Global Medical Device Nomenclature Overview

- Present a Brief History
- Describe its Development
- Describe its Current Status
- Discuss its Maintenance, Licensure Terms, FDA Utilization, other Pertinent Issues
Global Medical Device Nomenclature
Brief History

• Initiated 1993 by European Committee for Standardization to Meet EU Requirements of Medical Device Directives
  – product certification/registration
  – vigilance reporting
  – product recall

• Draft Standard Developed, with ISO, 1996
  – Nomenclature-specification for a nomenclature system for medical devices for the purpose of regulatory data exchange
  – EN 1874 & EN ISO 15225

• GMDN Project Initiated, 1997
GMDN Standard

• Structure
  – Device Category: active implantable
  – Generic Device group: pacemaker
  – Device Type: manufacturer, model

• Basic Naming Conventions
  – base concepts & qualifiers
  – types of terms (preferred, template, synonym)

• Data Files
  – numeric codes
  – field length (terms/definitions)
Nomenclature Systems Used in Development

- Universal Medical Device Nomenclature System (ECRI)
- Norwegian Nomenclature (NKKN)
- Classification Names for Medical Devices and In Vitro Diagnostic Products (FDA)
- Japanese Nomenclature (JFMDA)
- European Diagnostic Manufacturers Association’s In Vitro Diagnostic Product Classification (EDMA)
- International Organization for Standardization’s Technical Aids for Disabled Persons Classification (ISO 9999)
Candidate List of Medical Device Terms

- 13,000 Terms for Generic Device Groups
- Identification of Equivalent Sets of Terms

*Example*: Concept = Carbon Dioxide Absorber

- ECRI - Anesthesia Unit Absorber, Carbon dioxide
- NKKN - Anaesthesia, Absorber, Carbon dioxide
- FDA - Absorber, Carbon Dioxide

- automated processing
  - UMLS SPECIALIST Lexicon
- manual review
Device Categories for Distribution of Terms in Candidate List

- Active Implantable Devices
- Anesthetic/Respiratory Devices
- Dental Devices
- Electro-Medical/Mechanical Devices
- Hospital Hardware
- In Vitro Diagnostic Devices
- Non-active Implantable Devices
- Ophthalmic and Optical Devices
- Reusable Instruments
- Single-Use Devices
- Technical Aids for Disabled Persons
- Diagnostic and Therapeutic Radiation Devices
Global Medical Device Nomenclature

Project Organization

- PROJECT COUNCIL
- EXPERT ADVISORY TEAM
  - DEVICE EXPERT TASK GROUP 1
  - DEVICE EXPERT TASK GROUP 2
  - DEVICE EXPERT TASK GROUP 3
  - DEVICE EXPERT TASK GROUP 4
  - DEVICE EXPERT TASK GROUP 5
  - DEVICE EXPERT TASK GROUP 6
  - DEVICE EXPERT TASK GROUP 7
  - DEVICE EXPERT TASK GROUP 8
  - DEVICE EXPERT TASK GROUP 9
  - DEVICE EXPERT TASK GROUP 10
  - DEVICE EXPERT TASK GROUP 11
  - DEVICE EXPERT TASK GROUP 12
Device Expert Task Group Work Activities
Terms

• Select a “Preferred Term” to Represent Each Generic Device Group
• Create a Preferred Term if No Satisfactory Term Exists
• Link Remaining Terms in Equivalent Set to the Preferred Term as a “Synonym Term” or “Equivalent Term”
• Create Synonym Terms
## Device Expert Task Group Work Activities Example

<table>
<thead>
<tr>
<th>Candidate List Terms</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fundus Camera</td>
<td>NKKN</td>
</tr>
<tr>
<td>Cameras, Fundus</td>
<td>ECRI</td>
</tr>
<tr>
<td>Fundus Camera</td>
<td>JFMDA</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>GMDN Terms</th>
<th>Term Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera, fundus</td>
<td>Preferred</td>
</tr>
<tr>
<td>Fundus camera</td>
<td>Synonym</td>
</tr>
<tr>
<td>Fundus camera</td>
<td>Equivalent</td>
</tr>
<tr>
<td>Candidate List Terms</td>
<td>Source</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Cameras, Multi-Image</td>
<td>ECRI</td>
</tr>
<tr>
<td>Camera, Multi Format</td>
<td>FDA</td>
</tr>
<tr>
<td>Camera, laser</td>
<td>NKKN</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>GMDN Terms</th>
<th>Term Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Camera, diagnostic imaging, multi-format</td>
<td>Preferred</td>
</tr>
<tr>
<td>Camera, multi-image</td>
<td>Synonym</td>
</tr>
<tr>
<td>Camera, multi format</td>
<td>Synonym</td>
</tr>
<tr>
<td>Camera, laser</td>
<td>Synonym</td>
</tr>
<tr>
<td>Laser imager, multi-format</td>
<td>Synonym</td>
</tr>
</tbody>
</table>
Device Expert Task Group Work Activities
Definitions

