	<b>LRA Technical Model Infrastructure Specification Part 1: Care Components</b>			
	<b>Programme</b>	NPFIT	<b>Document Record ID Key</b>	
	<b>Sub-Prog / Project</b>	Informatics Data Standards Programme	NPFIT-FNT-TO-DPM-0935.05	
	<b>Prog. Director</b>	D. Perry	Status	Draft for comment
	<b>Owner</b>	S. Bentley	Version	0.5
	<b>Author</b>	J. Arnett D. Markwell R. Challen	Version Date	2009-12-08

## Logical Record Architecture for Health and Social Care **Technical Model Infrastructure Specification Part 1:** **Care Components**

**Amendment History:**

Version	Date	Amendment History
0.1	2009-03-25	First draft for comment
0.1.1	2009-03-27	Section 7: Fig. 2 updated to show both ENTRY and ITEM derived classes and Fig. 3 deleted; updated representation of constraints listed in constraint tables.
		Section 7.1.1: added details of constraints to description of ACTIVITY_ENTRY.
		Section 7.1.1: made ELEMENT class abstract
		Section 7.1.3.3: added invariant (targetSET) to ATTESTATION_INFO stating that for each and every II instance in the SET there exists within the EHR extract an instance of a RECORD_COMPONENT specialisation with an rc_id attribute value equal to the value of the member instance.
		Section 7.1.12: added details of constraints to description of ENTRY.
		Section 7.1.14: added details of constraints to description of FINDING_OBSERVATION_ENTRY.
		Section 7.1.15.3: added invariant (compositionsSET) to COMPOSITION stating that for each and every II instance in the SET there exists within the EHR extract a COMPOSITION instance with an rc_id attribute value equal to the value of the member instance.
		Section 7.1.20.3: added invariant (targetSET) to LINK stating that for each and every II instance in the SET there exists within the EHR RECORD_COMPONENT instance with an rc_id attribute value equal to the value of the member instance.
		Section 7.1.24: added details of constraints to description of PROPERTY_OBSERVATION_ENTRY.
0.2	2009-04-22	Corrected typographical and other minor errors throughout document.
		Section 4.2: reordered sections.
		Section 8: added level 4 headings.
0.2.1	2009-05-06	Issues 1052, 1054 and 1074 <ul style="list-style-type: none"> <li>Combined section 5 with section 4 and revised content so that the intended uses of the model align with the class section specification of section 6 (previously section 7).</li> </ul>
		Issue 1057 <ul style="list-style-type: none"> <li>Section 6.1.12: made class ENTRY non-abstract</li> <li>Replaced ENTRY specialisation hierarchy (previously sections 7.1.1, 7.1.2, 7.1.5, 7.1.11, 7.1.14, 7.1.17, 7.1.18, 7.1.21, 7.1.24, 7.1.28 and 7.1.29) with ELEMENT hierarchy (sections 6.1.1, 6.1.4, 6.1.5, 6.1.16, 6.1.19, 6.1.20, 6.1.21, 6.1.25 and 6.1.26).</li> <li>Section 6.1.6: made class CLUSTER non-abstract</li> <li>Removed CLUSTER specialisation hierarchy (previously sections 7.1.11 and 7.1.22)</li> <li>Section 6.1.6.2: relaxed association role CLUSTER.parts cardinality from 1..1 to 0..*.</li> <li>Section 6.1.6.3: removed constraint partsSize from context CLUSTER; added constraint meaningUndefined.</li> </ul>

		<ul style="list-style-type: none"> <li>Section 6.1.11.3: added constraint meaningDefined to require assignment to ELEMENT.meaning attribute.</li> <li>Section 6.1.12.2: updated association role ENTRY.items description with constraint that collection contains a single member instance which is of type CLUSTER.</li> <li>Section 6.1.17.3: removed constraint meaningUndefined from context ITEM.</li> </ul>
		<p>Issue 1058</p> <ul style="list-style-type: none"> <li>Section 6.1.12.1: updated definition and cardinality of attribute act_status to prohibit use of attribute as semantics overlap with the SNOMED CT Procedure Context attribute used by the LRA within the RECORD_COMPONENT meaning attribute expression.</li> <li>Section 6.1.12.3: added constraint act_statusUndefined to prohibit use of attribute act_status.</li> </ul>
		<p>Issue 1060</p> <ul style="list-style-type: none"> <li>Section 6.1.12.1: updated definition and cardinality of attribute subject_of_information_category to prohibit use of attribute as semantics overlap with the SNOMED CT Subject Relationship Context attribute used by the LRA within the RECORD_COMPONENT meaning attribute expression.</li> <li>Section 6.1.12.3: added constraint subject_of_information_categoryUndefined and subject_of_information_categoryNoDefault to prohibit use of attribute subject_of_information_category and any implied default value in its absence.</li> </ul>
		<p>Issue 1065</p> <ul style="list-style-type: none"> <li>Section 6.1.22.1: clarified use of attribute archetype_id within the LRA.</li> </ul>
		<p>Issue 1070</p> <ul style="list-style-type: none"> <li>Section 4.3: revised description of use of EHR_EXTRACT to state that class not suitable for returning or communicating aggregated results of population analyses or record fragments selected from multiple COMPOSITIONS.</li> </ul>
		<p>Issue 1071</p> <ul style="list-style-type: none"> <li>Removed FOLDER class (previously section 7.1.15)</li> <li>Sections 6.1.3, 6.1.3.2, 6.1.3.3, 6.1.10.2, 6.1.22, 6.1.22.2 and 7.2.1: removed references to FOLDER class.</li> <li>Section 4.3: revised description of record organisation to exclude use of FOLDER class.</li> </ul>
0.3	2009-05-21	<p>Addressed issues 1051, 1063, 1064, 1073, 1078, 1079, 1080, 1083, 1085, 1086, 1087, 1088, 1089, 1091, 1104, 1105, 1106, 1114, 1115, 1116, 1155, 1156, 1157, 1158, 1159, 1160. Specific resolutions documented with issues.</p> <p>Added section on linkage in LRA.</p> <p>Added appendix about component relationship vocabulary.</p> <p>Multiple formatting fixes.</p> <p>Revisions to constraints in model plus addition of linkage to participations model.</p> <p>External reference to vocabulary specification.</p>

		Pending re-insertion of model documentation into section 5.
0.3.1	2009-05-30	Section 4.6 Major design considerations of LRA Care Components moved to section 7 and renamed to Aspects of Representation.
		Miscellaneous minor updates to improve consistency.
		Issues 1051 and 1089 <ul style="list-style-type: none"> <li>Section 7.3 Representing Subject of Information Participation (previously under section 4.6 as "Participations model and subject of information"): updated text to clarify explanation.</li> </ul>
		Issue 1073 <ul style="list-style-type: none"> <li>Section 7.4 Linking Record Components (previously under section 4.6 as "Linkage classes in the LRA"): minor updates to text of section and subsections for consistency; updated LINK illustrations (figs 4 and 5) with class diagrams.</li> </ul>
		Issue 1076 <ul style="list-style-type: none"> <li>Removed sections 8.2 and 8.2.1 which described semantic constraints on organisers.</li> <li>Added sections 8.1.5 and 8.1.5.1 to describe semantic constraints on RECORD_ARTEFACT_ELEMENTS.</li> </ul>
		Issue 1077 and 1116 <ul style="list-style-type: none"> <li>Removed section 8.2.4 as no longer applicable – instead see appendix B for LraComponentRelationship value set.</li> </ul>
		Issues 1081 and 1084 <ul style="list-style-type: none"> <li>Section 6.3.5.2: updated description of CLUSTER.parts to remove LRA-specific constraints and deconstrained cardinality to 0..*.</li> <li>Section 6.3.5.3: removed constraints 'cluster cannot be empty' and 'cluster contains only elements'.</li> <li>Section 6.3.11: updated description of ENTRY to state that the items collection may contain member instances of type ELEMENT only.</li> <li>Section 6.3.11.2: updated description of items to state that the collection may contain member instances of type ELEMENT only and deconstrained cardinality to 0..*.</li> <li>Section 6.3.11.3: removed constraints 'entry only contains one item in LRA' and 'entry must contain a cluster'; added constraint 'entry items may only contain elements'.</li> </ul>
		Issues 1062 and 1086 <ul style="list-style-type: none"> <li>Sections 6.3.14.1 and 6.3.14.3: constrained cardinality to 0..0 and added constraints to prohibit use of FUNCTIONAL_ROLE attributes healthcare_facility and service_setting.</li> <li>Section 7.3 Representing Participations (previously under section 4.6 as "Participations model and participations in the Care Component model"): updated text to clarify explanation.</li> </ul>
		Issue 1097 and 1102 <ul style="list-style-type: none"> <li>Section 6.3.4: STRUCTURED_ELEMENT renamed to BOUND_DATA_ELEMENT and class description updated to clarify role of SNOMED CT.</li> <li>Section 6.3.26: UNSTRUCTURED_ELEMENT renamed to UNBOUND_DATA_ELEMENT and class description updated to</li> </ul>

		<p>allow any data type.</p> <ul style="list-style-type: none"> <li>Section 4 and subsections: updated various occurrences of 'ELEMENT hierarchy' to refer specifically to 'BOUND_DATA_ELEMENT hierarchy'.</li> </ul>
		<p>Issue 1098</p> <ul style="list-style-type: none"> <li>Section 6.3.4: clarified use of inherited attribute meaning within class description of BOUND_DATA_ELEMENT.</li> <li>Standardised description of BOUND_DATA_ELEMENT subclasses with regard to their coded meaning.</li> </ul>
		<p>Issues 1099 and 1109</p> <ul style="list-style-type: none"> <li>Removed CARE_TRANSFER_ACTIVITY_ELEMENT</li> </ul>
		<p>Issue 1101</p> <ul style="list-style-type: none"> <li>Section 6.3.15: SURGICAL_ACTIVITY_ELEMENT renamed to GENERAL_ACTIVITY_ELEMENT</li> </ul>
		<p>Issue 1107</p> <ul style="list-style-type: none"> <li>Section 4.1: updated example to reflect current antenatal practice.</li> </ul>
		<p>Issue 1108</p> <ul style="list-style-type: none"> <li>Removed CARE_ACTIVITY_ELEMENT.</li> <li>Section 6.3.25: Updated INVESTIGATION_ACTIVITY_ELEMENT to specialise ACTIVITY_ELEMENT</li> <li>Section 6.3.25: Updated SUBSTANCE_ACTIVITY_ELEMENT to specialise ACTIVITY_ELEMENT</li> </ul>
		<p>Issues 1114</p> <ul style="list-style-type: none"> <li>Section 7.1 Representing Roles (previously under section 4.6 as "Participations model and participations in the Care Component model"): updated text to clarify explanation.</li> </ul>
		<p>Issues 1163</p> <ul style="list-style-type: none"> <li>Section 6.3.21: added class RECORD_ARTEFACT_ELEMENT as specialisation of BOUND_DATA_ELEMENT.</li> <li>Section 7.4: removed Simple Link Pattern sub-section and merged Complex Link Pattern sub-section into section.</li> <li>Section 7.5: added section to describe use of RECORD_ARTEFACT_ELEMENT.</li> </ul>
0.3.2	2009-05-30	<p>Miscellaneous corrections and clarifications</p> <ul style="list-style-type: none"> <li>Section 6.3.6: clarified para 1 by replacing references to 'source' and 'target' with 'subject' and 'object' respectively; removed para 2 which stated incorrectly that data value of inherited value attribute is constrained to a null flavour.</li> <li>Section 6.3.6.2: corrected OCL of 'must have exactly 2 links', 'one link to subject', 'one link to object' and 'coded meaning from LRA vocab' constraints.</li> <li>Section 6.3.11.3 changed 'meaning must be defined in LRA' to 'meaning undefined' constraint.</li> </ul>
		<p>Issue 1159</p> <ul style="list-style-type: none"> <li>Sections 6.3.6.3, 6.3.7.3, 6.3.13.3, 6.3.15.3, 6.3.16.3, 6.3.20.3, 6.3.21.3, 6.3.24.3, 6.3.25.3 and 6.3.26.3: added 'name value' constraint to set name values of specialised ELEMENT</li> </ul>

		<p>instances to their unqualified class name;</p> <ul style="list-style-type: none"> <li>Sections 6.3.7.3, 6.3.10.3, 6.3.11.3 and 6.3.24.3: removed class '[class] name LRA vocab' constraint.</li> </ul>
0.3.3	2009-07-28	<p>Issue 1199</p> <ul style="list-style-type: none"> <li>Section 6.4.11.1: updated attribute ENTRY.uncertainty_expressed to have a fixed value of nullFlavor = NA;</li> <li>Sections 6.4.11.3: replaced initial value constraint 'uncertainty expressed defaults to false' with LRA invariant 'uncertainty expressed has nullFlavor'.</li> </ul> <p>Sections 1.1, 2, 4 and 5.1: updated to clarify exceptions to EN 13606-1:2007 conformance.</p> <p>Section 6.3: added package lra.technical.en13606.extended containing class CR_Participation (moved from package lra.technical.participations; replaced all occurrences of lra.technical.participations.CR_Participation in document with lra.technical.en13606.extended.CR_Participation.</p> <p>Section 6.4.25: changed data type of attribute RELATED_PARTY.relationship from CD.CV to subtype CD.CV.SCT constrained for use with SNOMED CT.</p> <p>Section 8.1.1: replaced reference to class CARE_ACTIVITY_ELEMENT with ACTIVITY_ELEMENT</p> <p>Section 8.2.2: added reference to Participations specification.</p> <p>Section 9: added list of open issues.</p> <p>Appendix A: added table listing changes made to EN 13606-1:2007 EXTRACT model for use by LRA.</p>
0.4	2009-10-14	<p>Issues 1090, 1100 and 1191.</p> <ul style="list-style-type: none"> <li>Section 6.4.20: added MATERIAL_ENTITY_CLASS as specialisation of BOUND_DATA_ELEMENT to represent physical entities (acting in a passive capacity).</li> <li>section 6.4.19: renamed SUBSTANCE_ACTIVITY_ELEMENT to MATERIAL_ACTIVITY_ELEMENT; (previously) to resolve issues 1090 and 1100.</li> <li>Sections 6.4.1.2, 6.4.15.2 and 6.4.16.2: removed constraint 'value is null' from ACTIVITY_ELEMENT and applied directly to INVESTIGATION_ACTIVITY_ELEMENT and GENERAL_ACTIVITY_ELEMENT to enable MATERIAL_ACTIVITY_ELEMENT (previously SUBSTANCE_ACTIVITY_ELEMENT) to hold a value representing an amount of material supplied or administered.</li> </ul> <p>Miscellaneous minor changes:</p> <ul style="list-style-type: none"> <li>Section 6.4.13 and 6.4.22: removed text outlining SNOMED CT constraints applied to FINDING_OBSERVATION_ELEMENT and PROPERTY_OBSERVATION_ELEMENT as detailed elsewhere.</li> </ul>
0.4.1	2009-10-28	Section 7.3 Representing Subject of Information Participation as topic now dealt with in document <i>LRA Technical Model Developer's Manual Part 1: Model Design</i> .
0.5	2009-12-08	<p>Changes to align with <i>LRA Technical Model Developer's Manual Part 1: Model Design</i></p> <ul style="list-style-type: none"> <li>Section 6.4.1 Abstract Class ACTIVITY_ELEMENT: updated</li> </ul>

		<p>class description</p> <ul style="list-style-type: none"> <li>• Section 6.4.6 Class COMPONENT_RELATIONSHIP_ELEMENT: updated class description</li> <li>• Section 6.4.7 Class COMPOSITION: updated class description</li> <li>• Section 6.4.11 Class ENTRY: updated class description</li> <li>• Section 6.4.13 Class FINDING_OBSERVATION_ELEMENT: updated class description</li> <li>• Section 6.4.15 Class GENERAL_ACTIVITY_ELEMENT: updated class description</li> <li>• Section 6.4.16 Class INVESTIGATION_ACTIVITY_ELEMENT: updated class description</li> <li>• Section 6.4.20 Class MATERIAL_ENTITY_ELEMENT: updated class description</li> <li>• Section 6.4.21 Abstract Class OBSERVATION_ELEMENT: updated class description</li> <li>• Section 6.4.22 Class PROPERTY_OBSERVATION_ELEMENT: updated class description</li> <li>• Section 6.4.23 Class RECORD_ARTEFACT_ELEMENT: updated class description</li> <li>• Section 8 SNOMED CT Semantic Expression Constraints: updated to align with <i>LRA Technical Model Developer's Manual Part 1: Model Design</i></li> </ul> <p>Changes to prohibit use of MATERIAL_ACTIVITY_ELEMENT attribute value:</p> <ul style="list-style-type: none"> <li>• Section 6.4.1.2 Constraints: added ACTIVITY_ELEMENT invariant constraint value is null</li> <li>• Section 6.4.19 Class MATERIAL_ACTIVITY_ELEMENT: updated class description</li> <li>• Section 6.4.19.2 Constraints: deleted invariant 'value is type QTY'</li> </ul> <p>Miscellaneous minor changes and corrections:</p> <ul style="list-style-type: none"> <li>• Section 6.4.4.2 Constraints: changed BOUND_DATA_ELEMENT constraint types to 'LRA Invariant'; updated 'meaning is coded data' constraint expression from meaning.ocllsKindOf(CD) to meaning.ocllsKindOf(CD.CV.SCT); and updated constraint 'meaning is defined' to 'meaning is defined and is not null'.</li> <li>• Section 6.4.7.1 Attributes: changed multiplicity of COMPOSITION attribute session_time from 0..1 to 1..1 (for use within the LRA)</li> <li>• Section 6.4.20.2 Constraints: added MATERIAL_ACTIVITY_ELEMENT constraint 'obs_time is undefined in LRA'</li> <li>• Section 6.4.24.1 Attributes: updated description of RECORD_COMPONENT attribute rc_id</li> </ul>
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**Related Documents:**

These documents will provide additional information.

