

# ISO/TS 5499:2024-01 (E)

## Health informatics - Clinical particulars - Core principles for the harmonization of therapeutic indications terms and identifiers

---

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