

ISO/TS 21405:2026-03 (E)

Health informatics - Identification of medicinal products - Methodology and framework for the development and representation of IDMP ontology

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Benefits of an ontological approach for IDMP	4
4.1	General	4
4.2	Recommended methodology for collaborative IDMP ontology development - Ontology governance in a collaborative ontology development framework	4
4.3	Governance structures in ontology development and maintenance in alignment with the ISO standards on IDMP	5
5	Use cases for an IDMP ontology	6
5.1	Practical applications of IDMP ontology in regulatory frameworks	6
5.2	Identifying substances, pharmaceutical and medicinal products unambiguously	6
5.2.1	Use case 1 (UC1): Ensuring unambiguous identification of substances	6
5.2.2	Area of focus	7
5.2.3	UC1 description	7
5.2.4	Stakeholders, actors, interfaces	8
5.2.5	UC1 usage scenarios	8
5.3	Enabling interoperability between regulatory, manufacturing and healthcare domains	14
5.3.1	Use case 2 (UC2): overview	14
5.3.2	Scope of UC2	14
5.3.3	Stakeholders and actors	15
5.3.4	UC2 description	15
5.3.5	Usage scenarios	18
5.3.6	Competency questions	19
5.4	Jurisdiction-agnostic medicinal products	23
5.4.1	Use case overview	23
5.4.2	Competency question (CQ)	24
5.5	Ensuring interoperability between regulatory, clinical development and healthcare domains	24
5.5.1	Use case overview	24
5.5.2	Linking therapeutic indication(s) to their medicinal products and associated active substances: competency question	25
5.6	Ensuring global interoperability for the detection of supply chain and drug shortages	25
Annex A (informative) Examples of regional implementation		26
Bibliography		30