Ref no	Doc Reference Number	Title	Version
1.	NPFIT-SHR-QMS-PRP-0015	Glossary of Terms Consolidated.doc	
2.		Logical Record Architecture for Health and Social Care: Production Environment Project Plan	
3.		Logical Record Architecture for Health and Social Care: Artefacts Overview	
4.	External document	Health informatics — Electronic health record communication — Part 1: Reference model, EN 13606-1:2007	
5.		Logical Record Architecture for Health and Social Care Production Environment Business Context	
6.	External document	HL7 Version 3 Standard: Data Types - Abstract Specification, Release 2, Normative Ballot 2 - May 2008	
7.	External document	Health informatics – Harmonized data types for information interchange, INTERNATIONAL DRAFT STANDARD ISO 21090, 2007-09-24	
8.		Logical Record Architecture for Health and Social Care Terminology Binding Technical Specification	
9.		LRA Technical Model Infrastructure	



		Specification Part 2: Participations	
10.		LRA Technical Model Infrastructure Specification Part 3: Passive Participations	
11.	External document	Terminology Binding Requirements and Principles	
12.	External document	SNOMED CT User Guide	
13.	External document	SNOMED CT Technical Reference Guide	
14.	External document	SNOMED CT Technical Implementation Guide	
15.	External document	SNOMED CT Transforming Expressions to Normal Forms	
16.	External document	SNOMED CT Abstract Logical Models and Representational Forms	
17.		Logical Record Architecture for Health and Social Care - Care Record Entries and Organisers Abstract Specification	
18.	External document	HL7 Version 3 Standard: Clinical Document Architecture, Release 2, Normative Ballot 2 - May 2008	
19.	External document	The <i>openEHR</i> Reference Model - EHR Information Model, Release 1.0.2	
20.	External document	A Clinicians Guide to Record Standards - Part 2 : Standards for the structure and content of medical records and communications when patients are admitted to hospital. Academy of Royal Medical Colleges and NHS.	
21.	NPFIT-NCR-DES-0135.07	NHS Care Record Elements	

### Glossary of Terms:

List any new terms created in this document. Mail the NPO Quality Manager to have these included in the master glossary above [1].

Term	Acronym	Definition

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# 1 About this Document

## 1.1 Purpose

This document describes the Care Components reference model that forms part of the LRA Production Environment (PE) Technical Model Infrastructure. [2] The reference models and constraint rules specified by the Technical Model Infrastructure underpin that part of the Model Development and Production Framework and the LRA Toolset used to construct computable *Technical Model Artefacts* [3] for use in LRA record of care specifications.

With the exception of the non-conformances listed in section 5.1, the Care Components reference model is derived by constraint from EN 13606-1:2007 [4] (referred to within this specification as the *general standard*). As such the reference model specifies the record entry, organiser and supporting structures required to communicate an extract containing part or all of the Electronic Health Record (EHR) of an individual patient or service user. The reference model also adopts part of the EN 13606-1:2007 demographics model to enable the details of participating roles to be specified.

Derivation of the model for use by the LRA has focused in particular on ensuring that where required, the static information structures support fully the binding and integral (i.e. non-duplicating and non-conflicting) use of the SNOMED Clinical Terms® (CT) terminology model.

## 1.2 Audience

The intended audience of this specification is any individual, group or organisation involved in the development or use of the *LRA*.

## 1.3 Content

This document comprises the following sections:

- Introduction
- Rationale
- Scope
- Intended Uses of the Reference Model
- Conformance to International Standards
- Class Model Specification
- SNOMED CT Domain Applicability
- Appendices

The document refers to value sets and named SNOMED CT constraints. In the interest of maintainability these definitions are maintained in a single resource outside of this document. This resource is available in various forms at an interim <sup>1</sup> location until a specific vocabulary and constraint repository can be established.

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<sup>1</sup> [https://svn.connectingforhealth.nhs.uk/svn/public/lra/TRUNK/prod\\_env/infrastructure/doc/lraVocab/](https://svn.connectingforhealth.nhs.uk/svn/public/lra/TRUNK/prod_env/infrastructure/doc/lraVocab/)

## 2 Introduction

This document specifies an EN 13606-1:2007 derived and SNOMED CT aware reference model as part of a framework for the common representation of care records information. The Care Components reference model, in keeping the purpose of the LRA Technical Model Infrastructure as a whole, is principally concerned with expressing record content logically, to satisfy meaningful automated data retrieval and re-use requirements rather than specifying a particular physical representation for communicating information between machine and user or between machines.

### 2.1 Other Documents

This document incorporates all of the relevant material presented in the Care Record Entries and Organisers Abstract Specification [17] concerning the binding and constraint of SNOMED CT and applies it to deriving the Care Components reference model from the general standard. Given that all of the relevant material of the previous document is restated here, this document supersedes and replaces the Care Record Entries and Organisers Abstract Specification.

The internal and external documents cited throughout this specification are listed in the Related Documents section at the head of this document. In addition to those cited, the terminology binding and constraint discussions are based on and reference the following documents.

- Terminology Binding Requirements and Principles [11]
  - Describes the requirements for *terminology binding*, to minimise ambiguity and thus to maximise the reusability of clinical data.
  - Explains principles that form the foundation for a coherent approach to *terminology binding*.
  - Summarises the relative strengths of structure and terminology in respect of representing particular aspects of meaning.
  - Categorises different structural and semantic units and different types of *terminology binding*.
  - Summarises and references other relevant material and notes some issues and outstanding challenges.
- SNOMED CT publications (dated 2008-07-31)
  - SNOMED CT User Guide [12]
  - SNOMED CT Technical Reference Guide [13]
  - SNOMED CT Technical Implementation Guide [14]
  - SNOMED CT Transforming Expressions to Normal Forms [15]
  - SNOMED CT Abstract Logical Models and Representational Forms [16]

### 2.2 LRA PE Technical Model Infrastructure

The Care Components reference model is one of a set of Static Model Specifications that form part of the LRA PE Technical Model Infrastructure that underpins the

construction of computable *Technical Model Artefacts*. In addition to the Static Model Specifications, the Technical Model Infrastructure includes the following:

- Terminology Binding Technical Specification, [8]
- Structural Constraint Specification,
- Instance Exemplifier Specification and
- Querying and Inferencing Specification.

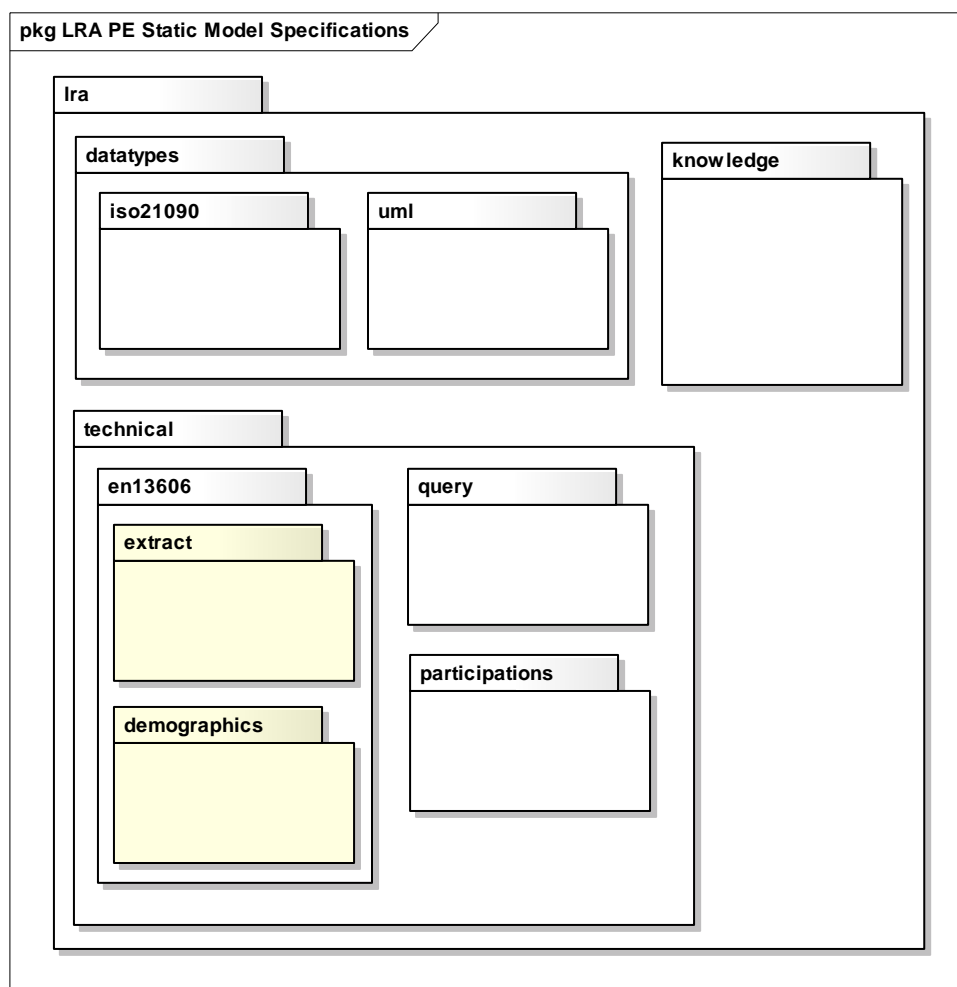
The UML models upon which the Static Model Specifications are based are maintained as UML packages under a *lra* root package as shown in Figure 1  
Package hierarchy of LRA PE Static Models

below. The top level sub-packages of the *lra* hierarchy are:

- *datatypes* – specifies the data types used by the LRA
- *knowledge* – specifies the Knowledge Model Infrastructure and Artefact classes
- *technical* – specifies the Technical Model Infrastructure and Artefact classes

The Care Components reference model classes, relationships and constraints are defined within the *extract* and *demographics* subpackages of the *lra.technical.en13606* package.





**Figure 1 Package hierarchy of LRA PE Static Models**

### 3 Design Rationale

LRA Technical Model Artefacts are logical specifications designed to facilitate the consistent reuse of meaningful care record statement information throughout data entry, display, querying and analysis and communication for various information uses. Development of a consistent approach to constructing and binding terminology to the model structures that comprise the Technical Model Artefacts has been considered key to meeting these requirements. Throughout its evolutionary development, the design rationale of the Care Components model has therefore been to:

- maximise data consistency and minimise the potential for ambiguity;
- support those aspects of care record information that are most effectively represented as
  - logical structures in data models
  - SNOMED CT code expressions
  - non-SNOMED CT terminologies or classifications;
- allow the structural elements to be constrained or extended to meet different use cases while preserving consistency between the representations of similar information;
- allow the use of SNOMED CT to be constrained to meet different use cases while ensuring comparability of similar information collected for different purposes;
- allow use of specified non-SNOMED CT terminologies or classifications (as appropriate) to meet those use cases that cannot adequately be addressed by the SNOMED CT terminology bound structures;
- minimise the risk of duplicate and / or conflicting semantics in the structural and terminology representations of information;
- facilitate understandable rules that can be applied to new information requirements to deliver consistently reproducible decisions on representation using combinations of logical structures and terminologies.

In addition to these requirements and in accordance with the IDSP design principle of adopting established standards wherever appropriate, [5] the Care Components reference model has been specified so as to conform to those parts of the general standard that fall within the scope of the LRA. Similarly, the data types specified for use by the reference model are mandated to conform to the ISO 21090:2007 draft standard *Health informatics – Harmonized data types for information interchange* [6] (which are themselves an implementation of the HL7 v3 R2 Abstract Datatypes). [7]

Previous work<sup>2</sup> has illustrated that simply adopting a reference model without prior regard to the specific terminology used by that model, is not adequate for

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<sup>2</sup> Previous work on terminology binding referred to here is HL7 TermInfo, the NHS pilot work using *openEHR* with SNOMED and current continuing work in the specific specialty streams of the LRA. All these illustrate the issues caused by applying a specific terminology to an information model designed without reference to properties of that terminology. This is discussed in more detail in other documents the HL7 Draft Standard for Trial Use 'Guide to

establishing an information architecture that allows for the reliable, efficient and consistent automated retrieval of care records data for multiple uses. To avoid unnecessary duplication or ambiguity there is therefore a requirement to align the construction of LRA model structures with SNOMED CT when a combination of both is used to express computer-processable data meaning. This requires, for example, prohibiting or constraining the use of those attributes of the general standard that are 'bound' to SNOMED CT in the derived reference model.<sup>3</sup>

Other work<sup>4</sup> has shown that it is possible to transform data between EN 13606 and HL7 v3-based models but suggests that the underlying semantics of the resulting transformations can only be made end-to-end consistent by imposing further constraints on the two standards. Otherwise, while it is possible to transform from either formalism to the other, the resulting target representation of particular items of information is not the same as (nor necessarily readily comparable with) the native representation of the same information.

Against this background, the Care Components reference model has been derived from the general standard so as to reduce the variability of representation and to help ensure that where required, the static information structures support fully the binding and integral use (i.e. non-conflicting and non-duplicating) of SNOMED CT.

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Use of SNOMED CT in HL7 Version 3' and in the NHS document 'Terminology Binding Requirements and Principles'.

<sup>3</sup> In following this principle, in addition, it will be necessary during the development of detailed LRA data models (based on the Care Components reference model) to minimise any multiplicity of forms to represent the same data meaning.

<sup>4</sup> NHS CFH document 'Results of Investigating the Transformability Between HL7 V3, openEHR and EN/ISO 13606' concluded that bidirectional transformation was possible within a 'framework of agreed business rules and agreed categorisations'. The detailed aspects of the report indicated that this framework in effect must constrain the use of the two Standards in effect aligning the relevant aspects into a common shared model.

## 4 Reference Model Scope and Intended Uses

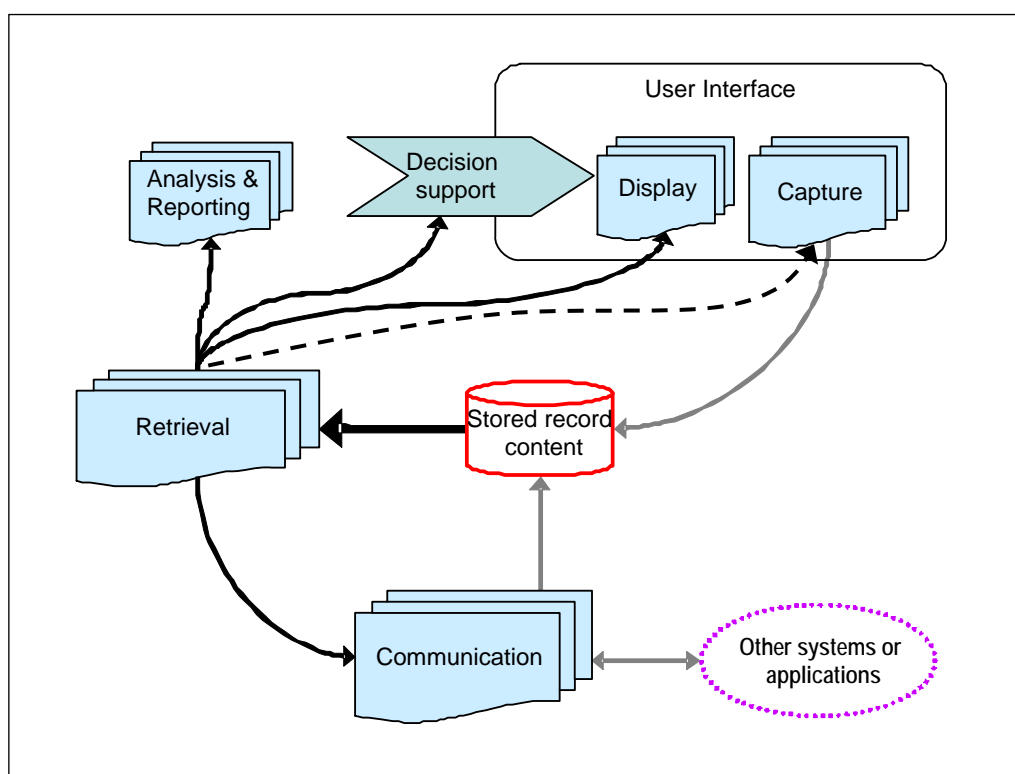
The Care Components reference model is designed to enable the construction of domain-specific Technical Model Artefacts that facilitate the consistent reuse of meaningful care record statement information throughout data entry, display, querying and analysis and communication. These are considered the core end uses of care record information all of which should be supported by retrieval. In addition the Care Components reference model supports the specification of record content requirements and allows the representation of the following supporting functions:

- Identification of participants
- Auditing
- Attestation

To enable consistent reuse of meaningful care record statement information the model is underpinned by a hierarchy of terminologically bound and semantically linkable BOUND\_DATA\_ELEMENT classes (derived from the EN 13606-1:2007 ELEMENT class) whose purpose is to facilitate 'meaning-based retrieval', i.e. retrieval involving selection and processing of parts of a record (or a set of records) based on the meaning of the contained information and the links between them. The intention of this is to enable common types of question about the content of a care record (or set of records) to be expressed in a common form. The BOUND\_DATA\_ELEMENT hierarchy is therefore particularly applicable to the retrieval and reuse of electronic care record content which in turn supports the other stages of the care record information life-history as shown in Figure 2.

The ELEMENT hierarchy and the SNOMED CT concept model that the classes use are together designed to form part of a framework for a normalised representation of richly meaningful care information. Therefore, the BOUND\_DATA\_ELEMENT hierarchy is designed so as to align with the use SNOMED CT expressions in a manner that follows the principles of the guidelines developed by earlier work. This part of the model provides a substrate for queries and related processing at the level of an individual statement. A system whose behaviour demonstrates conformance to the LRA Care Components reference model should be capable of responding to implementations of LRA query definitions 'as if' the model was being used to structure the information stored within it.

For a variety of reasons, care statement information in implemented care record systems is unlikely to be represented in precisely the form specified by the reference model. Implemented systems are likely to incorporate proprietary features and optimisations that enhance performance and address functionality beyond the scope of a standard concerned primarily with semantic operability.



**Figure 2 Generalised view of the clinical information life-cycle**

The following sections illustrate the intended use of the reference model in respect of different stages in the care record information life-cycle shown in Figure 2. The key record component classes that support the core functions of the care record belong to the *RECORD\_COMPONENT* class hierarchy:

- ELEMENT
- ENTRY
- COMPOSITION

The descriptions of these and other record components in following sections are either taken or adapted from the general standard [4] which should be consulted for further information.

