

SNOMED CT MedDRA Simple Map package Release Notes - January 2021

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Page At A Glance

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1. Introduction

The SNOMED CT terminology provides a common language that enables a consistent way of indexing, storing, retrieving, and aggregating clinical data across specialties and sites of care. The International Health Terminology Standards Development Organisation (IHTSDO®) maintains the SNOMED CT technical design, the content architecture, the SNOMED CT content (including the concepts table, the descriptions table, the relationships table, a history table and mappings), and related technical documentation.

This document is intended to give a brief description, background context and explanatory notes on the SNOMED CT International/ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) work through the EU funded WEB RADR 2 project and the resulting SNOMED CT/MedDRA maps, which are being published as a Production release in April 2021. This document covers the background to the collaboration between SNOMED International and ICH, through the MedDRA MSSO, as part of the project and goes on to cover the consequent release artefacts. It is not a detailed technical document of SNOMED CT, MedDRA or the SNOMED CT International/ MedDRA release. Nor does it seek to provide an editorial policy for this content though does provide a link to the Mapping conventions developed and used.

The Production release in April 2021 is available to licensed users of either SNOMED CT or MedDRA.

2. Audience for this document

This document should be read by all those (SNOMED International National Release Centers, vendors of electronic health records, terminology developers, Regulators and Pharmaceutical Industry) with an interest in the usage of this content in SNOMED CT and its linkage with MedDRA i.e. the SNOMED CT to MedDRA and MedDRA to SNOMED CT maps based on a priority set of MedDRA.

3. Background

In 2018, SNOMED International and ICH joined the WEB-RADR 2 project, funded by Innovative Medicines Initiative (IMI). SNOMED International and ICH (through MedDRA MSSO) led the effort to develop 2 maps between SNOMED CT and MedDRA. A specific work package was devoted to this purpose and included participants from regulatory authorities and industry as well as SNOMED International and MedDRA MSSO. The project delivered the following:

- 2 maps (MedDRA to SNOMED CT and SNOMED CT to MedDRA) of frequently-used pharmacovigilance MedDRA terms that were identified from databases from the UK's Medicines & Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA). This subset represents the high value terms to support interoperability between the terminologies.
- A set of Mapping conventions that were drafted as part of a pilot set and updated for the main body of work.
- A small number of content additions to SNOMED CT in support of the MedDRA high value terms as defined by scope and editorial rules of SNOMED CT.

The Use cases of the project and the process of maintenance and updating of the 2 maps are defined as follows:

SNOMED CT to MedDRA map use case:

Key pharmacovigilance concepts when coded in SNOMED CT in an electronic health record could be converted to MedDRA for the purpose of adverse event reporting to regulatory authorities or for the purposes of epidemiological research.

MedDRA to SNOMED CT map use case:

Clinical care decision support: Terms coded in MedDRA representing adverse events, warnings, and other regulatory information in product labeling could be converted into SNOMED CT so that the information is integrated into the electronic health record or decision support system to be visible to healthcare professionals when prescribing, dispensing, or administering the product to patients.

Map development process:

The mapping work was undertaken using dual independent review by mappers who were Consortium members of the WEB RADR 2 project and experts in either SNOMED CT or MedDRA. Quality Assurance, based on the mapping conventions specifically developed against the use cases, was managed as part of the process by SNOMED International and MedDRA MSSO (on behalf of ICH) and technical assurance reports provided weekly using the Mapping tool used by all participants. In parallel to the mapping work, the operational aspects have been developed to support the activities and processes to enable the 2 Maps to move in to Production in April 2021 and from there to be maintained and updated according to changes within the 2 terminologies and Use Case based requirements for additions to the Maps - thus meeting one of the key requirements of IMI to produce products in the project that are sustainable over time.

In April 2020, the Alpha release of the SNOMED CT to MedDRA and MedDRA to SNOMED CT maps was made available by both SNOMED International and MedDRA MSSO (on behalf of ICH), based on the work done in the WEB RADR 2 project (which finished in June 2020). The maps were in RF2 format to support those who have SNOMED CT enabled systems, and a human readable format for other users. All feedback received from the Alpha release has been considered and where appropriate updates or revision to the maps have been undertaken.

In particular it was found necessary to add new content to support the capture of data to support the COVID-19 pandemic as identified by the regulators.

