## Questionnaire regarding nomenclatures for concepts related to health technologies

1. **Name of the "nomenclature"**
   
   Universal Medical Device Nomenclature System (UMDNS)

2. **Name and legal status (Inc, Plc, Ltd, …) of the organization that manages the nomenclature system**
   
   ECRI Institute is a 501(c) iii nonprofit organization.

3. **The organization that manages the nomenclature**
   
   a. **Please describe the governance and management of the body responsible for maintaining the nomenclature.**
      
      ECRI Institute is a 42-year-old independent nongovernmental, nonprofit organization, governed by an Executive Committee and a Board of Trustees.

      ECRI Institute uses UMDNS in all of its own databases, tools and publications related to medical devices. Updating and maintaining the nomenclature is a necessity for ECRI Institute, both for its internal use and to provide support to our external clients and licensees. ECRI’s obligation to maintain UMDNS is formally recognized by its Board of Trustees and was part of its terms of reference as a World Health Organization Collaborating Centre.

   b. **How is broad stakeholder representation ensured?**
      
      UMDNS has been licensed and used for decades by a wide variety of stakeholders worldwide. These include governmental agencies, hospitals, medical device manufacturers, researchers, developers of software applications, medical equipment procurement websites, global consulting firms, and many others. All stakeholders may request new terms or request guidance for applying existing terms.

   c. **How is broad geographical representation ensured in governing bodies?**
      
      UMDNS has more than 3,200 licensees in more than 100 countries, all of whom are entitled to request new terms or request guidance for applying existing terms. ECRI Institute, headquartered in the U.S, has regional offices in Europe, Asia and the Middle East. Regional Directors are involved in setting strategy and policy for UMDNS to ensure that the needs of UMDNS users in these areas are met.
4. Background to the creation of the nomenclature

Please outline the scope of the mandate to engage in classification and naming

ECRI Institute is an EN 1572 Registration Authority Issuing Organization under ISO/IEC 15459, Information Technology. UMDNS has been incorporated into the Unified Medical Language System (UMLS) for more than 20 years. UMDNS is and has been the central organizing concept in all ECRI medical device and patient safety information products and tools for 41 years.

5. What is the intended purpose/use of the system?

The purpose of UMDNS is to facilitate identifying, processing, filing, storing, retrieving, transferring, and communicating data about medical devices.

The nomenclature is used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device management databases. UMDNS is used in a range of patient safety applications, including for tracking device-related adverse incidents and problems. The latest use of UMDNS is for horizon scanning of emerging medical technologies in the research and development phase.

6. Mandatory use of the nomenclature

a. Has any country or organization made it mandatory to use the nomenclature for specific purposes?

The Hong Kong Ministry of Health Medical Device Control Office mandates the use of AMDNS/UMDNS codes for product registration. UMDNS is also the official nomenclature system in Israel, Jordan, Panama, and, along with GMDN, in Switzerland. Most countries that encourage the use of UMDNS for product registration and identification do so on a voluntary basis. Many agencies and organizations have utilized UMDNS in internal applications (eg, the U.S. Dept. of Defense Defense Medical Logistics System, the U.S Veteran’s Administration). Other agencies offer access to ECRI databases that are built with UMDNS (eg, Kingdom of Saudi Arabia Food and Drug Authority Medical Device Data Base). Many agencies use UMDNS in their tender offers and bulletins to specify hospital equipment (eg, South Africa).

7. Please comprehensively describe the structure of the system. The structure and format of terms, the relations between terms, design principles for creating terms etc. Current IT implementations by the "management organization" and by users are also of interest.
UMDNS includes all medical devices and supplies, clinical laboratory equipment and in vitro diagnostics, genetic tests, medical software related to devices, selected hospital furniture, systems and test equipment, as well as personal and assistive devices. It is a formal, polyhierarchical system for organizing device-related information. It is maintained as a relational database which includes attributes and properties.

