

# ISO 13972:2022-02 (E)

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

<b>Contents</b>		<b>Page</b>
Foreword.....		v
Introduction.....		vi
<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>
3.1	Terms and definitions.....	1
3.2	Abbreviated terms.....	7
<b>4</b>	<b>Health care information models - Concept, purpose, contexts and position.....</b>	<b>8</b>
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
<b>5</b>	<b>Quality Management System for Clinical Information Models.....</b>	<b>19</b>
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
<b>6</b>	<b>Clinical Information Model content, structure and requirements.....</b>	<b>23</b>
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
<b>7</b>	<b>Metadata for clinical information models.....</b>	<b>39</b>
7.1	General.....	39
7.2	The metadata elements of the Clinical Information Models .....	39
<b>8</b>	<b>Version management of clinical information models.....</b>	<b>43</b>
<b>Annex A</b>	<b>(informative) Release and maintenance process example in the Netherlands .....</b>	<b>44</b>
<b>Annex B</b>	<b>(informative) Version management backwards compatibility.....</b>	<b>45</b>
<b>Annex C</b>	<b>(informative) Guidelines and principles for Clinical Information Modelling .....</b>	<b>46</b>
<b>Annex D</b>	<b>(informative) Example mapping a CIM to ADL specification: Glasgow Coma Scale .....</b>	<b>53</b>
<b>Annex E</b>	<b>(informative) Datatype profile used for the logical model parts for Clinical Information Models .....</b>	<b>61</b>
<b>Annex F</b>	<b>(informative) Example Clinical Information Model in UML and Table format.....</b>	<b>62</b>
<b>Annex G</b>	<b>(informative) Example Clinical Information Model transformation in HL7® FHIR® .....</b>	<b>64</b>
	<b>Bibliography.....</b>	<b>74</b>