

# MedDRA Coding in secuTrial®: A Validated Solution From Free Text to Structured Safety Data

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## Acknowledgements

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# MedDRA Coding in secuTrial®: A Validated Solution

## From Free Text to Structured Safety Data

In clinical research, it is essential that safety data such as adverse events (AEs), serious adverse events (SAEs), and patient medical histories are collected in a standardised way. Only then can results be compared across patients, sites, and studies — and reviewed consistently by Sponsors, Data Safety and Monitoring Boards (DSMBs), investigators, and regulators.

To achieve this, researchers worldwide use **MedDRA (Medical Dictionary for Regulatory Activities)** — the official **ICH M1 Guideline**. Using MedDRA ensures that safety data is structured, comparable, and aligned with **ICH E9 (Statistical Principles for Clinical Trials)**, which recommends:

*“It is recommended that a consistent methodology be used for the data collection and evaluation throughout a clinical trial program in order to facilitate the combining of data from different trials. The use of a common adverse event dictionary is particularly important.”*

MedDRA's hierarchical structure — from detailed Lowest Level Terms (LLTs), which allow high granularity to capture practically any medical term, through summarising Preferred Terms (PTs), up to broad System Organ Classes (SOCs) — ensures precise data entry and enables consistent aggregation and analysis of safety data, as recommended by ICH E9.

### Why MedDRA's Structure Matters

MedDRA is **multiaxial**: a medical term can belong to more than one SOC. For example, *Influenza* is primarily categorized under “Infections and infestations”, but it also appears in “Respiratory, thoracic and mediastinal disorders”. This feature allows researchers to analyse safety data from different perspectives.

#### Examples: From Free Text to Standardised Coding

Free text entry	MedDRA Preferred Term & Code	System Organ Class
“Patient experienced headache.”	Headache (10019211)	Nervous system disorders
“Patient diagnosed with influenza.”	Influenza (10022000)	Primary: Infections and infestations Secondary: Respiratory, thoracic and mediastinal disorders

### Benefits for Clinical Research

- **Standardisation of safety data:** Free text descriptions are harmonised into machine-readable terms and codes, enabling consistent analysis across patients, sites, and studies.
- **Data quality:** Reduces transmission errors and improves consistency.
- **Efficiency:** No need to manually transfer codes between systems.
- **All data in one database:** All study data (including MedDRA-coded AEs/SAEs) stored centrally in secuTrial®.
- **Support for DSMBs:** Safety data can be aggregated and analysed across multiple organ systems.
- **Regulatory compliance:** Aligns with ICH guidelines and Swissmedic requirements.

## The Challenge

The electronic data capture system secuTrial®, used in the SCTO Network, cannot directly read MedDRA files from the MSSO. To enable MedDRA coding within secuTrial®, the files must first be converted into a compatible catalogue.

## Our Solution

The SCTO Data Management Platform now offers a **validated MedDRA Converter**, developed by Khaled Mostaguir at the Centre de Recherche Clinique (CRC), University of Geneva, and validated by the DKF Basel as part of an SCTO project.

This tool allows Data Managers to:

- Convert MedDRA source files from MSSO into secuTrial®-compatible catalogues
- Include only primary or primary and secondary SOC's
- Decide whether to keep or exclude outdated ("non-current") terms

## How is MedDRA Coding Technically Done in secuTrial®

MedDRA coding in secuTrial® is straightforward: Investigators can search for a term directly within the MedDRA catalogue integrated into the eCRF.

By selecting the most appropriate LLT, the system automatically fills in all corresponding ten fields — covering all five MedDRA hierarchy levels (LLT, PT, HLT, HLGT, and SOC) — for the primary SOC. If required, the same process can be applied for the secondary SOC. Figure 1 below illustrates this functionality within an eCRF.

The screenshot displays the secuTrial® interface for MedDRA coding. It is divided into two main sections: 'Primary SOC' and 'Secondary SOC'. Each section contains a list of fields for different MedDRA hierarchy levels, each with a dropdown menu and a checkmark icon. The 'Primary SOC' section shows the following values: SOC code (10021881), SOC term (Infections and infestations), HLGT code (10047438), HLGT term (Viral infectious disorders), HLT code (10022005), HLT term (Influenza viral infections), PT code (10022000), PT term (Influenza), LLT code (10022000), and LLT term (Influenza). The 'Secondary SOC' section shows: SOC code (10038738), SOC term (Respiratory, thoracic and mediastinal disorders), HLGT code (10024970), HLGT term (Respiratory tract infections), HLT code (10047483), HLT term (Viral upper respiratory tract infections), PT code (10022000), PT term ([\*secondary SOC\*] Influenza), LLT code (10022000), and LLT term (Influenza).

Hierarchy Level	Code	Term
SOC	10021881	Infections and infestations
HLGT	10047438	Viral infectious disorders
HLT	10022005	Influenza viral infections
PT	10022000	Influenza
LLT	10022000	Influenza

  

Hierarchy Level	Code	Term
SOC	10038738	Respiratory, thoracic and mediastinal disorders
HLGT	10024970	Respiratory tract infections
HLT	10047483	Viral upper respiratory tract infections
PT	10022000	[*secondary SOC*] Influenza
LLT	10022000	Influenza

**Figure 1.** Example of MedDRA coding in a secuTrial® eCRF.

## Availability

The validated MedDRA Converter is **freely available for the entire SCTO Network** and represents an important step towards harmonised, high-quality data management in Swiss clinical research. For further information, please contact your local CTU Data Manager or reach out to the SCTO Data Management Platform.

## Ownership and Copyright

The MedDRA Converter tool was developed and is copyrighted by the **University of Geneva**. Developer: Khaled Mostaguir ([khaled.mostaguir@hug.ch](mailto:khaled.mostaguir@hug.ch)), CRC (Centre de Recherche Clinique), University of Geneva.

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## Disclaimer

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The use of MedDRA is subject to a licence from the MedDRA Maintenance and Support Services Organization (MSSO). Each institution that codes, analyses, or reports MedDRA-coded data must hold a valid MedDRA subscription.

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