

DIN CEN ISO/TS 5499:2024-05 (E)

**Health informatics - Clinical particulars - Core principles for the harmonization of therapeutic indications terms and identifiers (ISO/TS 5499:2024); English version
CEN ISO/TS 5499:2024**

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviated terms	1
3.1 Terms and definitions	1
3.2 Abbreviated terms	3
4 Terminologies used for the coding of Therapeutic Indications	4
4.1 General	4
4.2 SNOMED CT	4
4.3 MedDRA	4
4.4 ICD	4
4.5 MeSH	5
5 Use Cases for Coding of Therapeutic Indications	5
5.1 General	5
5.2 IDMP data exchange between global regulators and bio/pharmaceutical companies during regulatory processes	6
5.2.1 Clinical Trials (Medicinal Product Development Lifecycle)	6
5.2.2 Regulatory Submission and Coded Labelling Information	6
5.2.3 Clinical protocol	8
5.2.4 Risk Management	8
5.3 Pharmacovigilance	9
5.3.1 General	9
5.3.2 Clinical information in the EHR supporting regulation for Pharmacovigilance	9
5.3.3 Identify potentially inappropriate prescribing/off-label use	10
5.4 Registries	10
6 Mapping principles specific to therapeutic indications	10
6.1 Maps between Terminologies	10
6.1.1 General	10
6.1.2 Mapping Prerequisites	10
6.1.3 Required Processes	11
6.2 Therapeutic Indications - Mapping best practice principles and conventions	11
6.3 General mapping guidance	13
6.3.1 General	13
6.3.2 Mapping of national and regional terms	13
6.3.3 Regulatory agencies	13
Annex A (informative) Implementations of the IDMP Therapeutic Indications Data Model	16
Bibliography	22