UMDNS is a richly interrelated vocabulary based on preferred and entry terms. Terms are assigned a 5 digit code using consecutive numbering with no intrinsic meaning. Properties provide additional attributes for classification such as clinical specialty, reusable, disposal, etc.

UMDNS follows best practices for controlled vocabulary development where each device concept is associated with a nonambiguous definition. This is a very important point as the nomenclature approach, in addition to facilitating the hierarchical structure, clarifies the scope and boundaries among concepts used in practice. This approach is also intended to facilitate at first glance a clear idea of the type of devices that the concept includes.

A few examples of the UMDNS category approach are presented below:

Laboratory and Point of Care Analyzers always mean devices designed to be used for in vitro detection/measurement of specified analytes.

Physiologic Analyzers always mean devices designed to assess one or more characteristics related to the processes and/or functions of the human body (i.e., human physiology).

Hierarchically structured nomenclatures and clear definitions facilitate the addition of new concepts and evaluation of usefully related categories of devices.

8. **Are the terms used in the classification system generic i.e. non proprietary?**

   UMDNS terms are generic. Proprietary terms may be used as entry terms leading the user to the preferred term for that concept.

9. **Maintenance of the nomenclature system**
   
   a. **How is the system maintained?**
UMDNS is maintained using the Apelon Terminology Development Environment (TDE) application. The work processes are managed via Microsoft SharePoint. There is a core group of ECRI dedicated nomenclature specialists who focus on developing and maintaining the vocabulary on a daily basis, according to documented and systematic protocols. They are supported by 380 ECRI staff members who contribute their technical knowledge to nomenclature development and review processes.

b. **Please describe the process for creating or modifying terms in the system.**

Term modification/development is triggered by requests from internal (ECRI) or external users of the vocabulary. Suggestions for new terms and modifications may be made through an online form available on the UMDNS webpage or by email to UMDNS@ecri.org. These suggestions are automatically queued and triaged by members of the UMDNS development team. ECRI has developed decision algorithms to determine whether the suggestion should result in a new term, a modification of an existing definition, or guidance leading the requestor to the appropriate existing term. Additional algorithms have been developed to determine where the new term should be placed within UMDNS’s classification structure.

Each UMDNS term is researched by an ECRI nomenclature specialist and is reviewed by both nomenclature and topic specialists for technical merit and consistency. All new UMDNS terms must include a definition, clinical specialty, and UMDNS is updated continuously.

c. **How is transparency ensured with regard to development and maintenance of the nomenclature?**

Procedures for UMDNS development are documented and all suggestions, term proposals and review documents are archived. Date stamps are maintained for all modifications to the dataset.

10. **Different language versions of the nomenclature**

a. **How is the translation of terms and definitions managed?**

The Spanish translation of UMDNS has been created and is maintained by Spanish-speaking nomenclature experts at ECRI. Previous translations (e.g. German) have been made by other organizations such as DIMDI with input from ECRI nomenclature experts. In general, ECRI offers special assistance to groups involved in translation.

b. **What language versions exist as of February 2011?**

The Spanish translation of the UMDNS maintained by ECRI, and German, French, Polish, and Arabic translations based on earlier version of the vocabulary.
c. What language versions are under translation as of February 2011?

The Spanish translation is currently being updated.

11. Endorsement of the nomenclature system

a. Has the system been endorsed by stakeholders (healthcare professionals, Ministries of Health, industry, regulatory bodies etc.)?

[ ] Yes [ ] No

Please indicate the names of the entities which have endorsed the system.

Members of the Asian Harmonization Working Party (AHWP), such as the Hong Kong MDCO, currently use the Asian Medical Device Nomenclature System (AMDNS) which is 100% compatible with UMDNS. AMDNS is updated monthly by ECRI Institute.

The Healthcare Information and Management Systems Society (HIMSS) recommends using ECRI's UMDNS in its new Manufacturer Disclosure Statement for Medical Device Security (MDS2) form.

The Committee on Data Standards for Patient Safety of the U.S. Institute of Medicine recommended UMDNS as one of the core terminologies for the electronic health record.

