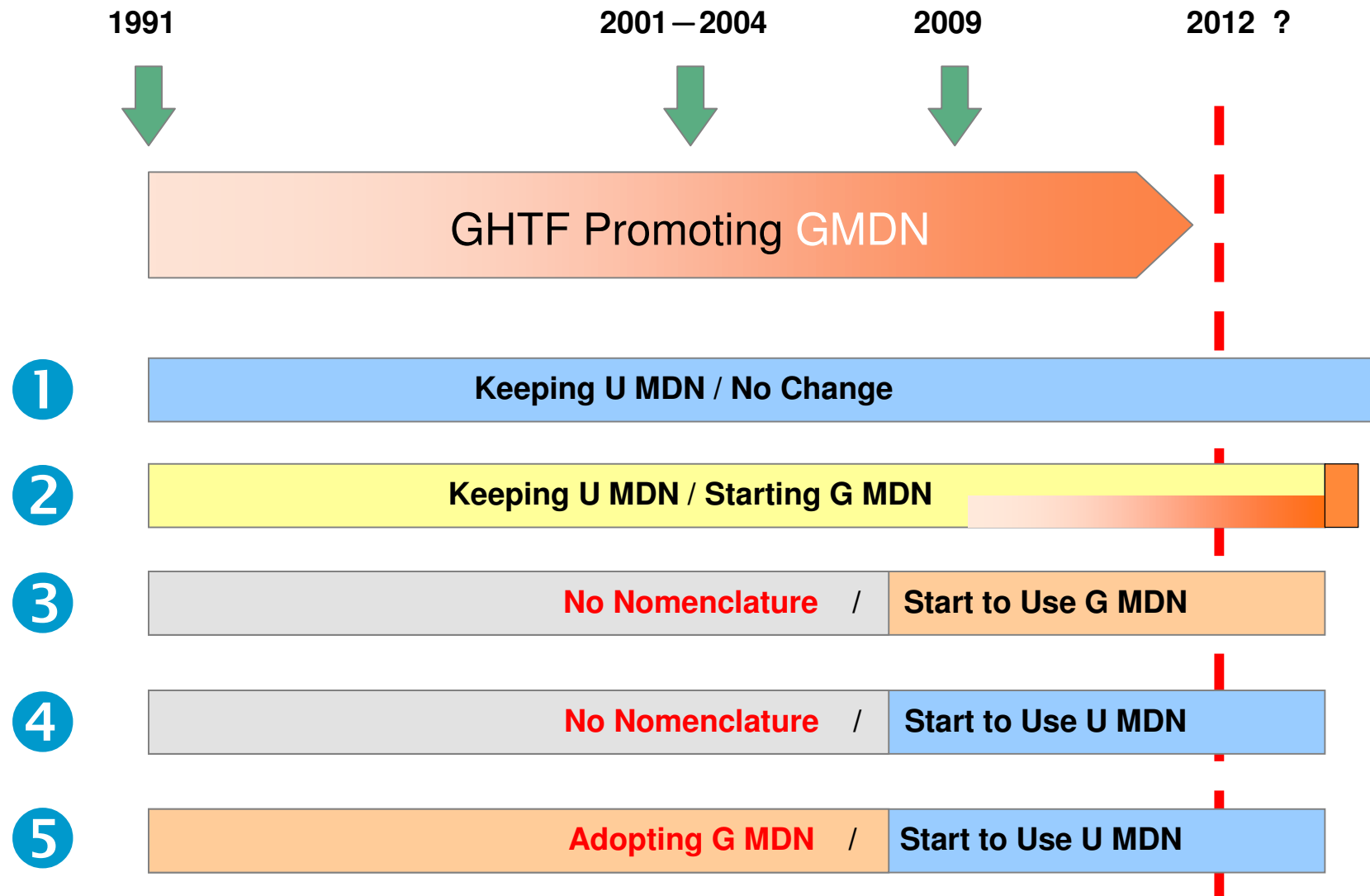
Next Step:



- Keep align with GHTF direction
 - Join GHTF efforts on GMDN
 - Finalize nomination, participate GMDN governance and committee its continuous improvement
- At the same time:
 - In view of the urgency, AHWP members choice and implement nomenclature based on their own needs and judgment
 - Share experience with other AHWP members

GHTF harmonizing for adopting GMDN, GHTF Never promoting UMDN

- Where will we go? you take the decision





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Thank You

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