## 4.1 Record Content Requirement Specifications

The Care Components reference model is intended to be used to enable the particular requirements for clinical information content to be specified in a consistent manner.

- For example, if there is a requirement for an antenatal appointment encounter note to include a measurement of the patient's weight:
  - The reference model must allow this requirement to be specified in a way that can be:
    - Expressed and understood by a human-reader.

- Tested by a computer to confirm compliance with the requirement.
  - The way it is specified must be the same as requirements for the recording patient's weight in other settings (e.g. in a routine health check, as part of an admission record, etc).
  - The way this requirement is specified should follow the same pattern as other measurements (e.g. height, pulse rate or serum sodium concentration).

The requirement for testable content constraints is an example of a requirement for meaning-based retrieval.

- For example, to test that the record of an antenatal consultation includes the patient's urine test results it must be possible to specify retrieval criteria that are able to identify record entries containing a particular type of measurement made during a specified encounter.

To enable this the reference model defines the `BOUND_DATA_ELEMENT` hierarchy whose classes allow content requirements to be expressed in a consistent way based on the meaning of each represented data item. Content requirements in their simplest form may be thought of as 'a minimum data set'. However, the reference model is designed to support a broader set of clinical use cases in which content requirements are more extensive and may be interdependent.

- For example, a requirement for a blood test for 'sickle cell trait' may depend on aspects of the patient's medical and family history.
  - The reference model allows conditional content to be specified so that, when required, this content is also represented in a consistent testable manner.

Content requirements are sometimes visualised as a data entry box (on a paper or screen form). However, the LRA domain models, which derive from the reference model, are designed to represent the underlying meaning consistently and as a result may not match the individual boxes on such a form.

- For example, a form might have an input box labelled 'fetal heart rate' with the following options 'normal' / 'X beats/minute' / 'not heard' / 'not examined'. These may be sensible user entry options, but 'not examined' is not a value for the observation of 'fetal heart rate' but a statement that an activity was not done.
  - To meet the requirement for consistency, the reference model represents these different types of information separately.

The support that the reference model provides for data capture, whilst being independent of it is detailed in section 4.4.1.

## 4.2 Querying and Analysis

Querying and analysis, using meaning-based retrieval, is supported by the BOUND\_DATA\_ELEMENT hierarchy derived from the general standard. In addition to ELEMENTs, querying and analysis are supported by three other EN 13606-1:2007 CARE\_COMPONENT classes.

- The COMPONENT\_RELATIONSHIP\_ELEMENT class is used by the LRA to specify semantic links between specific ELEMENTs (see section 7.3).
- The ENTRY class is used by the LRA as a use case oriented design pattern of one or more ELEMENTs which supports one or more core functions, i.e. the entry, display, analysis, reporting or communication of meaningful care record statement information. Such patterns are typically used to provide representations of information acquired and recorded for a single observation or observation-set (battery or time series), a single clinical statement such as a portion of the patient's history or an inference or assertion, or a single action that is intended or has actually been performed. [4] The ENTRY class therefore serves as a container for a reusable set of ELEMENTs but importantly does not affect on the semantics of the ELEMENT content within.
- The COMPOSITION class maintains a set of zero or more ENTRYs (some or all of which may be organised in SECTIONS<sup>5</sup>) composed (authored) during one encounter or documentation session, and committed within one EHR. [4] Instances of the class may therefore be queried to retrieve information from a given session or from multiple sessions (e.g. all significant past medical conditions).

### 4.2.1 Data or Information Retrieval

The following examples of requirements for meaning-based data or information retrieval are used to illustrate different uses of this part of the model.

For a selected patient or service user, retrieve...

- all records of body weight, excluding body weight while pregnant.
- most recent body weight.
- most recent body mass index (BMI). This may be recorded explicitly or computed
- all surgical procedures carried out.
- any pending (e.g. planned/waiting list) surgical procedures
- all significant past medical conditions
- all current problems.
- details of a selected current problem or past medical condition.
- the known family history.

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<sup>5</sup> The role and usage of the SECTION class within LRA Technical Models is currently undefined within this specification.

- records of any allergies.
- details of current medication
- results of laboratory investigations for 'sickle cell trait'
- records of fetal heart rate made aurally or using a fetal monitor.

For a population, retrieve the records of patients / service users who have/had ...

- a body mass index above a specified value.
- a family history of diabetes mellitus and a body mass index over a specified value.
- a particular procedure
- a particular symptom disorder or complication
- a particular medication

#### **4.2.2 Decision Support**

One aspect of decision support is a set of requirements to retrieve relevant care information from the patient or service user record. These requirements can be expressed as queries against LRA domain models. This enables consistent interpretation of information derived from different systems or from different data collection protocols.

- For example, a decision support rule triggered by a family history of 'diabetes mellitus' requires that any existing record indicating a positive family history of this disorder is retrieved from the record.

The scope of decisions support also includes identifying the records of patients or service users with particular risk factors so they can be invited for assessments or reviews. This involves retrieval of selected data from a particular cohort of a population, based on a set of criteria which can be specified as queries against the reference model.

- For example, a review of the records of all patients with a family history of risk factors for heart disease might require factors such as a raised Body Mass Index (BMI), and/or a family history of cardiac disease or diabetes mellitus to be taken into account. The LRA reference model allows these queries to be specified consistently at a logical level, and should be suitable for use with any physical implementations of care records data (as long as the logical meanings in implementations have been mapped or translated appropriately to the LRA).

#### **4.2.3 Data Aggregation, Analysis and Reporting**

Clinical research, epidemiology, service planning and audit require records to be retrieved based on specified criteria. Relevant information needs to be aggregated



and analysed in a manner that provides consistency across systems and between different care specialties.

- For example, patterns of symptoms following a treatment with particular medication may provide evidence of a side-effect. Searches for new symptoms in patients treated with a particular medication can be expressed as logical queries using the LRA reference model.

### 4.3 Records Communication

Within the general standard, the EHR\_EXTRACT class represents the top-level container used to communicate part or all of the EHR of a single patient or service user, between an EHR Provider system and an EHR Recipient. [4] The LRA uses the class for representing the communication of one or more COMPOSITIONs pertaining to a single patient or service user. Optionally and in addition an extract may contain set of demographic descriptors for each of the identified persons, organisations, devices or software components.

The general standard optionally allows the EHR\_EXTRACT class to contain a directory of FOLDERS that provide a high-level grouping and organising of COMPOSITIONs; however, the FOLDER class is not used for record organisation or semantic retrieval within the LRA and is therefore not included within this specification.

As noted above, COMPOSITIONs contain ENTRYs and optionally SECTIONs. SECTIONs are used to organise each ENTRY within a COMPOSITION under one clinical heading, often reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership. [4]

Significantly for the LRA, the intended purpose of the EHR\_EXTRACT class is to communicate part or all of the health record information of a *single* patient or service user in the form of *whole* COMPOSITIONs. Instances of the class are therefore not suitable for returning or communicating aggregated results of population analyses or record fragments selected from multiple COMPOSITIONs (e.g. a discontinuous set of test results derived from multiple of encounters).

Outbound records communication also often has implications for retrieval in that it requires the retrieval of selected information and this requirement is similar to the display and decision support requirements. In addition, both outbound and inbound communications involve the transformation of information between internal proprietary storage and a messaging communication standard.

Previous work investigating the transformability between HL7 CDA and EN 13606 representations predicted that these transforms lead to loss of information unless a common underlying semantic framework is used in the model design process. The BOUND\_DATA\_ELEMENT hierarchy of the reference model has been designed to overcome this problem using terminology binding constraints in a way that aims to

streamline the automated data retrieval process. Thus, detailed and further-constrained models based on this reference model and constructed according to clear design guidance, are intended to provide a normal form for representing particular types of care records data or information meaning. This in turn should act as a framework for more effective transformations between models based on existing standards.

Messaging standards and other communication oriented standards are often designed to support a particular process-based view of the information. This is entirely appropriate since the primary reason for many communications is to enable steps in a process.

- For example, a message may request a test for 'sickle cell trait' to be undertaken. Another message may report the outcome of that test. If the outcome of the test is positive the conclusion that the patient has 'sickle cell trait' may subsequently be included in other messages such as referrals or requests for other blood tests.

The ELEMENT hierarchy as a whole supports the exchange of records data, derived data or summary information as part of a shared care process. Information about a patient or service user may be exchanged between two services responsible for different aspects of the care of the same person. The systems they use may differ due to a difference in perspective, but common items of information need to be recognised and interpreted in a consistent manner and it is the ELEMENT, as used by the LRA, that provides the common definition.

- For example, the records data that an antenatal maternity patient has a family history of diabetes mellitus, has tested positive for 'sickle-cell trait' and has a raised BMI should be accessible to the appropriate GP, midwife and obstetrician. If the patient requires a Caesarean section, then the anaesthetist should also be aware of this. Similarly, decision support tools used by different members of the care team should have access to this information. The Care Components reference model provides the basis for a common view and computable interpretation of this type of information.

## 4.4 Data Capture and Display

The notion of the *composition* is used by a number electronic health interoperability standards to represent the attestable unit of modification of a single EHR by the atomic commitment of information from a single encounter or documentation session. When retrieved, whole compositions can serve as the unit of display (or communication) of the data as attested. [4] [18] The Archetype and Template-based frameworks that use the *openEHR* reference model [19] extend this notion further and the use compositions as abstract representations of data entry forms.

The support provided by the LRA through the Care Components reference model for data capture and display is discussed below.

#### 4.4.1 Data Capture

The care information required for storage, retrieval and reuse must be collected through user interfaces that are easy to use as part of the process of delivering care. The Care Components reference model does not support the detailed specification of how information should be captured. This is instead addressed in depth by the NHS Common User Interface specifications. The reference model does, however, allow data items that have a requirement to be captured to be enumerated as individual ELEMENTs grouped by one or more ENTRYs within a single attestable COMPOSITION. As noted previously, ENTRY do not affect the meaning based interpretation of the ELEMENTs contained therein. Thus regardless of the way in which the data is captured, the reference model provides a means of consistently specifying its retrieval. It is preferable therefore that the chosen method of capture should be designed in a way that supports meaning-based retrieval in an LRA conformant manner.

- For example, an item of family history can be captured in many different ways and at different levels of detail<sup>6</sup>. The resulting care record should be able to answer a question such as 'does the patient have a family history of heart disease?' without requiring knowledge of the way the data was captured in any particular care record application.

Constrained data models based on the reference model can also be used to support specification of data capture requirements.

- The reference model can be used to support automated form building as indicated by the broken line between the retrieval and capture stages in Figure 2.
- As noted previously the ELEMENT hierarchy provides a framework for machine testable specification of information content requirements. This provides a way to determine the completeness of a record during (or after) an interaction with the record.
  - For example, a record content requirement for each antenatal consultation record could be specified as the need to record the patient's weight unless it was recorded previously within the last 7 days. This would translate to a conditional data capture requirement<sup>7</sup>.
- As noted in the next section the reference model provides support for display requirements - this could be extended to support the pre-population of data entry fields where appropriate.

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<sup>6</sup> The methods used to capture family history may include i) using check-boxes, ii) searching the relevant SNOMED CT family history hierarchy, iii) searching the SNOMED CT disorder hierarchy and setting the selected item in the family history situation, iv) free-text with natural language processing, v) following a detailed form base protocol or by confirming previously recorded information. The level of clinical detail may vary depending on whether the precise nature of the condition is known. The detail available about the relationship between the patient and the affected family member or members may vary.

<sup>7</sup> A record content requirement is more flexible than a data capture requirement since it can, where relevant, take account of pre-existing data. Furthermore, it is more easily generalised as it does not assume a particular user interface or order of data entry.

- For example, if the patient or service user record indicates a family history of 'diabetes mellitus' then this can be pre-populated on the data entry screen<sup>8</sup> for possible entry by the author of the current record.
- With respect to the use of SNOMED CT coded expressions, classes from the ELEMENT hierarchy can also be used for the specification of constraints on data capture. The semantic binding and structural constraints used to specify content requirements and retrieval can also be applied to limit options for data entry. In addition, the 'selection support' terminology binding can be used to specify commonly used concepts and expressions within a broader semantic constraint.
  - For example, the semantic constraint on family history recording may include SNOMED CT coded expressions for family history of any disorder and may allow the disorder and family relationships involved to be specified in detail. However, selection support implementation may provide a picking list of familial conditions that are either commonly encountered or are of particular interest. Local implementations may store this data without using SNOMED CT. Whichever approach is taken within a care record application, the resulting record of a positive family history should be retrievable (with respect to coded expression references) in the same way, particularly in terms of the range and level of detail in the meaning of possible family histories, which will be scoped within the LRA.

#### 4.4.2 Display

As with data capture, the details of how information should be displayed are addressed in depth by the NHS Common User Interface specifications. The reference model does, however, allow data items that have a requirement to be displayed to be enumerated as individual ELEMENTs grouped by one or more ENTRYs (optionally organised by SECTIONs) within a single attestable COMPOSITION. Furthermore, a pre-requisite for display is selective retrieval of the information to be displayed and the reference model facilitates this by providing a common framework for meaning-based retrieval. This enables consistent display of information irrespective of the way in which it was collected.

- For example, a requirement to display the patient's latest weight requires the parts of the historical record containing 'weight' measurements to be identified and from these the most recent can then be selected and the measurement and date can then be displayed.

### 4.5 Supporting Functions

#### 4.5.1 Identifying Roles and Responsibilities

The Care Components model allows for the identification of participants as follows.

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<sup>8</sup> According to clinical guidelines there may be a requirement to reconfirm some or all pre-populated information.

#### 4.5.1.1 Subject of Care

The `subject_of_care` attribute of the `EHR_EXTRACT` class identifies the patient or service user (within the context of the EHR Extract) from whose EHR the EHR Extract was created.

The `subject_of_care` serves to identify a snapshot of demographic information as held by the EHR Provider, to enable the patient to be matched to the demographics repository of the EHR Recipient, and / or for the `EHR_EXTRACT` to be referenced to the individual subject of care even if external demographics services are not available. [4]

#### 4.5.1.2 Functional Roles

The `FUNCTIONAL_ROLE` class identifies of an individual agent who contributed to the care or care record of the patient or service user. The class requires the identity of the performer<sup>9</sup> and optionally allows for specification of:

- the function performed;
- the mode in which participation was made (e.g. in person, by telephone);
- the healthcare facility at which the agent was present; and
- the kind of service location, department or setting in which the agent performed that role.

#### 4.5.1.3 Subject of Information

The `RELATED_PARTY` class is used to represent information concerning the health or care of an individual other than the record subject. The commonest example of this requirement is family history, but information about other parties such as the patient or service user's life partner, sexual partner, employer, child, etc also may be of significance to the care of the record subject and therefore recorded in subject's care record.

The extract model supports the distinction of such data using a `RELATED_PARTY` class, an instance of which may be optionally associated with the `ENTRY` to which it applies.

This class enables:

- identification of the related party's relationship to the subject of care – this is constrained to a coded concept value within the LRA derivation of the class; and
- optionally, identification of the person through an identifier<sup>10</sup>.

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<sup>9</sup> The details of the performer, other than their unique identifier, are represented by classes and relationships defined within Participants infrastructure specification within this series.

<sup>10</sup> The details of any related party, other than the party's unique identifier, are represented by classes and relationships defined within Active Participants infrastructure specification within this series.

Assuming the use of a nationally recognised demographic identifier (i.e. NHS Number) and if data protection restrictions allow, this could be used to access details that related party has given consent to share. Possible use cases for this may occur in clinics providing genetic or family therapies as well as sometimes in primary care.

#### **4.5.2 Audit Information**

The AUDIT\_INFO class fulfils the medico-legal requirement of being able to document and to communicate when and by whom EHR data were entered into an EHR system. It is also used to track changes to EHR data if modifications are made. An instance of the class is held:

- optionally, by any RECORD\_COMPONENT, as a permanent record of its commitment in its originating EHR system; and
- by each COMPOSITION, as a record of its commitment within the EHR Provider system that generated the EHR\_EXTRACT.

The committal AUDIT\_INFO instance held by the COMPOSITION specifies the date and time of committal, and identifies the committer<sup>11</sup> and the EHR system into which the data were committed. The timestamp of the feeder\_audit AUDIT\_INFO instance reflects the date and time that the RECORD\_COMPONENT was persisted within an EHR system and therefore became part of the the patient's or service user's EHR.

For revision tracking, the class provides the version status, an optional reason for revision, the identity of the immediately previous version that was the basis of this revision, and an identifier that is common to all versions – so that non-sequential versions made on different EHR systems can still be related to each other.

#### **4.5.3 Attestation Information**

Attestation is the process of certifying and recording legal responsibility for a particular unit of information. The attestation of part of an EHR is a mechanism whereby the attester can provide his or her authority that those contents are, in his or her opinion, correct. This means that he or she is satisfied that the contents are a fair and faithful reflection of the processes they document, and do not deliberately misrepresent the truth. Attesting a part of an EHR will not have modified its content or interpretation, other than by adding weight to its authenticity. (Anything which added an opinion, a new viewpoint or perspective would have been either a revision or a new set of entries with a link to this one.)

The Care Components reference model adopts the from the general standard the ATTESTATION\_INFO class which provides for representation of:

- the date and time at which it occurred;

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<sup>11</sup> The details of the committer, other than their unique identifier, are represented by classes and relationships defined within Participants infrastructure specification within this series.

- the person who made this attestation, as a reference to the FUNCTIONAL\_ROLE class described above;
- the list of RECORD\_COMPONENTS that were attested;
- optionally the reason for, or legal significance of, this attestation;
- optionally the electronic signature (as encapsulated data, or as reference to it) that verifies the attestation; and
- optionally the encapsulated data, or a reference to it, that represents the visual image that was actually viewed by the attester.

## **5 Conformance to International Standards**

### **5.1 Conformance to EN 13606-1:2007**

The Care Components reference model is derived by constraint from EN 13606:2007 [4] with the exception of the following non-conformances:

- the Care Components model pre-adopts the use of ISO 21090:2008 data types (the generalised model was updated to use ISO 21090:2008 data types as shown in appendix A, prior to applying the constraints used to derive the Care Components model); and
- the Care Components model specifies an `Ira.technical.en13606.extended` package which defines a limited number of LRA-specific extensions to the general standard with aim of proposing them for adoption by the standard.