DIMDI references and links to ECRI’s information on UMDNS.

Many hospital maintenance management software providers (eg, Four Rivers) have endorsed UMDNS.

IBM has licensed UMDNS for incorporation into its products.

Kaiser Permanente is utilizing UMDNS in its device planning. Global consulting firms such as i3 have endorsed and implemented UMDNS. WHO itself uses UMDNS in its resource planning tool for developing countries.

12. Implementation in IT systems, interoperability and intellectual property

a. Please outline the intellectual property state of the nomenclature system. Please include reference to the ownership of the terms used.
UMDNS is owned and copyrighted by ECRI Institute, which makes it freely available to licensees via a website.

b. Is the system available as a package for integration into user IT systems (maintenance management, adverse event reporting, procurement….)?

c. [ ] Yes [ ] No

d. Please specify the conditions of agreements for use in user IT systems.

UMDNS has been delivered via web services as an integral part of ECRI information products embedded in various computerized maintenance management systems (CMMS) systems for several years. In these cases, the UMDNS agreement is included with the purchase of additional ECRI data. Individual contracts and agreements are also created based on requests from the user and the requirements of the specific application. UMDNS data can be delivered in XML, text, Excel or other formats, according to the needs of the IT system vendor or owner. UMDNS is currently embedded in IT systems used by thousands of hospitals in the US and elsewhere.

13. Interoperability

   Please specify compatibilities ensured and mappings to other nomenclatures maintained.
14. Model for sustainable financing
a. How is the system financed? I.e. user fees, member fees, subscriptions, one off payments, open source?

ECRI Institute funds the development and maintenance of UMDNS from the proceeds of its own patient safety and medical technology management databases, publications, and tools that utilize UMDNS. There are no user or access fees for regulatory agencies, hospitals, manufacturers and other non-commercial uses. We do not seek to derive any revenue from the basic UMDNS.

b. What is the cost of the nomenclature to specific users (governments, industry, health care providers)?

UMDNS has been a source vocabulary in the U.S. National Library of Medicine’s Unified Medical Language System (UMLS) Metathesaurus since the tool’s creation. Inclusion in this tool links UMDNS to the more than 150 other languages in the Metathesaurus at the concept level, including to ICD and SNOMED.

« The Metathesaurus is a very large, multi-purpose, and multi-lingual vocabulary database that contains information about biomedical and health related concepts, their various names, and the relationships among them. Designed for use by system developers, the Metathesaurus is built from the electronic versions of many different thesauri, classifications, code sets, and lists of controlled terms used in patient care, health services billing, public health statistics, indexing and cataloging biomedical literature, and/or basic, clinical, and health services research. These are referred to as the "source vocabularies" of the Metathesaurus. »

Following an agreement established in 2010 with GS1, ECRI has recently completed a bidirectional mapping between UMDNS and UNSPSC. This mapping will be maintained on an ongoing basis. An additional mapping between UMDNS and HCPCS will be undertaken, partially based on tools available via the UMLS.

Unfortunately, we are no longer able to maintain the UMDNS to GMDN mapping, since we are not granted access to GMDN. The GMDN to UMDNS mapping that is referenced by the GMDN Agency is based on a very old version of UMDNS (1998) and is no longer compatible with current UMDNS.
The Universal Medical Device Nomenclature System™ (UMDNS™) is available via ECRI’s Website (www.ecri.org), and is licensed **free of charge** to all government agencies, not-for-profit organizations including hospitals, and to medical device manufacturers.

The Asian Medical Device Nomenclature System (AMDNS), which is fully compatible with UMDNS, is available via the Hong Kong MDCO Website, and is also licensed **free of charge**.

Commercial vendors and application developers seeking to sell or lease UMDNS to third parties must request ECRI Institute’s permission, and may be charged a fee.

Authorized users of UMDNS and AMDNS may request new or modified nomenclature and code assignments, or clarifications of meaning, from ECRI Institute at any time at no charge.