



GMDN and IHTSDO sign Cooperation Agreement

Oxford, UK and Copenhagen, Denmark: 27 April, 2012

The Global Medical Device Nomenclature Agency (GMDNA) responsible for the international naming system for medical devices (GMDN) and the International Health Terminology Standards Development Organization (IHTSDO), the leading provider of standardized clinical terminology (SNOMED CT), are pleased to announce that they have signed a Cooperation Agreement.

The Cooperation Agreement shall result in the use of the GMDN as the basis for the medical device component of SNOMED CT and the opportunity for GMDN to be populated with any SNOMED CT medical device component content that is not pre-existing. The Agreement is consistent with the aims of both organizations to minimize duplication and to support harmonization and is the culmination of discussions over the last year relating to how the two organizations can work together for the mutual benefit of their stakeholders, including:

- A more comprehensive and harmonized clinical terminology
- Greater utility and access to both terminologies
- Opportunities to improve organizational efficiencies

The initial duration of the Agreement is for a period of five years and the parties intend to identify further opportunities to work closer together for the benefit of their stakeholders.

The Agreement will benefit patients across the world and all users of SNOMED CT and the GMDN in promoting comprehensive terminology based medical records, covering the needs of regulators, the medical device industry and healthcare professionals. The arrangement will help to link the medical device supply chain to the application of care to individual patients for medical device, patient risk and safety use cases.

The arrangement will provide patient safety benefits in terms of recall of defective devices, when model and serial number or later UDI are stored in patient records, public health analysis on morbidity and mortality in correlation with medical devices and will also ensure the quality of the supply chain.

Andy Wiesenthal, acting Chair of the IHTSDO Management Board, said of the agreement, "I'm delighted with this cooperation arrangement. It will make it possible to incorporate the extensive medical device content of GMDN into SNOMED CT for the benefit of all SNOMED CT users".

Janet Trunzo, Chair of the GMDNA Committee, added "the agreement will make GMDN content more widely available for the ultimate benefit of patients and global health. Both parties have also committed to identify if there are ways of working more closely together to deliver further benefits".

About the GMDN Agency

GMDN or Global Medical Device Nomenclature is a system of internationally agreed descriptors used to identify medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. The main purpose of the GMDN is to provide health authorities / regulators, health care providers, medical device manufacturers and suppliers, conformity assessment bodies and others with a single naming system that will support patient safety. Information in the form of a 5 digit numeric code is cross referenced to a precisely defined descriptive term, with which the device can be identified by type with substantially similar generic features. This is important for reasons of data exchange between healthcare authorities, manufacturers and others, exchange of post-market vigilance information, inventory control and purchasing. GMDN is managed by the GMDN Agency, a non-profit organization, which reports to its Board of Trustees, that represents medical device regulators and industry. Access to GMDN is priced according to organization size. GMDN is available in English and other languages. The GMDN Agency updates the GMDN from subscriber change requests, to add a new device term in the GMDN or to change an existing code. The decisions are made by an international expert team on how the new term is to be described, according to ISO 15225. The GMDN Agency releases updated GMDN terms on a daily basis, on their interactive website.

For further information please visit www.gmdnagency.org

About IHTSDO

The IHTSDO (International Health Terminology Standards Development Organisation) and its current 19 Members seek to improve the health of humankind by fostering the development and use of suitable standardized clinical terminologies, notably SNOMED CT, in order to support the safe, accurate, and effective exchange of health information. IHTSDO's governance structure allows Members to control and guide the development of SNOMED CT, to ensure it meets both their joint needs and the specific needs of their individual countries. SNOMED Clinical Terms™ (SNOMED CT™) is a standardized terminology that can be used as the foundation for electronic health records and other applications. SNOMED CT contains more than 310,000 unique concepts and more than 1.3 million links or relationships between them that ensure that this information is captured consistently, accurately, and reliably across health systems. The terminology is in use in more than fifty countries around the world. SNOMED CT was originally created by the College of American Pathologists by combining SNOMED RT and a computer-based nomenclature and classification known as Clinical Terms Version 3, formerly known as Read Codes Version 3.

For more information please visit: www.ihtsdo.org

Notes to Editors

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FREQUENTLY ASKED QUESTIONS

Q: I have a licence agreement relating to GMDN and/or SNOMED CT. Will these arrangements be affected and do I need to take any action?

No. Your existing licence agreements will continue un-amended and you need take no action

Q: It has been announced that the Cooperation Agreement has a five year duration. What will happen to the medical device content from GMDN or SNOMED CT that is used to populate the other if the arrangement is not extended?

The parties have granted each other perpetual, irrevocable, worldwide licences to any content that is shared and so the shared content will remain on any expiry and there will be no impact, thus guaranteeing that content in Electronic Records will remain accessible.

Q: What will be the benefit to medical device manufacturers?

GMDN medical device content will be used to populate SNOMED CT so the terminology used to categorize medical devices for regulatory purposes will also be used to categorize devices used in health care. Where procedures are recorded using clinical software coded using SNOMED CT, it will be possible to produce aggregated health data involving patients with specific types of devices as categorized within GMDN. This will enable health outcomes related to medical devices to be more easily monitored and contribute to the development of more effective medical devices.

Q: What will be the benefit to users of SNOMED CT?

Users will have access to GMDN medical device content enabling the population of medical device use cases involving electronic health records. This, in turn, will also enable more effective medical device stock control, purchasing and procedure planning (e.g., implementation of controls to prevent the scheduling of procedures when there is no stock).

Q: What will be the benefit to patients?

It will enhance: traceability; a richer electronic health record; and measurement of health outcomes, all of which will support improvements to individual and general health care. The arrangement will enable patient safety benefits in terms of identification and review of patients with specific types of device, when safety issues arise with some makes or models of that type and public health analysis of morbidity and mortality in correlation with medical devices. It will also help to ensure the quality of the supply chain.

Q: What will be the benefit to regulators of medical devices?

GMDN medical device content will be used to populate SNOMED CT. Where procedures are recorded using clinical software coded using SNOMED CT, it will enable more effective traceability, audit and recall.

Q: Will there be any changes to the frequency at which GMDN and the International Release of SNOMED CT are updated/released?

There are no plans to change the frequency of updates/releases as a result of this arrangement. Updates to GMDN will continue to be made on an as required and daily basis and the International Release of SNOMED CT published every six months.

Q: What will happen if I identify a potential error or correction that is required to GMDN or SNOMED CT.

You should report it using the same method as now. GMDNA, National Release Centers and the IHTSDO will ensure that any necessary changes are transmitted to the relevant parties and that the terminologies are updated and harmonized as required.

Q: How will the arrangement be governed?

The respective CEOs will manage the routine operations and the parties have established an Executive Policy Group consisting of four members from each party to manage more strategic matters.