It should be noted that this specification does not adopt the EN 13606-1:2007 FOLDER class as it is not required for meaning retrieval within the LRA.

### **5.2 Conformance to ISO 21090:2008**

The Care Components reference model uses the set of data types specified by the LRA Data Types Specification. This set conforms to the ISO 21090:2008 [8] implementation technology specification of the HL7 v3 R2 Abstract Datatypes. [7]

### **5.3 Alignment with HL7 CDA Release 2**

The proposed model assumes that where a part of the care record needs to be represented as an electronic document, the top level structure of each document is structured in a manner that is aligned with HL7 CDA Release 2. [18]

The CDA document is assumed to provide record-subject, authoring and attributed information inherited by the contained information units; so this is not repeated.



## 6 Class Model Specification

This specification was generated from the UML source model using the RTF Class Model Specification template (v1.0.4) at 2010-01-07 10:19:48.

### 6.1 Package *lra.technical.en13606*

The en13606 package contains an Electronic Health Record (EHR) extract and a demographics package whose contents derive from and conform to the EN 13606-1:2007 and comprise the Care Components reference model.

### 6.2 Package *lra.technical.en13606.demographics*

The demographics package defines a single abstract class, *IDENTIFIED\_ENTITY* derived from the optional EN 13606-1:2007 demographics package. The main purpose of the class is to provide an attribute by which specialised instances of the class representing the details of roles played by person, organisation and device entities can be uniquely identified within the EHR and referenced within the extract.

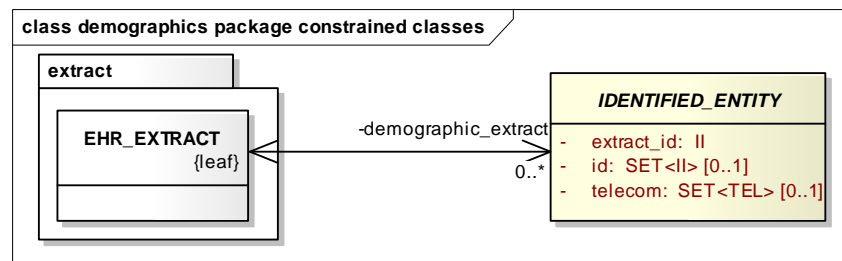


Figure 1: demographics package constrained classes

#### 6.2.1 Abstract Class *IDENTIFIED\_ENTITY*

*Specialises:*

*Realises:*

Any Identified Party, which may be an Organisation, Person, or Device or Software.

##### 6.2.1.1 Attributes

Attribute	Description
extract_id : II [1..1]	<p>The unique identifier used consistently within the Extract Package of this EHR_EXTRACT to represent the <i>IDENTIFIED_ENTITY</i> referred to in this Demographics Package.</p> <p>In the LRA <i>IDENTIFIED_ENTITY</i> is specialized in the participations package by a <i>CR_Role</i>. The unique identifier used within the Extract package will refer to a <i>CR_Role</i> class.</p>
id : SET<II> [0..1]	<p>An optional set of identifiers by which this <i>IDENTIFIED_ENTITY</i> may be referenced within EHR systems, by health services, professional bodies etc, to support</p>

Attribute	Description
	<p>demographic matching of this <i>IDENTIFIED_ENTITY</i> by the EHR Recipient.</p> <p>In the LRA this is used to identify the entity playing this role using a designated identification scheme (e.g. using an NHS Number, SDS etc.).</p> <p><b><u>NHS Data Dictionary:</u></b></p> <ul style="list-style-type: none"> <li>• <b>NHS NUMBER:</b> A number used to identify a PATIENT uniquely within the NHS in England and Wales.</li> <li>• <b>CARE PROFESSIONAL IDENTIFIER:</b> A number or set of characters which uniquely identifies a CARE PROFESSIONAL.</li> </ul> <p><b><u>Derivation:</u></b></p> <ul style="list-style-type: none"> <li>• <b>HL7:</b> Role.id</li> <li>• <b>HL7:</b> Patient.id</li> <li>• <b>EN 13606:</b> SUBJECT_OF_CARE_PERSON_IDENTIFICATION.id</li> <li>• <b>EN 13606:</b> FUNCTIONAL_ROLE.performer</li> <li>• <b>EN 13606:</b> HEALTHCARE_PROFESSIONAL_ROLE.id</li> </ul>
telecom : SET<TEL> [0..1]	<p>A set of communications descriptors by which this <i>IDENTIFIED_ENTITY</i> may be contacted or connected to.</p> <p>In the LRA this represents an entity's telecommunication details whilst playing this role.</p> <p><b><u>NHS Data Dictionary:</u></b></p> <ul style="list-style-type: none"> <li>• <b>COMMUNICATION CONTACT INFORMATION:</b> A contact method for an ORGANISATION or a PERSON, for a particular COMMUNICATION CONTACT METHOD (e.g. facsimile, telephone, e-mail or website).</li> </ul> <p><b><u>Derivation:</u></b></p> <ul style="list-style-type: none"> <li>• <b>HL7:</b> Role.telecom</li> <li>• <b>EN 13606:</b> IDENTIFIED_ENTITY.TELECOM</li> </ul>

Attribute	Description

### 6.2.1.2 Relationships

Relationship Type	Source	Target	Description
Association	EHR_EXTRACT	demographic_extract IDENTIFIED_ENTITY 0..*	An optional set of demographic descriptors corresponding to relevant identifiers used within other parts of this EHR_EXTRACT to reference persons, organizations, devices or software.
Generalization	CR_Role	IDENTIFIED_ENTITY	An IDENTIFIED_ENTITY is specialized by a CR_Role.

## 6.3 Package **lra.technical.en13606.extended**

This package defines LRA-specific extensions to the EN 13606-1:2007 standard with a view to them being proposed for adoption by the standard.

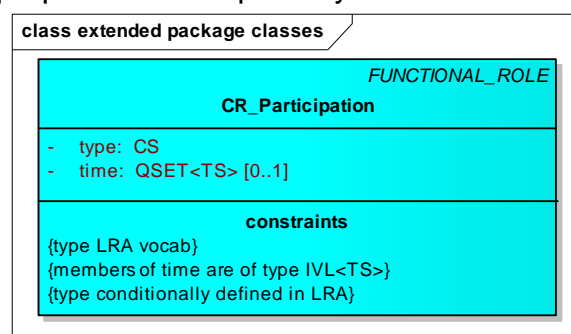


Figure 2: extended package classes

### 6.3.1 Class **CR\_Participation**

*Specialises:* FUNCTIONAL\_ROLE

*Realises:*

A class to represent the involvement (e.g. subject, author, performer) of a role (e.g. patient, healthcare professional).

**6.3.1.1 Attributes**

Attribute	Description
type : CS [1..1]	<p>A coded representation of the nature of the involvement (e.g. subject, author, performer) of a role (e.g. patient, healthcare professional).</p> <p><b>Derivation:</b></p> <ul style="list-style-type: none"> <li>• <b>HL7:</b> Participation.typeCode</li> <li>• <b>EN 13606:</b> ENTRY.subject_of_information_category</li> <li>• <b>EN 13606:</b> FUNCTIONAL_ROLE.function</li> </ul>
time : QSET<TS> [0..1]	<p>The point in time or time period when the participation occurred.</p> <p><b>NHS Data Dictionary:</b></p> <ul style="list-style-type: none"> <li>• <b>ACTIVITY DATE TIME:</b> Any date or time that is pertinent to an ACTIVITY.</li> <li>• <b>TIME:</b> The TIME (using a 24 hour clock) at which an event, or the action in an event, takes place.</li> </ul> <p><b>Derivation:</b></p> <ul style="list-style-type: none"> <li>• <b>HL7:</b> Participation.time</li> <li>• <b>EN 13606:</b> ATTESTATION_INFO.time</li> </ul>

**6.3.1.2 Relationships**

Relationship Type	Source	Target	Description
Generalization	CR_Participation	FUNCTIONAL_ROLE	A FUNCTIONAL_ROLE is specialized by a CR_Participation.

**6.3.1.3 Constraints**

Constraint Type	Name	Details
LRA Invariant	type LRA vocab	--The value of attribute type.code is a member of the value set

Constraint Type	Name	Details
		LRAParticipationType inv: type.code.ocllsTypeOf(LRAParticipationType)
LRA Invariant	members of time are of type IVL<TS>	inv: time->forAll(t t.ocllsKindOf(IVL<TS>))
Invariant	type conditionally defined in LRA	-- Attribute type is undefined (i.e. value assignment is prohibited) if extract::COMPOSITION.other_participations.performer or extract::ENTRY.other_participations.performer are undefined inv: if (extract::all_compositions->forAll(other_participations->forAll(performer)).ocllsUndefined() and extract::content->forAll(other_participations->forAll(performer)).ocllsUndefined()) type.ocllsUndefined()

## 6.4 Package **lra.technical.en13606.extract**

The extract package defines the classes, relationships and constraints that comprise the Care Components reference model. The model is derived from and conforms to the EN 13606-1:2007 EHR extract model and specifies the record entry, organiser and supporting structures required communicate part or all of the EHR of an individual patient or service user. The derived reference model constrains many elements of the source model and adds a number of constrained specialisations of class ELEMENT. The constraints specified by these classes are concerned primarily with reducing variability of representation and ensuring that the structural components and bound terminological components act together to represent the computer-processable meaning of the data without unnecessary conflict or duplication.

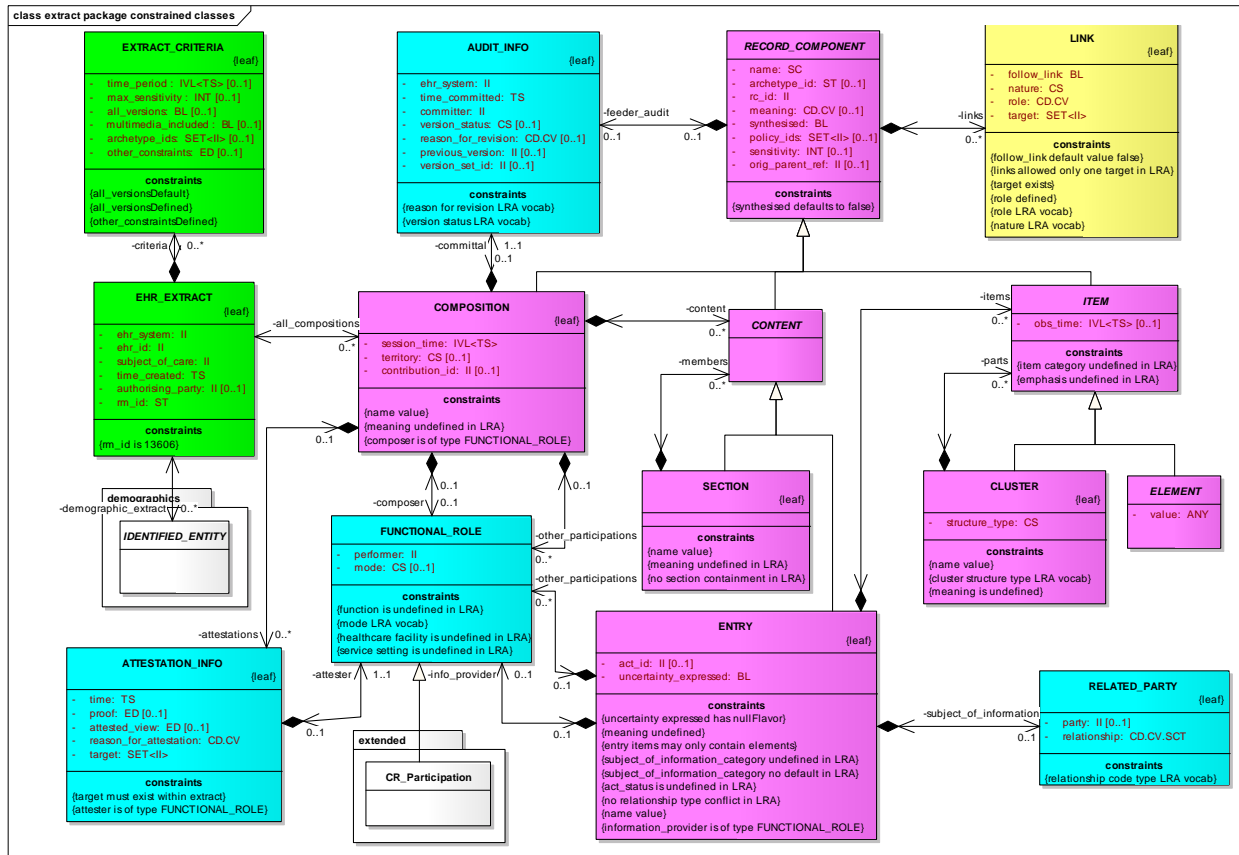


Figure 3: extract package constrained classes

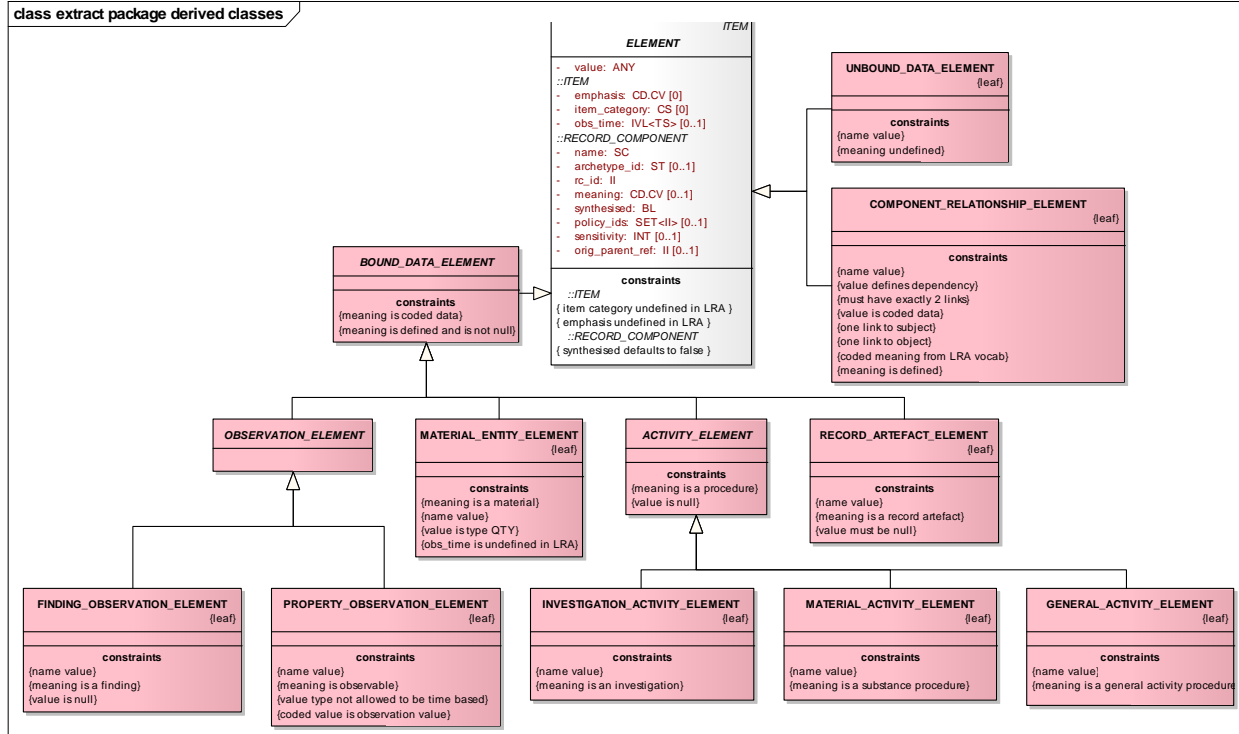


Figure 4: extract package derived classes

### 6.4.1 Abstract Class ACTIVITY\_ELEMENT

*Specialises:* BOUND\_DATA\_ELEMENT

*Realises:*

The ACTIVITY\_ELEMENT class is a BOUND\_DATA\_ELEMENT whose coded meaning is constrained to represent a SNOMED CT procedure situation. The focus concept of the procedure situation must be subsumed either by 71388002 | procedure | or by 363787002 | observable entity | (for any evaluation activity that does not have a corresponding 'evaluation procedure').

Types of information represented by ACTIVITY\_ELEMENT includes:

- Treatments - procedures that are intended to have a therapeutic, preventative, curative or palliative effect.
- Investigations - procedures that are undertaken to find out more information about a patient's state of health or wellbeing.
- Administrative Procedures - procedures, typically of a clerical nature, that support the investigation and/or treatment of a patient.
- Provision of Advice and Information to Patients and Carers - the activity of providing advice and information about a patient's health or social care, to the patient or to their specified carer.

The value attribute is constrained to the null flavor NA | not applicable | so as to prohibit its use within the LRA whilst maintaining conformance to EN 13606-1:2007.

#### 6.4.1.1 Relationships

Relationship Type	Source	Target	Description
Generalization	ACTIVITY_ELEMENT	BOUND_DATA_ELEMENT	
Generalization	MATERIAL_ACTIVITY_ELEMENT	ACTIVITY_ELEMENT	
Generalization	GENERAL_ACTIVITY_ELEMENT	ACTIVITY_ELEMENT	
Generalization	INVESTIGATION_ACTIVITY_ELEMENT	ACTIVITY_ELEMENT	

**6.4.1.2 Constraints**

Constraint Type	Name	Details
Invariant	meaning is a procedure	--The meaning.code conforms to the specified semantic constraint. inv: meaning.code.semantic(LraProcedureObservationElementMeaning)
Invariant	value is null	-- Attribute value has null flavor NA not applicable  value.nullFlavor.ocllsDefined and value.nullFlavor = LraAnyNullFlavor.NA

**6.4.2 Class ATTESTATION\_INFO***Specialises:**Realises:*

This class documents the details of any attestations that pertain to the RECORD\_COMPONENTS within a COMPOSITION.