4. Production release and ongoing maintenance and updating.

The scope of the SNOMED International and ICH work through the WEB RADR 2 project has been outlined above. SNOMED International and ICH have subsequently entered in to a Collaboration Agreement, for an initial period of 5 years to support the ongoing maintenance and updating of the 2 maps.

Under the terms of the Collaboration agreement between SNOMED International and the ICH, the Maps will be issued annually by both SNOMED International in RF2 format and MedDRA MSSO in spreadsheet format. Documented quality assurance processes will ensure both formats are the same and supporting materials are produced jointly. In addition, criteria for extending the Maps have been agreed and managed through agreed processes to ensure that the products meet the needs of the different stakeholder groups as defined by the Use Cases. A change request system has been developed, separate to SNOMED International CRS, and is managed on a day to day basis by MedDRA MSSO. Details of the change request system, how to use it and the criteria against which decisions for change are made can be found at:

<https://mapcr.meddra.org/>

5. Release content

5.1. Overview

The MedDRA derivative content is released under a project-specific module (816211006) with component identifiers that are within the main IHTSDO (International Release) namespace. Placement in the SNOMED hierarchy is based on existing MedDRA groupings ('collective terms').

5.2. Content detail

The content is based on a high value set of MedDRA terms identified as part of the WEB RADR 2 project, taking data from European Medicines Agency and UK's Medicines & Healthcare products Regulatory Agency (MHRA) - just under 7500 were evaluated for being in scope of SNOMED CT. Approximately 100 new concepts have been added to SNOMED CT as a consequence of this work.

5.3. Dependent Content

The January 2021 SNOMED CT International Edition is the baseline for the April 2021 SNOMED CT MedDRA Map package, and therefore all filenames and record have been assigned the value of 20210131 in the effectiveTime field. [The Maps use MedDRA version 23.1, released September 2020.](#)

6. Obtaining the release package

Access within IHTSDO member countries is provided by the Member National Release Centre in each country, via the relevant Member page. Affiliates of IHTSDO in non-member countries can access the table through their Member Licensing and Distribution Service (MLDS) account. Please contact info@snomed.org for more information if required.

MedDRA users can access the map files in the Downloads section of www.meddra.org.

Reviewers of the Maps should have a licence for either MedDRA and SNOMED CT.

If you're having any problems getting hold of the SNOMED CT MedDRA Simple Map Package, please contact info@snomed.org

Additional information

Please visit <https://www.snomed.org/snomed-ct/Use-SNOMED-CT/maps> for links to:

- Mapping Conventions (for these maps)
- Criteria for accepting requests for changes or additions to these 2 maps
- Links to Map Change Request tool and Map Change Request Tool guidance

7. Technical Notes

7.1. RF2 package format

The RF2 package convention dictates that it contains all relevant files, regardless of whether or not there is content to be included in each particular release. Therefore, the package contains a mixture of files which contain both header rows and content data, and also files that are intentionally left blank (including only a header record). The reason that these files are not removed from the package is to draw a clear distinction between:

1. ...files that have been deprecated (and therefore removed from the package completely), due to the content no longer being relevant to RF2 in this or future releases, and

2. ...files that just happen to contain no data in this particular release (and are therefore included in the package but left blank, with only a header record), but are still relevant to RF2, and could therefore potentially contain data in future releases.

This allows users to easily distinguish between files that have purposefully been removed or not, as otherwise if files in option 2 above were left out of the package it could be interpreted as an error, rather than an intentional lack of content in that release.

7.2. RF2 map files

Both SNOMED CT to MedDRA and MedDRA to SNOMED CT simple map files are contained in the same package, and therefore are linked by the same moduleID (816211006).

However, they can be individually identified by their relative refset ID's, as follows:

- SNOMED CT to MedDRA = 816210007
- MedDRA to SNOMED CT = 816209002

Approvals

Final Version	Date	Approver	Comments
1.0	29 Apr 2021	Jane Millar	Approved
0.1		Monica Harry	
1.0	29 Apr 2021	Donna Morgan	Approved

Draft Amendment History

Version	Date	Editor	Comments
0.1	11/04 /2021	Andrew Atkinson	Initial draft
0.2	15/04 /2021	Donna Morgan	Comments added
0.3	27/04 /2021	Andrew Atkinson	Fixes to format and technical notes added, plus refinements from MedDRA
1.0	29/04 /2021	Jane Millar	Final Updates

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