Based on CEN draft standard: Medical informatics - categorical structure of systems of concepts - medical devices

- express device intended use
- express target area of intended use
- describe device technical principal or working method
- describe materials/components involved
- describe device form/shape/physical state
“Camera, fundus” - Definition
A box-like device that holds photographic film and is used specifically to focus and record magnified images of the ocular fundus (posterior region of the internal eye) viewed through the pupil.
**Expert Advisory Team Work Activities**

**Example**

<table>
<thead>
<tr>
<th>GMDN Term</th>
<th>Category</th>
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<tr>
<td>Camera, cine</td>
<td>Electro/Mech</td>
</tr>
<tr>
<td>Camera, diagnostic imaging, minifying</td>
<td>Radiological</td>
</tr>
<tr>
<td>Camera, diagnostic imaging, multi-format</td>
<td>Radiological</td>
</tr>
<tr>
<td>Camera, fundus</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Camera, ophthalmic</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Camera, oscilloscope</td>
<td>Electro/Mech</td>
</tr>
<tr>
<td>Camera, thermographie</td>
<td>Radiological</td>
</tr>
<tr>
<td>Camera, video</td>
<td>Electro/Mech</td>
</tr>
</tbody>
</table>
Global Medical Device Nomenclature

Camera, <specify>
  Camera, cine
Camera, diagnostic imaging, minifying
    X-ray film minifier
Camera, diagnostic imaging, multi-format
  Camera, multi-image
  Laser imager, multi-format
Camera, fundus
Camera, ophthalmic
Camera, oscilloscope
  Oscilloscope camera
Camera, thermographic

Camera, video, <specify>
  Camera, video, endoscopic
Camera, video, microsurgical
Camera, video, surgical
Global Medical Device Nomenclature
Current Status of Development

• Work Performed since September 2002
  - Base Concept Standardization
  - Improved Definitions
  - Newly linked Synonym Terms
  - Preferred Terms added for New Devices

• Comprised of 17,000 Terms
  - 6,400 preferred terms
  - 10,000 synonym terms
  - 600 template terms
Global Medical Device Nomenclature Maintenance Agency

• Structure
  - **Policy Group**: regulators, CEN/ISO members, industry representatives, Commission, GHTF
  - **Experts**: FDA, NKKN, Health Canada, Academia
  - **Secretariat**: BSI transitioning to Commercial Company

• Roles
  - Policy Group to provide oversight, set policy
  - Experts to develop/amend terms and definitions
  - Secretariat to maintain/publish GMDN; receive proposals, develop user guidance, publicize program
Global Medical Device Nomenclature
Regulatory Body Licensure/Distribution

• GMDN use requires signed license
• Voluntary sponsorship to assist in maintenance costs
• License valid for 12 months, automatically renewed
• Data file distributed to licensed users on CD-Rom
• Transitioning to include direct data access via the internet
• Regulatory body public access limited to word searches
Global Medical Device Nomenclature
Data Maintenance

• Maintenance Agency must be contacted to modify data
• Data continuously updated by Expert Team
• Requests for new terms dealt with as received
• Responses provided within a few weeks
• New version with updates released at least once a year
Global Medical Device Nomenclature

Funding

- Regulatory body voluntary sponsorship
- License fee for all other users
- Secretariat to use GMDN as trade name in association with the sale of other products and services via the internet
Global Medical Device Nomenclature

UMDNS Issues

- **GMDN**: International Nomenclature, provides Generic Descriptors for Medical Devices.

- **GMDN**: based on an International Standard – ISO 15225 – which ensures that the structure of nomenclature terms are based on a consistent, standardized format.

- **UMDNS**: one of 6 nomenclatures used to develop the GMDN.

- At inception of GMDN, UMDNS did not cover all devices – although it has since publication of GMDN taken many terms from GMDN to expand its scope – nevertheless GMDN is much wider in its scope.

- Attempting to develop plans with ECRI to merge
Global Medical Device Nomenclature
FDA Utilization

- FDA investing in GMDN structure
- Beginning mapping efforts 2003
- Converting systems to use of GMDN: 2004
- Developing web-interface for industry and consumers: 2004/2005
Global Medical Device Nomenclature
International Utilization

• GMDN used 70 experts from 16 countries; available for development and maintenance.
• GMDN adopted for use by EEA – i.e. 18 members plus 10 Eastern European countries.
• Japan adopted GMDN: translated the terms & definitions
• Australian Regulation: GMDN in its requirements.
• A number of South American Countries are adopting GMDN and some have already translated this into appropriate Spanish or Portuguese Language.
• “Asian Harmonization Working Party” starting to adopt GMDN
• GMDN adopted by GHTF (Global Harmonization Task Force – for medical devices) as the means of establishing generic descriptors for devices.