**6.4.2.1 Attributes**

Attribute	Description
time : TS [1..1]	The date and time at which this attestation occurred.
proof : ED [0..1]	The electronic signature (as encapsulated data, or as reference to it) that verifies the attestation. This is optional as it may not always be required when communicating EHR_EXTRACTS, particularly within a single health service.
attested_view : ED [0..1]	The encapsulated data, or a reference to it, that represents the reproducible rendering (image or presentation specification) that was actually viewed by the attester.
reason_for_attestation : CD.CV [1..1]	A coded value giving the reason for this attestation, to define its specific purpose or the legal requirement it meets.
target : SET<II> [1..1]	A set containing the rc_id of each RECORD_COMPONENT that was attested.

**6.4.2.2 Relationships**



Relationship Type	Source	Target	Description
Association	COMPOSITION 0..1	attestations ATTESTATION_INFO 0..*	This association permits a COMPOSITION to contain any number of attestations that pertain to it or to its contents.
Association	ATTESTATION_INFO 0..1	attester FUNCTIONAL_ROLE 1..1	The identification and role of the person making the attestation.

#### 6.4.2.3 Constraints

Constraint Type	Name	Details
Invariant	target must exist within extract	--For each and every II instance, i, in SET target there exists within the EHR extract an instance of a RECORD_COMPONENT specialisation with an rc_id attribute value equal to i inv: target->forAll(i ehr_extract.all_compositions>exists(rc_id.equal(i))) OR target->forAll(i ehr_extract.all_compositions.content->exists(rc_id.equal(i)))
LRA Invariant	attester is of type FUNCTIONAL_ROLE	inv: attester.ocllsTypeOf(FUNCTIONAL_ROLE)

#### 6.4.3 Class AUDIT\_INFO

*Specialises:*

*Realises:*

This class represents the committal and revision data about a RECORD\_COMPONENT. Through the committal association from COMPOSITION this class represents the committal and revision data about this COMPOSITION in the EHR Provider system. Through the feeder\_audit association from RECORD\_COMPONENT this class represents the committal and revision data about

this RECORD\_COMPONENT in the original EHR system in which it was first committed.

#### 6.4.3.1 Attributes

Attribute	Description
ehr_system : II [1..1]	This attribute identifies the EHR system in which this RECORD_COMPONENT was committed.
time_committed : TS [1..1]	Date and time at which this RECORD_COMPONENT was committed within the identified EHR system and therefore became part of that EHR of the subject of care.
committer : II [1..1]	The party responsible for committing this RECORD_COMPONENT within the EHR of this subject of care.
version_status : CS [0..1]	The medico-legal status of this version of the RECORD_COMPONENT. The code set for this attribute is defined in EN 13606-3:2008.
reason_for_revision : CD.CV [0..1]	A code for the reason for assigning the current version status.
previous_version : II [0..1]	This attribute is the rc_id of the RECORD_COMPONENT of which the current RECORD_COMPONENT is a revision. If this attribute is null, there is no previous version (i.e. it is the very first version).
version_set_id : II [0..1]	This attribute value is the rc_id of the very first version of this RECORD_COMPONENT. This attribute may be null if this RECORD_COMPONENT is the very first version.

#### 6.4.3.2 Relationships

Relationship Type	Source	Target	Description
Association	COMPOSITION 0..1	committal AUDIT_INFO 1..1	This mandatory association contains the committal (and optionally revision) information for this COMPOSITION in the EHR Provider's system.

Relationship Type	Source	Target	Description
Association	RECORD_COMPONENT 0..1	feeder_audit AUDIT_INFO 0..1	This association represents the committal and revision information specifically for this RECORD_COMPONENT in the EHR system in which it was originally committed. This association may be omitted if this RECORD_COMPONENT shares the same committal information as its parent RECORD_COMPONENT. In the case of a COMPOSITION, this association may also be omitted if the EHR Provider system is its originating system (since the data will be identical to that represented via the committal association).

#### 6.4.3.3 Constraints

Constraint Type	Name	Details
LRA Invariant	reason for revision LRA vocab	inv: reason_for_revision.code.ocllsTypeOf(LraAuditInfoReasonForRevision)
LRA Invariant	version status LRA vocab	inv:

Constraint Type	Name	Details
		version_status.code.ocllsTypeOf(LraAuditInfoVersionStatus) --This is a mandatory set in 13606

#### 6.4.4 Abstract Class BOUND\_DATA\_ELEMENT

*Specialises:* ELEMENT

*Realises:*

The BOUND\_DATA\_ELEMENT class is an ELEMENT whose meaning is constrained and processable, for the purpose of automated retrieval, using SNOMED CT. The inherited meaning attribute is therefore used to specify the coded meaning including all coded context. Specialisations of BOUND\_DATA\_ELEMENT further constrain the permissible meanings of instances which must be guaranteed to conform to their constraints when evaluated.

From the perspective of the data retriever, the content of interest of a BOUND\_DATA\_ELEMENT instance may be the meaning itself and / or a typed data value described by the meaning.

##### 6.4.4.1 Relationships

Relationship Type	Source	Target	Description
Generalization	MATERIAL_ENTITY_ELEMENT	BOUND_DATA_ELEMENT	
Generalization	BOUND_DATA_ELEMENT	ELEMENT	
Generalization	ACTIVITY_ELEMENT	BOUND_DATA_ELEMENT	
Generalization	RECORD_ARTEFACT_ELEMENT	BOUND_DATA_ELEMENT	

Relationship Type	Source	Target	Description
Generalization	OBSERVATION_ELEMENT	BOUND_DATA_ELEMENT	

#### 6.4.4.2 Constraints

Constraint Type	Name	Details
LRA Invariant	meaning is coded data	inv: meaning.ocllsKindOf(CD.CV.SCT)
LRA Invariant	meaning is defined and is not null	--Attribute meaning is defined (i.e. must be assigned a value) inv: meaning.ocllsDefined() and meaning.isNull = false

#### 6.4.5 Class CLUSTER

*Specialises:* ITEM

*Realises:*

This class represents the hierarchical organisation of the data structure of each ITEM within an ENTRY, to permit the nesting or grouping of ELEMENTs with the same obs\_time, or of one item\_category or to organise rows of tabular data.

##### 6.4.5.1 Attributes

Attribute	Description
structure_type : CS [1..1]	This will indicate the time and/or spatial organisation of the data within this CLUSTER. The code set for this attribute is defined in EN 13606-3:2008.  The code value of this attribute is constrained by the LRA to being a member of the LraStructureType value set.

##### 6.4.5.2 Relationships

Relationship Type	Source	Target	Description
Generalization	CLUSTER	ITEM	

Relationship Type	Source	Target	Description
Association	CLUSTER	parts ITEM 0..*	This association permits a CLUSTER to contain other CLUSTERs and/or ELEMENTs.

#### 6.4.5.3 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.CLUSTER
LRA Invariant	cluster structure type LRA vocab	--The value of attribute name.code.code is a member of the value set LraClusterStructureType. inv: structure_type.code.ocllsTypeOf(LraClusterStructureType)
LRA Invariant	meaning is undefined	--Attribute meaning is undefined (i.e. value assignment is prohibited) inv: meaning.ocllsUndefined()

#### 6.4.6 Class COMPONENT\_RELATIONSHIP\_ELEMENT

*Specialises:* ELEMENT

*Realises:*

The COMPONENT\_RELATIONSHIP\_ELEMENT class is an ELEMENT whose coded meaning is constrained to represent an asserted relationship between two other RECORD\_COMPONENTs. The association role links collection is therefore constrained to two member LINKs, one of which references the subject RECORD\_COMPONENT and the other the object.

Because the COMPONENT\_RELATIONSHIP\_ELEMENT is a RECORD\_COMPONENT in its own right, it can be asserted, revised or maintained separately from both the related RECORD\_COMPONENTs.

##### 6.4.6.1 Relationships

Relationship Type	Source	Target	Description
Generalization			

Relationship Type	Source	Target	Description
	COMPONENT_RELATIONSHIP_ELEMENT	ELEMENT	

#### 6.4.6.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.COMPONENT_RELATIONSHIP_ELEMENT
LRA Invariant	value defines dependency	-- Attribute value is from a coded set which defines the dependency of this individual relationship inv: value.code.ocllsTypeOf(LraComponentRelationshipElementValue)
LRA Invariant	must have exactly 2 links	-- Association role links collection has two members inv: links->size() = 2
LRA Invariant	value is coded data	inv: value.ocllsKindOf(CD.CV)
LRA Invariant	one link to subject	inv: links->exists(link link.role = LraRoleCode.SUBJECT)
LRA Invariant	one link to object	inv: links->exists(link link.role = LraRoleCode.OBJECT)
LRA Invariant	coded meaning from LRA vocab	inv: meaning.isOclKindOf(CD.CV) and meaning.code.ocllsTypeOf(LraComponentRelationshipElementValue)
LRA Invariant	meaning is defined	--Attribute meaning is defined (i.e. must be assigned a value) inv: meaning.ocllsDefined()

### 6.4.7 Class COMPOSITION

*Specialises:* RECORD\_COMPONENT

*Realises:*

A COMPOSITION represents the set of RECORD\_COMPONENTs composed (authored) during one clinical encounter or documentation session, and committed within one EHR.

The COMPOSITION is constrained for use within the LRA to comprise a set of ENTRY instances each of which contains one or more ELEMENTs.

#### 6.4.7.1 Attributes

Attribute	Description
session_time : IVL<TS> [1..1]	The date and time or interval during which the clinical encounter or documentation session occurred.
territory : CS [0..1]	Code for the territory in which this COMPOSITION was created, identified by ISO 3166. This will indicate the country under whose laws this COMPOSITION was created.
contribution_id : II [0..1]	This optional identifier may be used to logically group the set of COMPOSITIONs committed by one user at one point in time in the EHR of one subject of care, if an EHR system has permitted data to be committed simultaneously into multiple COMPOSITIONs.

#### 6.4.7.2 Relationships

Relationship Type	Source	Target	Description
Association	COMPOSITION 0..1	attestations ATTESTATION_INFO 0..*	This association permits a COMPOSITION to contain any number of attestations that pertain to it or to its contents.
Generalization	COMPOSITION	RECORD_COMPONENT	
Association	EHR_EXTRACT	all_compositions COMPOSITION	All COMPOSITIONS



Relationship Type	Source	Target	Description
		0..*	included in this EHR_EXTRACT are included by value through this association.
Association	COMPOSITION 0..1	committal AUDIT_INFO 1..1	This mandatory association contains the committal (and optionally revision) information for this COMPOSITION in the EHR Provider's system.
Association	COMPOSITION	content CONTENT 0..*	This association contains the set of SECTIONs and ENTRYs that are part of this COMPOSITION. A COMPOSITION may have no content if it is a revision of a COMPOSITION previously recorded in error.
Association	COMPOSITION 0..1	other_participations FUNCTIONAL_ROLE 0..*	This association permits the representation of any other agents who have contributed to this clinical encounter or documentation session.  Within the LRA the members of the association role collection may be specified as being of type

Relationship Type	Source	Target	Description
			Ira.technical.en13606.extended.CR_Participation to allow for the specification of the participation type and (optionally) participation time. However, because CR_Participation is an LRA-specific extension to EN 13606, any information specified by instances of the class is outside of the scope of interpretation by systems that conform to the general standard only.
Association	COMPOSITION 0..1	composer FUNCTIONAL_ROLE 0..1	Agent (person, device or software) responsible for creating, synthesising or organising information that is committed to an EHR. This agent takes responsibility for its inclusion in that EHR, even if not the originator of it and even if not the committer of it. The content of the COMPOSITION is primarily attributed to this person. Whether or not the composer is changed when a

Relationship Type	Source	Target	Description
			revision is made is optional, usually depending upon the extent of the changes made.

#### 6.4.7.3 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.COMPOSITION
LRA Invariant	meaning undefined in LRA	--Attribute meaning is undefined (i.e. value assignment is prohibited) inv: meaning.ocllsUndefined()
LRA Invariant	composer is of type FUNCTIONAL_ROLE	inv: composer.ocllsDefined() implies composer.ocllsTypeOf(FUNCTIONAL_ROLE)

#### 6.4.8 Abstract Class CONTENT

*Specialises:* RECORD\_COMPONENT

*Realises:*

This class is the abstract parent of SECTION and ENTRY, which constitute the EHR data content of a COMPOSITION.

##### 6.4.8.1 Relationships

Relationship Type	Source	Target	Description
Generalization	CONTENT	RECORD_COMPONENT	
Association	COMPOSITION	content CONTENT 0..*	This association contains the set of SECTIONS and ENTRIES that are part of this

Relationship Type	Source	Target	Description
			COMPOSITION. A COMPOSITION may have no content if it is a revision of a COMPOSITION previously recorded in error.
Association	SECTION	members CONTENT 0..*	This association permits a SECTION to contain other SECTIONs.  The members collection is constrained for use by the LRA to exclude the containment ENTRY instances.
Generalization	ENTRY	CONTENT	
Generalization	SECTION	CONTENT	

#### 6.4.9 Class EHR\_EXTRACT

*Specialises:*

*Realises:*

This class represents the root node of an EHR Extract: of part or all of the health record information extracted from an EHR Provider system for the purposes of communication to an EHR Recipient (which might be another repository, a client application or a middleware service such as an electronic guideline component).

##### 6.4.9.1 Attributes

Attribute	Description
-----------	-------------

Attribute	Description
ehr_system : II [1..1]	The identity of the EHR Provider system from which this EHR Extract has been created.
ehr_id : II [1..1]	The identity of the EHR from which this EHR Extract has been created. It shall be unique for that EHR Provider system for this subjectofcare.
subject_of_care : II [1..1]	Unique identifier of the subject of care from whose EHR this EHR Extract was created, as defined by the EHR Provider system.
time_created : TS [1..1]	The date and time at which data from this subject of care's EHR was queried or exported in order to create this EHR Extract.
authorising_party : II [0..1]	Agent authorising the EHR Extract to be created and sent. This attribute is optional since some extracts might be created automatically between (authorised) interacting computing services.
rm_id : ST [1..1]	The identity and version of the Reference Model standard under which this EHR_EXTRACT was made. For an EHR Extract conforming to this standard the attribute will have the string value "EN13606".

#### 6.4.9.2 Relationships

Relationship Type	Source	Target	Description
Association	EHR_EXTRACT	all_compositions COMPOSITION 0..*	All COMPOSITIONS included in this EHR_EXTRACT are included by value through this association.
Association	EHR_EXTRACT	demographic_extract IDENTIFIED_ENTITY 0..*	An optional set of demographic descriptors corresponding to relevant identifiers used within other parts of this

Relationship Type	Source	Target	Description
			EHR_EXTRACT to reference persons, organizations, devices or software.
Association	EHR_EXTRACT	criteria EXTRACT_CRITERIA 0..*	The set of criteria by which the EHR of the subject of care was queried or filtered in order to generate this EHR_EXTRACT. These might not correspond directly to the criteria supplied in an EHR_EXTRACT Request.

#### 6.4.9.3 Constraints

Constraint Type	Name	Details
Invariant	rm_id is 13606	inv: rm_id.value = 'EN 13606'

#### 6.4.10 Abstract Class ELEMENT

*Specialises:* ITEM

*Realises:*

This class represents the leaf nodes within the EHR hierarchy. Each instance of this class will have a single data value, which is one of a defined set of data types.

The ELEMENT class is declared abstract for use by the LRA and thus may be instantiated only through one of its non-abstract specialisations.

##### 6.4.10.1 Attributes

Attribute	Description
value : ANY [1..1]	An ELEMENT has a single DATA_VALUE containing the value, unless this is indicated as absent by a null_flavour attribute.

##### 6.4.10.2 Relationships

Relationship Type	Source	Target	Description
Generalization	BOUND_DATA_ELEMENT	ELEMENT	
Generalization	UNBOUND_DATA_ELEMENT	ELEMENT	
Generalization	ELEMENT	ITEM	
Generalization	COMPONENT_RELATIONSHIP_ELEMENT	ELEMENT	

#### 6.4.11 Class ENTRY

*Specialises:* CONTENT

*Realises:*

The ENTRY class contains (as ITEMS) the information acquired and recorded for a single observation or observation-set (battery or time series), a single clinical statement such as a portion of the patient's history or an inference or assertion, or a single action that is intended or has actually been performed. An ENTRY may have zero ITEMS if it is a revision of an ENTRY previously recorded in error.

By implication of the Reference Model, each and every ELEMENT instance within an ENTRY must share the same information provider (i.e. source of information) and refer to the same subject of information.

The items collection of the ENTRY class is constrained for use by the LRA to contain member instances of type ELEMENT only.

##### 6.4.11.1 Attributes

Attribute	Description
act_id : II [0..1]	The identifier value of this attribute relates this ENTRY, if it documents an activity, to an act management or workflow system.

