# Criteria for accepting requests for additions or changes to SNOMED CT to MedDRA map and MedDRA to SNOMED CT map

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# Contents

# Document Review & Revision History

| Date | Version | Name/Organization | Review / Revision |
|---|---|---|---|
| 18.08.2020 | 0.01 | SNOMED International | Draft for comment/review |
| 29.09.2020 | 0.02 | MedDRA MSSO | Updated version based on feedback from MedDRA MSSO |
| 24.11.2020 | 0.03 | Both organisations | Updates ready for formatting |
| 05.01.2021 | 0.04 | MedDRA MSSO | Further feedback |
| 07.01.2021 | 0.05 | Both organisations | Agreement on outstanding points – ready for publication |

# About SNOMED International

SNOMED International is a not-for-profit organization that owns and develops SNOMED CT. We play an essential role in improving the health of humankind by determining standards for a codified language that represents groups of clinical terms. This enables healthcare information to be exchanged globally for the benefit of patients and other stakeholders. We are committed to the rigorous evolution of our products and services, to deliver continuous innovation for the global healthcare community. SNOMED International is the trading name of the International Health Terminology Standards Development Organisation. Learn more at www.snomed.org.

# About ICH

ICH is an international non-profit association whose purpose is to promote public health through international harmonisation of technical requirements. ICH owns the Medical Dictionary for Regulatory Activities, a standardised medical terminology to facilitate sharing of regulatory information internationally for medical products for human use ("MedDRA") and works to ensure its scientific and technical maintenance, development and dissemination as a standardised dictionary which facilitates the sharing of regulatory information internationally for medicinal products used by humans.

# Purpose

It is essential to ensure that additions and changes to the SNOMED CT to MedDRA and MedDRA to SNOMED CT maps are managed in an agreed manner between SNOMED International and ICH/MedDRA Maintenance and Support Services Organization (MSSO) and this includes criteria for managing requests for changes to existing content of the maps and additions to the maps.

The following sets out key points/criteria for consideration as part of the initial review/triage of such requests which are managed through the online request tool (MapCR) that can be accessed and reviewed by both SNOMED International and MedDRA MSSO (on behalf of ICH).

By defining the key points/criteria for initial review/triage, it will ensure there is a transparent process of decision making for those requesting changes/additions to either/both of the maps and agreement between both organisations on any resulting actions, with resources applied. The MapCR tool enables the relevant information to be collected to ensure the review as part of the triage process can be undertaken.

# Criteria

1. Requests for changes/updates to maps must be from a licensed user of MedDRA and/or Member country or Affiliate in a non-Member country of SNOMED International.

2. Requestor must confirm in the submission that they are either using one/both of the maps or planning to within the next year.

3. The requestor must provide a clear use case for additions to either/both of the maps, which might include the following purposes:
    - Regulatory
    - Clinical
    - Pharmacovigilance
    - Pharmacoepidemiology
    - Public health
    - Scientific/academic need

4. The use case described should further demonstrate that it is a ‘real world’ requirement for implementation and not a theoretical use case, for example:

- Real world data for label extension, alternative use, risk evaluation and mitigation.
- “Black box warning” on label needs to be converted into SNOMED CT to be visible in the EHR.
- To respond to new/updated adverse event data to flow from the EHR encoded in SNOMED CT for reporting purposes

5. The requestor must clearly identify the relevant terms/concepts in either/both SNOMED CT and MedDRA to which the request is applying.

6. For requests to change existing mapped terms, instead of a use case, the requestor must provide a justification for why the map needs to be changed.

7. Requests for maps involving the following will not be accepted as they are out of scope:
    A. Unqualified test name terms in MedDRA (available on the MedDRA.org site)
    B. Physical object concepts
    C. Substances
    D. Organisms
    E. Product names
    F. Device names

8. All necessary information is provided by the requestor to enable a full impact assessment to be done of the amount of work required by both SNOMED International and MedDRA MSSO, volume, resource implications etc. Any requests from an individual organization for more than 50 terms to be added to the maps will be referred to the Resource Group for consideration.

9. The requestor has identified any strategic/policy timelines for responding to the request, in line with the defined use case.

## Additional Information

Contact mapping@meddra.org or info@snomed.org for additional information or inquiries regarding request for change criteria.