

ISO 13972:2022-02 (E)

Health informatics - Clinical information models - Characteristics, structures and requirements

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms, definitions and abbreviated terms	1
3.1	Terms and definitions	1
3.2	Abbreviated terms	7
4	Health care information models - Concept, purpose, contexts and position	8
4.1	The Concept of Clinical Information Models	8
4.2	Purpose for Clinical Information Models	10
4.3	Context of Health and Care Information Models	11
4.4	Architectural Considerations for Clinical Information Models	13
4.4.1	General	13
4.4.2	CIMs in an architectural view	13
4.4.3	CIMs placed in the Generic Component Model	14
4.4.4	The Interoperability and Integration Reference Architecture in ISO 23903	15
4.4.5	Representation of ReEIF through the ISO Interoperability and Integration Reference Architecture Framework	17
5	Quality Management System for Clinical Information Models	19
5.1	General	19
5.2	CIMs quality management system	19
5.3	CIMs Requirements	20
5.4	CIMs acceptance, adoption and use	21
5.5	Achieving quality CIMs	21
5.6	Governance of CIMs	22
5.7	Repositories of CIMs	22
5.8	CIMs Development Processes	22
6	Clinical Information Model content, structure and requirements	23
6.1	Clinical Information Model content and context	23
6.2	Concept specification of a Clinical Information Model	24
6.3	Purpose of the Concept	24
6.4	Patient Population for which the Clinical Information Model is intended	24
6.5	Evidence Base for the Clinical Information Model topic	24
6.6	Description of the information model and its data elements in CIMs	25
6.6.1	General requirements for the information model	25
6.6.2	Data elements	26
6.6.3	Data Element Name and Identifier	28
6.6.4	Data Element descriptions	29
6.6.5	Semantic coding of data elements	29
6.6.6	Datatype	30
6.6.7	Value	31
6.6.8	Value set expression	32
6.6.9	Relationships in CIMs	32
6.6.10	Localization of CIMs	33
6.7	Example instances	33
6.8	Interpretation	33
6.9	Constraints or Limitations for use	34
6.10	Instructions for use of CIMs	35

6.11	Care process / dependence.....	36
6.12	Issues.....	36
6.13	Example of the use of a CIM	37
6.14	References.....	37
6.15	Intellectual property issues around Clinical Information Models.....	37
7	Metadata for clinical information models.....	39
7.1	General.....	39
7.2	The metadata elements of the Clinical Information Models	39
8	Version management of clinical information models.....	43
Annex A	(informative) Release and maintenance process example in the Netherlands	44
Annex B	(informative) Version management backwards compatibility.....	45
Annex C	(informative) Guidelines and principles for Clinical Information Modelling	46
Annex D	(informative) Example mapping a CIM to ADL specification: Glasgow Coma Scale	53
Annex E	(informative) Datatype profile used for the logical model parts for Clinical Information Models	61
Annex F	(informative) Example Clinical Information Model in UML and Table format.....	62
Annex G	(informative) Example Clinical Information Model transformation in HL7® FHIR®	64
Bibliography	74