Attribute	Description
act_status : CS [0..0]	<p>This attribute represents the action state of the ENTRY if it is an activity being managed by an act management or workflow system. The code set for this attribute is defined in EN 13606-3:2008.</p> <p>This semantics of this attribute overlap with the SNOMED CT Procedure Context attribute used by the LRA within the RECORD_COMPONENT meaning attribute expression. Use of attribute act_status is therefore prohibited within the LRA.</p>
uncertainty_expressed : BL [1..1]	<p>This attribute is set to TRUE to advise the EHR Recipient that this ENTRY contains data that indicates some degree of uncertainty, and that care should be taken when using these data within automated processes and systems.</p> <p>The finding (or procedure) context values of the ENTRY's member ELEMENTs (expressed via the ELEMENT meaning attribute) may overlap with the semantics of uncertainty_expressed. This attribute therefore has a fixed value of nullFlavor = NA when used within the LRA.</p>
subject_of_information_category : CS [0..0]	<p>The relationship category of person or object about whom the information in this ENTRY relates to the subject of care.</p> <p>The semantics of this attribute overlap with the SNOMED CT Subject Relationship Context attribute used by the LRA within the RECORD_COMPONENT meaning attribute expression. Use of attribute subject_of_information is therefore prohibited within the LRA and the value stated in EN 13606-3 as the default value in the absence of the attribute (DS00 the patient or subject of care ) SHALL NOT apply.</p>

#### 6.4.11.2 Relationships

Relationship Type	Source	Target	Description
Association	ENTRY	subject_of_information RELATED_PARTY 0..1	The relationship to the subject of care, and optionally the identifier, of the person or object about whom the information in this ENTRY relates.
Generalization	ENTRY	CONTENT	



Relationship Type	Source	Target	Description
Association	ENTRY 0..1	other_participations FUNCTIONAL_ROLE 0..*	<p>This association represents any other agents who have contributed to the health or healthcare processes documented within this ENTRY.</p> <p>Within the LRA the members of the association role collection may be specified as being of type <code>Ira.technical.en13606.extended.CR_Participation</code> to allow for the specification of the participation type and (optionally) participation time. However, because <code>CR_Participation</code> is an LRA-specific extension to EN 13606, any information specified by instances of the class is outside of the scope of interpretation by systems that conform to the general standard only.</p>
Association	ENTRY 0..1	info_provider FUNCTIONAL_ROLE 0..1	Person, software or device that has provided the information

Relationship Type	Source	Target	Description
			documented in this ENTRY. The agent need not be specified if the information source is implicit from the clinical context or the participants identified for the COMPOSITION.
Association	ENTRY	items ITEM 0..*	<p>This association contains the data structure and values of the ENTRY.</p> <p>The items collection is constrained for use by the LRA to contain member instances of type ELEMENT only.</p>

#### 6.4.11.3 Constraints

Constraint Type	Name	Details
LRA Invariant	uncertainty expressed has nullFlavor	-- Attribute uncertainty_expressed has null flavor NA not applicable  uncertainty_expressed.nullFlavor.ocllsDefined and uncertainty_expressed.nullFlavor = LraAnyNullFlavor.NA
LRA Invariant	meaning undefined	inv: meaning.ocllsUndefined()
LRA Invariant	entry items may only contain elements	inv: items->forAll(i i.ocllsKindOf(ELEMENT))
LRA Invariant	subject_of_information_category undefined in LRA	--Attribute subject_of_information_category is undefined (i.e. value assignment is

Constraint Type	Name	Details
		prohibited) inv: subject_of_information_category.ocllsUndefined()
LRA Invariant	subject_of_information_category no default in LRA	-- The default value stated in EN 13606-3:2008 for subject_of_information_category does not apply. inv: subject_of_information_category.ocllsUndefined() implies not (subject_of_information_category.code.value = SUBJECT_CATEGORY.DS00)
LRA Invariant	act_status is undefined in LRA	--Attribute act_status is undefined (i.e. value assignment is prohibited) inv: act_status.ocllsUndefined()
LRA Invariant	no relationship type conflict in LRA	inv: items->select(meaning.ocllsTypeOf(CD) and meaning.codesystem = "OID for SNOMED") implies (subject_of_information.relationship.isNotNull() and subject_of_information.relationship.nullFlavour = DER)
Initial value	name value	inv: name.value = LraRecordComponentName.ENTRY
LRA Invariant	information_provider is of type FUNCTIONAL_ROLE	inv: information_provider.ocllsDefined() implies information_provider.ocllsTypeOf(FUNCTIONAL_ROLE)

#### 6.4.12 Class EXTRACT\_CRITERIA

*Specialises:*

*Realises:*

The attributes of this class list the constraints or restrictions that were placed on the query or filter process that created this EHR\_EXTRACT. The EHR Recipient is only

required to retain this information after receipt of this EHR\_EXTRACT if it might subsequently be communicated again with the same content.

#### 6.4.12.1 Attributes

Attribute	Description
time_period : IVL<TS> [0..1]	This attribute specifies a date or time interval to which this EHR_EXTRACT is limited
max_sensitivity : INT [0..1]	This attribute specifies the maximum permitted sensitivity level (extent of authorisation) that was used to extract the data from the EHR provider system.
all_versions : BL [0..1]	This attribute indicates if this EHR_EXTRACT is limited to the most recent version of each COMPOSITION or if it includes all historic versions.
multimedia_included : BL [0..1]	This attribute indicates if multimedia data have deliberately been excluded from this EHR_EXTRACT.
archetype_ids : SET<II> [0..1]	This attribute identifies a set of archetypes if these were used as a basis for selecting data to include in this EHR_EXTRACT.
other_constraints : ED [0..1]	This attribute may be used to represent additional criteria that were used; it is primarily intended for human readership, but might be used for locally-agreed structured criteria. This attribute is used by the LRA to specify the query definition required to create the parent EHR_EXTRACT

#### 6.4.12.2 Relationships

Relationship Type	Source	Target	Description
Association	EHR_EXTRACT	criteria EXTRACT_CRITERIA 0..*	The set of criteria by which the EHR of the subject of care was queried or filtered in order to generate this EHR_EXTRACT. These might not correspond directly to the criteria supplied in an EHR_EXTRACT Request.

**6.4.12.3 Constraints**

Constraint Type	Name	Details
Invariant	all_versionsDefault	--Attribute all_versions has default value false init: all_versions.value = false
LRA Invariant	all_versionsDefined	--Attribute all_versions has a cardinality of 1..1 inv: all_versions.ocllsDefined()
LRA Invariant	other_constraintsDefined	--Attribute other_constraints is defined inv: other_constraints.ocllsDefined()

**6.4.13 Class FINDING\_OBSERVATION\_ELEMENT**

*Specialises:* OBSERVATION\_ELEMENT

*Realises:*

The FINDING\_OBSERVATION\_ELEMENT class is an OBSERVATION\_ELEMENT whose coded meaning is constrained to represent a SNOMED CT finding or event situation. The focus concept of the finding situation must be subsumed either by 404684003 | clinical finding | or by 272379006 | event |.

FINDING\_OBSERVATION\_ELEMENT is used to represent both normal and abnormal clinical states found on examination or deduced from clinical reasoning (e.g. 'clear sputum', 'normal breath sounds', 'poor posture', 'diabetes mellitus') and events to which the patient or service user may have been to subject (e.g. 'physical abuse', 'exposure to mercury').

The value attribute is constrained to the null flavor NA | not applicable | so as to prohibit its use within the LRA whilst maintaining conformance to EN 13606-1:2007.

**6.4.13.1 Relationships**

Relationship Type	Source	Target	Description
Generalization	FINDING_OBSERVATION_ELEMENT	OBSERVATION_ELEMENT	

**6.4.13.2 Constraints**

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value =

Constraint Type	Name	Details
		LraRecordComponentName.FINDING_OBSERVATION_ELEMENT
Invariant	meaning is a finding	--The meaning.code conforms to the specified semantic constraint. inv: meaning.code.semantic(LraFindingObservationElementMeaning)
LRA Invariant	value is null	-- Attribute value has null flavor NA not applicable  value.nullFlavor.ocllsDefined and value.nullFlavor = LraAnyNullFlavor.NA

#### 6.4.14 Class FUNCTIONAL\_ROLE

*Specialises:*

*Realises:*

This class is used to document the participation of a person, device or software component in some activity recorded in the EHR.

##### 6.4.14.1 Attributes

Attribute	Description
function : CD.CV [0..0]	A coded representation of the function or role that was performed.  Within the LRA details of role functions are represented by the lra.technical.en13606.extended.CR_PersonRole.jobRoleCode attribute. Use of attribute function is therefore prohibited within the LRA.
performer : II [1..1]	The identity of the agent performing that the function or role.
mode : CS [0..1]	The mechanism by which that participation was made. The code set for this attribute is defined in EN 13606-3:2008.
healthcare_facility : II [0..0]	The organisation at which the role was performed.  Within the LRA details of role functions are represented by the lra.technical.en13606.extended.CR_RoleOrganisation.careSettingType. Use of attribute service_setting is therefore prohibited within the LRA.

Attribute	Description
	It is assumed that healthcare_facility is intended to describe a similar concept to a scoping organisation. Use of attribute healthcare_facility is therefore prohibited within the LRA.
service_setting : CD.CV [0..0]	The type of service location at which the role was performed.  Within the LRA details of role functions are represented by the <code>Ira.technical.en13606.extended.CR_RoleOrganisation.careSettingType</code> . Use of attribute service_setting is therefore prohibited within the LRA.

#### 6.4.14.2 Relationships

Relationship Type	Source	Target	Description
Generalization	CR_Participation	FUNCTIONAL_ROLE	A FUNCTIONAL_ROLE is specialized by a CR_Participation.
Association	COMPOSITION 0..1	other_participations FUNCTIONAL_ROLE 0..*	This association permits the representation of any other agents who have contributed to this clinical encounter or documentation session.  Within the LRA the members of the association role collection may be specified as being of type <code>Ira.technical.en13606.extended.CR_Participation</code> to allow for the specification of the participation type and (optionally) participation time. However, because CR_Participation

Relationship Type	Source	Target	Description
			is an LRA-specific extension to EN 13606, any information specified by instances of the class is outside of the scope of interpretation by systems that conform to the general standard only.
Association	ENTRY 0..1	other_participations FUNCTIONAL_ROLE 0..*	<p>This association represents any other agents who have contributed to the health or healthcare processes documented within this ENTRY.</p> <p>Within the LRA the members of the association role collection may be specified as being of type <code>Ira.technical.en13606.extended.CR_Participation</code> to allow for the specification of the participation type and (optionally) participation time. However, because <code>CR_Participation</code> is an LRA-specific extension to EN 13606, any information specified by instances of the class is outside of</p>



Relationship Type	Source	Target	Description
			the scope of interpretation by systems that conform to the general standard only.
Association	ATTESTATION_INFO 0..1	attester FUNCTIONAL_ROLE 1..1	The identification and role of the person making the attestation.
Association	ENTRY 0..1	info_provider FUNCTIONAL_ROLE 0..1	Person, software or device that has provided the information documented in this ENTRY. The agent need not be specified if the information source is implicit from the clinical context or the participants identified for the COMPOSITION.
Association	COMPOSITION 0..1	composer FUNCTIONAL_ROLE 0..1	Agent (person, device or software) responsible for creating, synthesising or organising information that is committed to an EHR. This agent takes responsibility for its inclusion in that EHR, even if not the originator of it and even if not the committer of it. The content of the COMPOSITION is primarily attributed

Relationship Type	Source	Target	Description
			to this person. Whether or not the composer is changed when a revision is made is optional, usually depending upon the extent of the changes made.

#### 6.4.14.3 Constraints

Constraint Type	Name	Details
LRA Invariant	function is undefined in LRA	inv: function.ocllsUndefined()
LRA Invariant	mode LRA vocab	inv: mode.code.ocllsTypeOf(LraFunctionalRoleMode)
Initial value	healthcare facility is undefined in LRA	inv: healthcare_facility.ocllsUndefined()
Initial value	service setting is undefined in LRA	inv: service_setting.ocllsUndefined()

#### 6.4.15 Class GENERAL\_ACTIVITY\_ELEMENT

*Specialises:* ACTIVITY\_ELEMENT

*Realises:*

The GENERAL\_ACTIVITY\_ELEMENT class is an ACTIVITY\_ELEMENT whose coded meaning is constrained to represent any procedure situation not represented by one of the other non-abstract specialisations of ACTIVITY\_ELEMENT.

The inherited value attribute is constrained to the null flavor NA | not applicable | so as to prohibit its use within the LRA whilst maintaining conformance to EN 13606-1:2007.

##### 6.4.15.1 Relationships

Relationship Type	Source	Target	Description
Generalization	GENERAL_ACTIVITY_	ACTIVITY_ELEMENT	

Relationship Type	Source	Target	Description
	ELEMENT		

#### 6.4.15.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.GENERAL_ACTIVITY_ELEMENT
Invariant	meaning is a general activity procedure	inv: meaning.code.semantic(LraGeneralActivityElementMeaning)

#### 6.4.16 Class INVESTIGATION\_ACTIVITY\_ELEMENT

*Specialises:* ACTIVITY\_ELEMENT

*Realises:*

The INVESTIGATION\_ACTIVITY\_ELEMENT class is an ACTIVITY\_ELEMENT whose coded meaning is constrained to represent a SNOMED CT procedure situation that resulted in (or is intended to result) in one or more observations (of type OBSERVATION\_ELEMENT). The focus concept of the observable situation must be subsumed either by 386053000 | evaluation procedure | or 108252007 | laboratory procedure | or by 363787002 | observable entity | (for any evaluation activity that does not have a corresponding 'evaluation procedure').

The value attribute is constrained to the null flavor NA | not applicable | so as to prohibit its use within the LRA whilst maintaining conformance to EN 13606-1:2007.

##### 6.4.16.1 Relationships

Relationship Type	Source	Target	Description
Generalization	INVESTIGATION_ACTIVITY_ELEMENT	ACTIVITY_ELEMENT	

##### 6.4.16.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value =

Constraint Type	Name	Details
		LraRecordComponentName.INVESTIGATION_ACTIVITY_ELEMENT
Invariant	meaning is an investigation	--The meaning.code conforms to the specified semantic constraint. inv: meaning.code.semantic(LraInvestigationActivityElementMeaning)

### 6.4.17 Abstract Class ITEM

*Specialises:* RECORD\_COMPONENT

*Realises:*

This class is the abstract parent of CLUSTER and ELEMENT, which represent the data structure and values contained by an ENTRY.

#### 6.4.17.1 Attributes

Attribute	Description
emphasis : CD.CV [0..0]	A way of denoting that the composer wished to mark this ITEM as being of particular note (an unusual measurement value, an unexpected outcome, anything that might be considered necessary to highlight to a future reader). The use case for this attribute within in the LRA is unclear. Use of attribute emphasis is therefore prohibited within the LRA.
item_category : CS [0..0]	This attribute value may be used to classify or logically group sub-components of the ITEM data structure, to distinguish core values from the method of investigation, the patient state etc.  It is unclear how this value will interact with SNOMED CT within the LRA. Use of attribute item_category is therefore prohibited within the LRA.
obs_time : IVL<TS> [0..1]	The date and time, or interval, at which the ITEM actually occurred or was true, if different from the session time of the COMPOSITION.

#### 6.4.17.2 Relationships

Relationship Type	Source	Target	Description
Generalization		RECORD_COMPONENT	

Relationship Type	Source	Target	Description
	ITEM	NT	
Generalization	CLUSTER	ITEM	
Association	CLUSTER	parts ITEM 0..*	This association permits a CLUSTER to contain other CLUSTERs and/or ELEMENTs.
Generalization	ELEMENT	ITEM	
Generalization	ELEMENT	ITEM	
Generalization	ELEMENT	ITEM	
Association	ENTRY	items ITEM 0..*	<p>This association contains the data structure and values of the ENTRY.</p> <p>The items collection is constrained for use by the LRA to contain member instances of type ELEMENT only.</p>

### 6.4.17.3 Constraints

Constraint Type	Name	Details
LRA Invariant	item category undefined in LRA	inv: item_category.ocllsUndefined()
LRA Invariant	emphasis undefined in LRA	inv: emphasis.ocllsUndefined()

#### 6.4.18 Class LINK

*Specialises:*

*Realises:*

The LINK class defines the semantics of a non-containment relationship between two RECORD\_COMPONENTs. A source RECORD\_COMPONENT may have links to any number of target RECORD\_COMPONENTs.

Unless further constrained a source RECORD\_COMPONENT may contain any number of semantically labelled LINK instances each of which specifies the unique identifier of a target RECORD\_COMPONENT. Linking is therefore by reference rather than actual containment.

The LRA uses the LINK class to represent predetermined semantic links between RECORD\_COMPONENTs at design time (similar in function to the ActRelationship construct used to link Acts in HL7 v3 message models). This is in contrast to arbitrary links between components which are asserted at runtime using the COMPONENT\_RELATIONSHIP\_ELEMENT class.

##### 6.4.18.1 Attributes

Attribute	Description
follow_link : BL [1..1]	If this attribute is TRUE then the COMPOSITION that contains the target RECORD_COMPONENT shall be included in this EHR_EXTRACT.
nature : CS [1..1]	The general semantic category of the link that is being declared between two RECORD_COMPONENTs. The code set for this attribute is defined in EN 13606-3:2008.
role : CD.CV [1..1]	The detailed semantic description of the relationship of the target RECORD_COMPONENT to the source RECORD_COMPONENT.  The cardinality of this attribute is constrained for use by LRA to 1..1.
target : SET<II> [1..1]	A set containing the rc_id of each RECORD_COMPONENT that is a target of the link. IN the LRA this set has been constrained to have a size of one. If a specific link is required

Attribute	Description
	more than once it must be restated.

#### 6.4.18.2 Relationships

Relationship Type	Source	Target	Description
Association	RECORD_COMPONENT	links LINK 0..*	Any RECORD_COMPONENT may have zero or more semantic links to other RECORD_COMPONENTs.

#### 6.4.18.3 Constraints

Constraint Type	Name	Details
Initial value	follow_link default value false	--Attribute follow_link has default value false. init: follow_link.value.default = false
Invariant	target exists	--For each and every II instance, i, in SET target there exists within the EHR an instance of a RECORD_COMPONENT specialisation with an rc_id attribute value equal to i inv: target->forAll(i ehr.record_component->exists(rc_id.equal(i)))
LRA Invariant	links allowed only one target in LRA	-- SET target has one member inv: target->size() = 1
LRA Invariant	role defined	--Attribute role is defined (i.e. must be assigned a value) inv: role.ocllsDefined
LRA Invariant	role LRA vocab	--The value of attribute role.code.code is a member of the value set LraLinkRole. inv: role.code.ocllsTypeOf(LraLinkRole)

Constraint Type	Name	Details
LRA Invariant	nature LRA vocab	--The value of attribute nature.code.code is a member of the value set LraLinkNature which must be consistent with 13606. inv: nature.code.ocllsTypeOf(LraLinkRole)

#### 6.4.19 Class MATERIAL\_ACTIVITY\_ELEMENT

*Specialises:* ACTIVITY\_ELEMENT

*Realises:*

The MATERIAL\_ACTIVITY\_ELEMENT class is an ACTIVITY\_ELEMENT whose coded meaning is constrained to represent a SNOMED CT procedure situation involving the administration of a product or substance or the provision of a material entity to a subject. Instances of material entity (including products and subsatnces) are represented by the MATERIAL\_ENTITY\_ELEMENT.

The value attribute is constrained to the null flavor NA | not applicable | so as to prohibit its use within the LRA whilst maintaining conformance to EN 13606-1:2007.

##### 6.4.19.1 Relationships

Relationship Type	Source	Target	Description
Generalization	MATERIAL_ACTIVITY_ELEMENT	ACTIVITY_ELEMENT	

##### 6.4.19.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.
Invariant	meaning is a substance procedure	inv: meaning.code.semantic(LraSubstanceActivityElementMeaning)

#### 6.4.20 Class MATERIAL\_ENTITY\_ELEMENT



*Specialises:* BOUND\_DATA\_ELEMENT

*Realises:*

The MATERIAL\_ENTITY\_ELEMENT class is a BOUND\_DATA\_ELEMENT whose coded meaning is constrained to represent a physical entity (i.e. an independent physical continuant) that that is either a:

- therapeutic pharmaceutical or biologic product;
- substance of relevance to health and social care, including active ingredients of drugs and medicaments, biological and dietary substances and allergens;
- specimen; or
- device, e.g. durable equipment, implantable devices, disposable supplies, etc.

The value attribute is redefined to represent the amount of the material entity present within a mixture or compound regardless of any amount administered or supplied.

#### 6.4.20.1 Relationships

Relationship Type	Source	Target	Description
Generalization	MATERIAL_ENTITY_ELEMENT	BOUND_DATA_ELEMENT	

#### 6.4.20.2 Constraints

Constraint Type	Name	Details
LRA Invariant	meaning is a material	--The meaning.code conforms to the specified semantic constraint. inv: meaning.code.semantic(LraMaterialElementMeaning)
LRA Invariant	name value	inv: name.value = LraRecordComponentName.MATERIAL_ENTITY_ELEMENT
LRA Invariant	value is type QTY	--The value of attribute value of type QTY inv: value.ocllsKindOf(QTY)
LRA Invariant	obs_time is undefined in LRA	inv: obs_time.ocllsUndefined()

#### 6.4.21 Abstract Class OBSERVATION\_ELEMENT

*Specialises:* BOUND\_DATA\_ELEMENT

*Realises:*

The OBSERVATION\_ELEMENT class is a BOUND\_DATA\_ELEMENT whose coded meaning is constrained to represent a SNOMED CT finding situation or observable situation.

Clinical findings are observations about a patient made by a Care Professional, patient, or a carer. Types of information represented by OBSERVATION\_ELEMENT includes:

- clinical observations,
- clinical findings on examination,
- investigation results,
- decisions arrived at as a result of a synthesis of signs, symptoms, investigations (i.e. findings) and clinical knowledge,
- findings resulting from formal assessment procedures such as whether a patient has been assessed under a section of the Mental Health Act,
- administrative findings and
- events.

The OBSERVATION\_ELEMENT class is defined as abstract and therefore can only be instantiated only through one of its non-abstract specialisations.

#### 6.4.21.1 Relationships

Relationship Type	Source	Target	Description
Generalization	FINDING_OBSERVATION_ELEMENT	OBSERVATION_ELEMENT	
Generalization	OBSERVATION_ELEMENT	BOUND_DATA_ELEMENT	
Generalization	PROPERTY_OBSERVATION_ELEMENT	OBSERVATION_ELEMENT	

#### 6.4.22 Class PROPERTY\_OBSERVATION\_ELEMENT

*Specialises:* OBSERVATION\_ELEMENT

*Realises:*

The PROPERTY\_OBSERVATION\_ELEMENT class is an OBSERVATION\_ELEMENT whose coded meaning is constrained to represent a SNOMED CT observable situation and whose value attribute represents an observed or asserted data value.

The focus concept of the observable situation must be subsumed either by 363787002 | observable entity | or by 386053000 | evaluation procedure | or 108252007 | laboratory procedure | (for any 'observation' that does not have a corresponding 'observable entity').

PROPERTY\_OBSERVATION\_ELEMENT is used to represent the results of investigations undertaken to find out more information about a patient's state of health or wellbeing (e.g. 'blood glucose concentration', 'jugular venous pressure', 'Apgar at 10 minutes') and device or procedure related parameter settings (e.g. 'haemodialysis blood flow rate').

The value attribute may be assigned a value of any data type other than QSET<TS> or any specialisation of QSET<TS>.

#### 6.4.22.1 Relationships

Relationship Type	Source	Target	Description
Generalization	PROPERTY_OBSERVATION_ELEMENT	OBSERVATION_ELEMENT	

#### 6.4.22.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.PROPERTY_OBSERVATION_ELEMENT
Invariant	meaning is observable	--The meaning.code conforms to the specified semantic constraint inv: meaning.code.semantic(LraPropertyObservationElementMeaning)
LRA Invariant	value type not allowed to be time based	--The value of attribute value is not permitted to be a of type GTS or a specialisation of GTS. inv: value.ocllsKindOf(QSET<TS>) = false and value.ocllsKindOf(TS) = false
LRA Invariant	coded value is observation	inv: value.ocllsKindOf(CD) implies

Constraint Type	Name	Details
	value	value.semantic() = LraPropertyObservationValue

#### 6.4.23 Class RECORD\_ARTEFACT\_ELEMENT

*Specialises:* BOUND\_DATA\_ELEMENT

*Realises:*

The RECORD\_ARTEFACT\_ELEMENT class is a BOUND\_DATA\_ELEMENT whose coded meaning is constrained to represent the name of a SNOMED CT record artefact type. The focus concept must be subsumed by 419891008 | record artifact |. Instances of RECORD\_ARTEFACT\_ELEMENT are used to organise or label other ELEMENTs so as to aid navigation, viewing and readability but are not permitted to affect the meaning of the content.

Examples of RECORD\_ARTEFACT\_ELEMENT include 'Problems' and 'Primary diagnosis'.

The value attribute is constrained to the null flavor NA | not applicable | so as to prohibit its use within the LRA whilst maintaining conformance to EN 13606-1:2007.

##### 6.4.23.1 Relationships

Relationship Type	Source	Target	Description
NoteLink		RECORD_ARTEFACT_ELEMENT	
Generalization	RECORD_ARTEFACT_ELEMENT	BOUND_DATA_ELEMENT	

##### 6.4.23.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.RECORD_ACTIVITY_ELEMENT
Invariant	meaning is a record artefact	--The meaning.code conforms to the

Constraint Type	Name	Details
		specified semantic constraint. inv: meaning.code.semantic(LraRecordArtefactElementMeaning)
Initial value	value must be null	-- Attribute value has null flavor NA not applicable  value.nullFlavor.ocllsDefined and value.nullFlavor = LraAnyNullFlavor.NA

#### 6.4.24 Abstract Class RECORD\_COMPONENT

*Specialises:*

*Realises:*

This abstract class is the super-class of all of the concrete nodes in the EHR hierarchy: COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and of two abstract class nodes: CONTENT and ITEM.

##### 6.4.24.1 Attributes

Attribute	Description
name : SC [1..1]	The name, expressed as a coded value or as plain text, specifies the clinical or administrative concept to which this EHR node corresponds, as labelled in the EHR system in which it was first committed.
archetype_id : ST [0..1]	The unique identifier of the archetype node to which this RECORD_COMPONENT corresponds, either in the EHR Provider system or as a mapping produced when this EHR_EXTRACT was created. The syntax for populating this attribute value is defined in EN 13606-2:2008.  Within the LRA the value assigned to this attribute SHALL have no effect on the interpretation of instances of this class and the attribute SHALL not be used as a predicate for semantic data retrieval.
rc_id : II [1..1]	The globally-unique identifier by which this node in the EHR hierarchy is referenced in the EHR system to which the data were first committed. This identifier shall be retained by the EHR Recipient and re-used whenever this RECORD_COMPONENT is subsequently included in another EHR_EXTRACT.  Within the LRA this identifier is a persistent UUID that uniquely

Attribute	Description
	identifies the specialised instance of the RECORD_COMPONENT.
meaning : CD.CV [0..1]	The standardised clinical or administrative concept to which the name attribute has been mapped. In archetyped systems it will correspond to the archetype node name. In non-archetyped systems it might be a coded term from an appropriate terminology system.
synthesised : BL [1..1]	This attribute value shall be TRUE if this RECORD_COMPONENT has been created in order to comply with this standard , but this point in the EHR hierarchy has no corresponding node in the EHR from which it was extracted.
policy_ids : SET<II> [0..1]	This attribute identifies one or more access control policies that specifically pertain to this RECORD_COMPONENT and which need to be communicated to the EHR Recipient to govern future access to it. The identifiers may refer to policy information included in this EHR_EXTRACT as defined in EN 13606-4:2007, or to policies held in external policy servers to which the EHR Recipient has access.
sensitivity : INT [0..1]	The sensitivity of this RECORD_COMPONENT, represented using the code set for this attribute defined in EN 13606-4:2007.
orig_parent_ref : II [0..1]	The identity of the RECORD_COMPONENT that is the original parent (context) for this RECORD_COMPONENT, to be present if this information has been copied from another part of the EHR of this subject of care..

#### 6.4.24.2 Relationships

Relationship Type	Source	Target	Description
Generalization	COMPOSITION	RECORD_COMPONENT	
Generalization	CONTENT	RECORD_COMPONENT	

Relationship Type	Source	Target	Description
Association	RECORD_COMPONENT	links LINK 0..*	Any RECORD_COMPONENT may have zero or more semantic links to other RECORD_COMPONENTs.
Generalization	ITEM	RECORD_COMPONENT	
Association	RECORD_COMPONENT 0..1	feeder_audit AUDIT_INFO 0..1	This association represents the committal and revision information specifically for this RECORD_COMPONENT in the EHR system in which it was originally committed. This association may be omitted if this RECORD_COMPONENT shares the same committal information as its parent RECORD_COMPONENT. In the case of a COMPOSITION, this association may also be omitted if the EHR Provider system is its originating system (since the

Relationship Type	Source	Target	Description
			data will be identical to that represented via the committal association).

#### 6.4.24.3 Constraints

Constraint Type	Name	Details
Initial value	synthesised defaults to false	--Attribute synthesised has default value false init: synthesised.value = false

#### 6.4.25 Class RELATED\_PARTY

*Specialises:*

*Realises:*

This Class is provided, for ENTRY.subject\_of\_information, to identify a person in terms of his or her relationship to the subject\_of\_care.

##### 6.4.25.1 Attributes

Attribute	Description
party : II [0..1]	The optional personal identification of the related party.
relationship : CD.CV.SCT [1..1]	The relationship of the Related_Party to the subject of care.

##### 6.4.25.2 Relationships

Relationship Type	Source	Target	Description
Association	ENTRY	subject_of_information RELATED_PARTY 0..1	The relationship to the subject of care, and optionally the identifier, of the person or object about whom the information in this ENTRY relates.

##### 6.4.25.3 Constraints



Constraint Type	Name	Details
LRA Invariant	relationship code type LRA vocab	inv: relationship.code.ocllsTypeOf(LraRelatedPartyRelationship)  -- this is defined as the SNOMED CT person hierarchy

#### 6.4.26 Class SECTION

*Specialises:* CONTENT

*Realises:*

SECTION contains the set of ENTRYs and optionally further SECTIONs that are grouped under one clinical heading.

##### 6.4.26.1 Relationships

Relationship Type	Source	Target	Description
Association	SECTION	members CONTENT 0..*	This association permits a SECTION to contain other SECTIONs.  The members collection is constrained for use by the LRA to exclude the containment ENTRY instances.
Generalization	SECTION	CONTENT	

##### 6.4.26.2 Constraints

Constraint Type	Name	Details
LRA Invariant	name value	inv: name.value = LraRecordComponentName.SECTION
LRA Invariant	meaning undefined in LRA	--Attribute meaning is undefined (i.e. value assignment is prohibited)

Constraint Type	Name	Details
		inv: meaning.ocllsUndefined()
LRA Invariant	no section containment in LRA	inv: members->size()=0 -- sections are defined in extracts in LRA but membership of an ENTRY to a section is done with an explicit link to allow an ENTRY to be part of more than one section. All ENTRYs must be directly contained by the COMPOSITION.

### 6.4.27 Class UNBOUND\_DATA\_ELEMENT

*Specialises:* ELEMENT

*Realises:*

The UNBOUND\_DATA\_ELEMENT class is an ELEMENT whose data value is not described by (i.e. bound to) a SNOMED CT coded concept or expression. The value attribute supports any type of content including text (plain or with mark up) or binary data intended to be presented for human viewing or some other form of interpretation. Also it supports terms and expressions codified using systems other than SNOMED CT.

It is important to note that the data content of an UNBOUND\_DATA\_ELEMENT is not necessarily unstructured (i.e. not machine processable). It may be processable by dedicated text (e.g. NLP), media or other data processing software that understands the content structure. Furthermore such processing may result in the output of assertions that can be expressed using one or more specialised instances of BOUND\_DATA\_ELEMENT and therefore amenable to meaning-based retrieval. However, from the perspective of meaning-based retrieval within the record, the content of the originating UNBOUND\_DATA\_ELEMENT is semantically opaque.

#### 6.4.27.1 Relationships

Relationship Type	Source	Target	Description
Generalization	UNBOUND_DATA_ELEMENT	ELEMENT	

#### 6.4.27.2 Constraints

Constraint Type	Name	Details
-----------------	------	---------

Constraint Type	Name	Details
Initial value	name value	inv: name.value = LraRecordComponentName.UNBOUND_DATA_ELEMENT
LRA Invariant	meaning undefined	inv: meaning.ocllsUndefined()

## 7 Aspects of Representation

### 7.1 Representing Roles

The Care Components model adopts the EHR\_EXTRACT, FUNCTIONAL\_ROLE, RELATED\_PARTY and AUDIT\_INFO classes defined by the general standard to specify the participation in the care process of the patients or service users and other parties with specified roles and responsibilities including care professionals, organisations and devices.

Demographic descriptions of the participating roles are represented by LRA-specific specialisations of the EN 13606-1:2007 abstract *IDENTIFIED\_ENTITY* class (defined in the EN 13606-1:2007 demographics package). The specialisations themselves are defined within the *lra.technical.en13606.extended* package as described in the Participations infrastructure specification. [9] Each specialised role descriptor holds an identifier which it inherits from *IDENTIFIED\_ENTITY* and whose value is unique within the body of the EHR. The EHR\_EXTRACT class allows for the specification of the set of descriptors of the roles that participate within the extract. Each participation instance is then linked to the description of its participating role, where specified, via a reference to its EHR-unique role identifier. This mechanism, which the general standard facilitates through use of *IDENTIFIED\_ENTITY* and EHR\_EXTRACT classes, allows the description of a role to be referenced by any number of participations without having to repeat the role details for each participation. Also it is designed to ensure that any EHR\_EXTRACT can be interpreted in isolation if the recipient system does not have access to the services needed to decode the entity (i.e. business) identifiers used by the EHR Provider. [4]

### 7.2 Representing Participations

The general standard defines a number of specific types of participation such as committer and attester as well as a general other\_participations type. Each specific type of participation implies directly, and therefore has a fixed participation type as shown in Table 1. Furthermore, the participation time of each specific type of participation can be inferred from the surrounding context.

The general standard, however, does not allow specification of the participation type of any other additional participations. Within the LRA other participations may therefore be specified as being of type

*lra.technical.en13606.extended.CR\_Participation* which extends the FUNCTIONAL\_ROLE class to allow for the specification of the participation type and (optionally) participation time. However, because CR\_Participation is an LRA-specific extension to EN 13606, any information specified by instances of the class is outside of the scope of interpretation by systems that conform to the general standard only.

**Table 1 Participation types and temporal scope**

Source class	Participation name	Target class	Reference to EHR-unique role id	Participation type	Implied / fixed	Temporal scope
ATTESTATION_INFO	attester	FUNCTIONAL_ROLE	performer	Authenticator (AUTHEN)	yes	ATTESTATION_INFO.time
COMPOSITION	commital	AUDIT_INFO	committer	Data entry person (ENT)	yes	AUDIT_INFO.time_committed
		AUDIT_INFO	ehr_system	Device (DEV)	yes	
	composer	FUNCTIONAL_ROLE	performer	Author (AUT)	yes	COMPOSITION.session_time
	other_participations	lra.technical.en13606.extended.CR_Participation	performer	Any value from LRAParticipationType except AUT.	no	
EHR_EXTRACT	-	-	authorising_party	Responsible Party (RESP)	yes	EHR_EXTRACT.time_created
	-	-	ehr_system	Device (DEV)	yes	
	-	-	subject_of_care	Record target (RCT)	yes	
ENTRY	info_provider	FUNCTIONAL_ROLE	performer	Informant (INF)	yes	COMPOSITION.session_time or (CLUSTER.obs_time or ELEMENT.obs_time) or CR_Participation.time
	other_participations	lra.technical.en13606.extended.CR_Participation	performer	Any value from LRAParticipationType except INF.	no	
	subject_of_information	RELATED_PARTY	party	Subject (SBJ)	yes	CLUSTER.obs_time or ELEMENT.obs_time
RECORD_COMPONENT	feeder_audit	AUDIT_INFO	committer	Data entry person (ENT)	yes	AUDIT_INFO.time_committed
		AUDIT_INFO	ehr_system	Device (DEV)	yes	

## 7.3 Linking Record Components

A key difference between the LRA Technical Model realisation of EN 13606-1:2007 and previous realisations of the standard is that the LRA strictly limits the use of explicit containment. The general standard allows extracts to be composed of *RECORD\_COMPONENT* aggregations, with several layers of a tree containment structure. It is possible for more than one extract to contain an individual *RECORD\_COMPONENT* in a different structure. The tree containment structure may, at one level, be arbitrary and determined by the authoring process of the extract, or at another level be specified at design time through the use of structure constraining archetypes, and enforced during the data collection process.

However, the semantics of containment often are either unspecified or ambiguous making it difficult to apply meaning-based retrieval. In some situations there is explicit definition inherent in the general standard, e.g. a *COMPOSITION* contains *RECORD\_COMPONENT*s attested by the same person during one “session”. However as the “session” may be the purposeful authoring of an extract composed of historical components, *COMPOSITION*s may implicitly act to contain and group information that has another functional purpose depending on the intention when it was authored. Thus the pre-defined containment semantics of *COMPOSITION* may become ambiguous in use, and the semantics of *COMPOSITION* aggregations can only be interpreted in the context of a controlled, design-time, framework such as archetypal constraints.

Although one solution for this problem lies in archetypes, they do not enforce the rigour required – in fact the design of archetypes in the past has been found not only to introduce further levels of implicit semantics in the design of constrained containment relationship, but also introduce implicit semantics from component sequencing. Consequently the whole archetype structure must be interpreted when accessing a single data point and the semantics of that data point is dependent on the structure.

The Care Components model therefore uses the *COMPONENT\_RELATIONSHIP\_ELEMENT* class to enable the explicit semantic linking of *RECORD\_COMPONENT*s (as shown in Figure 3) and thereby support the meaning-based retrieval of *RECORD\_COMPONENT*s independent of any structures used to constrain their capture or display. As well as specifying the meaning of the link, using the inherited meaning attribute, the class enables relationships between *RECORD\_COMPONENT* instances to be asserted after the instances themselves were created. This allows for perspective of the patient or service user’s care record in which *COMPONENT\_RELATIONSHIP\_ELEMENT* instances are able to have an information lifecycle independent of the subject and object *RECORD\_COMPONENT*s they link and can be asserted to represent dynamic and temporally evolving care-related situations such as an evolving problem.

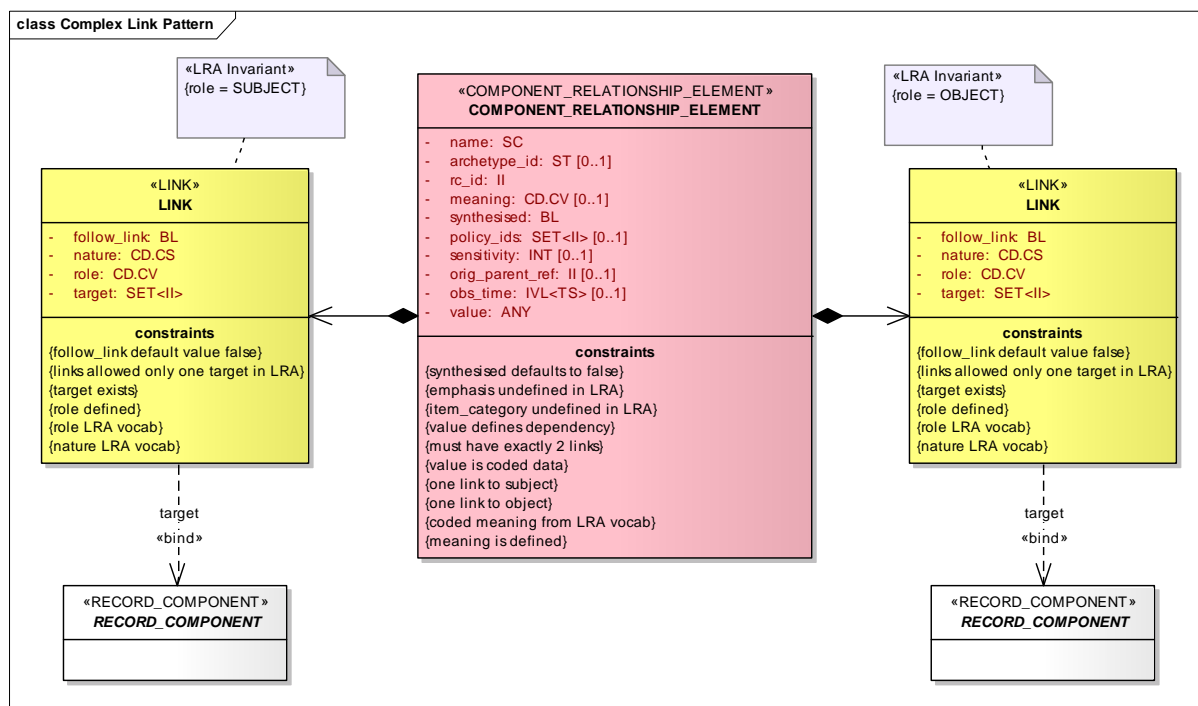


Figure 3 Semantic link pattern

The function of an individual linkage depends on its meaning, expressed using a value taken from the LraComponentRelationship vocabulary (see appendix C), which determines other behaviour of the linkage such as its transitivity, symmetry, domain and ranges. In the longer term it is considered that such rules could determine both the results of queries on the LRA, as well as control the derivation of human readable views of the information.

It is believed that conformance to this kind of model is relatively independent of the internal data representation of a conforming system, and explicit statement of relationship semantics should improve conformance by enabling transformation between different data models containing different implicit semantics, into a

## 7.4 Use of Record Artefacts

While the SECTION class is able to satisfy some record organisation requirements, the general standard only allows the class to contain ENTRYs, and then only from a single COMPOSITION. Representation of 'Problem', however, requires the linking of ENTRYs that relate to the same problem (or health issue) from multiple COMPOSITIONs. Furthermore the Technical Model Infrastructure uses the ELEMENT, not the ENTRY, to represent the primary unit of data retrieval. For this reason, an approach to record organisation that does not require containment is specified using explicit COMPONENT\_RELATIONSHIP\_ELEMENT between RECORD\_COMPONENTs. The RECORD\_ARTEFACT\_ELEMENT is used to represent the organising node of each such linked set.

## 8 SNOMED CT Semantic Expression Constraints

The following sections specify the semantic expression constraints maintained by the meaning attribute of each `BOUND_DATA_ELEMENT` specialisation. Each constraint restricts the range of permissible meanings of the class to which it applies and also serves as the default constraint for any domain-level realisations of the class.

### 8.1 FINDING\_OBSERVATION\_ELEMENT

The coded expression maintained by the `FINDING_OBSERVATION_ELEMENT` meaning attribute must conform to the following default semantic expression constraint:

```
243796009 | situation with explicit context | :
{ 246090004 | associated finding |
= ( ( < 404684003 | clinical finding | )
OR ( < 272379006 | event | )
)
, 408729009 | finding context | = < 410514004 | finding context value |
, 408731000 | temporal context | = < 410510008 | temporal context value |
, 408732007 | subject relationship context | = < 125676002 | person |
}
```

The SNOMED CT context model attributes enable the representation of goals, risks, past history and family history as well as uncertain and negative findings.

In the case of instance expressions that omit the associated context attributes the default finding context rules apply and the expression is interpreted as meaning that finding is present and occurring currently (or at a stated time in the past) and applies to the subject of the record.

### 8.2 PROPERTY\_OBSERVATION\_ELEMENT

The coded expression maintained by the `PROPERTY_OBSERVATION_ELEMENT` meaning attribute must conform to the following default semantic expression constraint:

```
243796009 | situation with explicit context | :
{ 246090004 | associated finding |
= ( ( < 363787002 | observable entity | )
OR ( < 386053000 | evaluation procedure | )
OR ( < 108252007 | laboratory procedure | )
)
, 408729009 | finding context | = < 410514004 | finding context value |
, 408731000 | temporal context | = < 410510008 | temporal context value |
, 408732007 | subject relationship context | = < 125676002 | person |
}
```



Although 'observable entity' on its own is not a 'clinical finding' it behaves as a 'clinical finding' when associated with a result value<sup>12</sup>.

The SNOMED CT context model attributes enable the representation of goals, risks, past history and family history as well as uncertain and negative findings.

The current release of SNOMED CT has limitations related to the representation of observable entities. There are some measurement or observation concepts without a corresponding 'observable entity'. The constraint therefore permits an evaluation procedure or laboratory procedure to be the focus concept when it is used as a proxy for the observable entity resulting from the procedure. Instances in which this workaround are used should be interpreted as meaning to 'the observable entity' (i.e. property or feature) observed or measured by the specified procedure. Note that these same concepts can be used to represent the investigative activities separate from the result of those activity (e.g. to record a request or to record completion of non-completion of the investigation) in the form of an INVESTIGATION\_ACTIVITY\_ELEMENT.

In the case of instance expressions that omit the associated context attributes the default finding context rules apply and the expression is interpreted as meaning that the finding is present currently (or at a stated time in the past) and applies to the subject of the record.

### 8.3 GENERAL\_ACTIVITY\_ELEMENT

The coded expression maintained by the GENERAL\_ACTIVITY\_ELEMENT meaning attribute must conform to the following default semantic expression constraint:

```
243796009 | situation with explicit context | :
{ 363589002 | associated procedure |
= ( ( < 71388002 | procedure | )
AND ( ! < 386053000 | evaluation procedure | )
AND ( ! < 108252007 | laboratory procedure | )
AND ( ! < 432102000 | administration of substance | )
AND ( ! < 433590000 | administration of substance via specific route | )
AND ( ! < 33633005 | prescription of drug | )
AND ( ! < 75658007 | prescription of therapeutic agent | )
AND ( ! < 103742009 | renewal of prescription | )
AND ( ! < 243704004 | provision of appliances | )
AND ( ! < 183253002 | provision of medical equipment | )
AND ( ! < 404919001 | wheat-free diet | )
AND ( ! < 223456000 | provision of a special diet | )
AND ( ! < 440298008 | dispensing of pharmaceutical/biologic product | )
)
, 408730004 | procedure context | = < 288532009 | context values for actions |
, 408731000 | temporal context | = < 410510008 | temporal context value |
, 408732007 | subject relationship context | = < 125676002 | person |
}
```

<sup>12</sup> The use of 'observable entity' as an 'associated finding' is explicitly permitted by the SNOMED CT User Guide (and explained in more detail in *Abstract Logical Models and Representational Forms* (available at <http://www.ihtsdo.org/our-standards/technical-documents/>).

The SNOMED CT context model attributes enable the representation of the degree of completion of the activity (in terms of whether the action has been requested, planned, has occurred, etc) as well as the past history and family history of the activity.

In the case of instance expressions that omit the associated context attributes the default procedure context rules apply and the expression is interpreted as meaning that the activity has actually occurred and applies currently (or at a stated time in the past) to the subject of the record.

## 8.4 INVESTIGATION\_ACTIVITY\_ELEMENT

The coded expression maintained by the INVESTIGATION\_ACTIVITY\_ELEMENT meaning attribute must conform to the following default semantic expression constraint:

```
243796009 | situation with explicit context | :
{ 363589002 | associated procedure |
= ( ( < 386053000 | evaluation procedure | )
OR ( < 108252007 | laboratory procedure | )
OR ( < 363787002 | observable entity | )
)
, 408730004 | procedure context | = < 288532009 | context values for actions |
, 408731000 | temporal context | = < 410510008 | temporal context value |
, 408732007 | subject relationship context | = < 125676002 | person |
}
```

The SNOMED CT context model attributes enable the representation of the degree of completion of the investigation activity (in terms of whether the action has been requested, planned, has occurred, etc) as well as the past history and family history of the activity.

The current release of SNOMED CT has limitations related to the representation of investigation procedure and the result of these investigations. There are some 'observable entity' concepts without corresponding measurement or observation procedures. The constraint therefore permits an 'observable entity' to be the focus concept when it is used as a proxy for the evaluation procedure that produced it. Instances in which this workaround are used should be clearly documented as a workaround and interpreted as meaning to 'the procedure of measuring or observing the specified observable entity'. Note that these same concept can be used to represent the 'observable entity' separate from the evaluation procedure that produced it the form of an PROPERTY\_OBSERVATION\_ELEMENT.

In the case of instance expressions that omit the associated context attributes the default procedure context rules apply and the expression is interpreted as meaning that the investigation activity has actually occurred and applies currently (or at a stated time in the past) to the subject of the record.

## 8.5 MATERIAL\_ACTIVITY\_ELEMENT

The coded expression maintained by the MATERIAL\_ACTIVITY\_ELEMENT meaning attribute must conform to the following default semantic expression constraint:

```

243796009 | situation with explicit context | :
{ 363589002 | associated procedure |
= ( ( 432102000 | administration of substance | )
OR ( 433590000 | administration of substance via specific route | )
OR ( 33633005 | prescription of drug | )
OR ( 75658007 | prescription of therapeutic agent | )
OR ( 103742009 | renewal of prescription | )
OR ( 243704004 | provision of appliances | )
OR ( 183253002 | provision of medical equipment | )
OR ( << 404919001 | wheat-free diet | )
OR ( << 223456000 | provision of a special diet | )
OR ( 440298008 | dispensing of pharmaceutical/biologic product | )
)
, 408730004 | procedure context | = < 288532009 | context values for actions |
, 408731000 | temporal context | = < 410510008 | temporal context value |
, 408732007 | subject relationship context | = < 125676002 | person |
}

```

The SNOMED CT context model attributes enable the representation of the degree of completion of the investigation activity (in terms of whether the action has been requested, planned, has occurred, etc) as well as the past history and family history of the activity.

In the case of instance expressions that omit the associated context attributes the default procedure context rules apply and the expression is interpreted as meaning that the investigation activity has actually occurred and applies currently (or at a stated time in the past) to the subject of the record.

## 8.6 MATERIAL\_ENTITY\_ELEMENT

The coded expression maintained by the MATERIAL\_ENTITY\_ELEMENT meaning attribute must conform to the following default semantic expression constraint:

```

( ( << 373873005 | pharmaceutical / biologic product | )
OR ( << 49062001 | device | )
OR ( << 123038009 | specimen | )
OR ( << 105590001 | substance | )
OR ( << 276339004 | environment | )
)

```

The concept 373873005 | pharmaceutical / biologic product | subsumes the UK drug extension concepts (dm+d).

The expression has no associated context attributes as none of the concepts are permitted values of an associated finding or an associated procedure.

## 8.7 RECORD\_ARTEFACT\_ELEMENT

### 8.7.1.1 General Semantic Constraint on Record Artefacts

The coded expression maintained by the RECORD\_ARTEFACT\_ELEMENT meaning attribute must conform to the following default semantic expression constraint:

```

< 419891008 | record artefact |

```

The expression has no associated context attributes as the concept is not a permitted value of an associated finding or an associated procedure. Also the record artefact hierarchy has no defining attributes by which individual concepts can be further refined.

The RECORD\_ARTEFACT\_ELEMENT is designed to assist with organising the record for display or for retrieving information related to particular types of event or document. Therefore the instance expression SHALL NOT have any impact on the meaning of any ELEMENTs linked to the record artefact.

## 9 Open Issues

Issue Id	Product	Version	Title	Description	Severity	Date
1066	Care Components	0.1.1	Use of RECORD_COMPONENT attribute sensitivity	Does the inclusion of the sensitivity attribute here imply a policy decision that the range of values in 13606-4:2007 are necessary and sufficient for UK NHS use cases? This does not accord with my understanding of the situation – but as this is not my area of expertise I raise this as a question rather than a critical issue.	S	17/04/2009
1068	Care Components	0.1.1	Representation CD.code attribute constraints	<p>The use of CD.CV + OCL to define an enumerated property plus vocabulary is different here to the way it was done in ISO 21090. In 21090 the enumeration is expressed as a class with stereotype &lt;enumeration&gt; and the attribute as a type of that class. I did the binding in an appendix. I am not convinced that oclIsTypeOf could realistically determine that enumeration, as it can only really evaluate UML datatype I think.</p> <p>So rather than: foo[0..1]: CD.CV &amp; foo.oclIsTypeOf(FooType)</p> <p>we just have:</p> <p>foo[0..1]: FooType where FooType is stereotyped as an enumeration.</p> <p>The implication of the first is that FooType is a subtype of CD.CV... but I think it isn't exactly that, because I think it is really a subtype of BAG&lt;CD.CV&gt; of which one is picked.</p> <p>Either way we need a consistent method for</p>	M	17/04/2009

				representing enumerations across all models.		
1069	Care Components	0.1.1	Use of EN 13606-1 standard text within specification	The text of the model is part of the 13606 standard I think. It may be better to only include LRA specific text & refer back to the original specification where required.	M	17/04/2009
1111	Care Components	0.2.1	Various minor amendments to improve clarity and consistency.	LS suggested various minor amendments (primarily to improve clarity and consistency) to content of the Care Entries document which was copied to the Care Components document. These need to be considered for inclusion in the final draft of the latter.	M	20/02/2009
1158	Care Components	0.2.1	Undefined purpose & vocab for audit_info.reason_for_revision	Audit_info.reason_for_revision vocabulary is undefined. Scope of the vocabulary is undefined. Attribute appears to be optional	S	39952
1160	Care Components	0.2.1	Undefined purpose & vocab for attestation_info.reason for attestation	Attestation_info.reason_for attestation vocab is undefined. Scope is unclear. Attribute is mandatory.	C	19/05/09
1197	Care Components	0.3.2	Differentiation of risks, expectations and goals	The proposed high level data elements for the care components model use the finding observation element and property observation element bound to a SNOMED CT expression to identify risks, expectations and goals. The terminology modelling for the context modifiers is not felt by Ed Cheetham to be ideal and may make the clinical distinction difficult to identify / compute.	S	12/06/2009
1198	Care Components	0.3.2	Risk likelihood is not clearly identified	There is a requirement, particularly from some scoring tools such as predicted mortality based on Acute Physiology and Chronic Health Evaluation (APACHE) Score, to record a risk outcome with numeric probability, such as 97.3% chance of subject of the record dying within 3 days.	S	12/06/2009

## 10 Appendices

### A Changes to EN 13606-1:2007 EXTRACT model for use by LRA

Class	Feature	Change	Rationale
EHR_EXTRACT	attribute rm_id	Type changed from String to ST	To conform to use of ISO 21090
		rm_id.value fixed to "EN 13606"	As specification (section 6.2.2): "For an EHR Extract conforming to this European Standard the attribute will have the string value "EN 13606""
EXTRACT_CRITERIA	attribute max_sensitivity	Type changed from Integer to INT	To conform to use of ISO 21090
	attribute all_versions	Type changed from Boolean to BL	
	attribute multimedia_included	Type changed from Boolean to BL	
	attribute other_constraints	Type changed from Boolean to BL	
RECORD_COMPONENT	attribute name	Type changed from TEXT to SC	To conform to use of ISO 21090 and as specification (section 6.2.4): "The name, expressed as a coded value or as plain text".
	attribute archetype_id	Type changed from String to ST	To conform to use of ISO 21090

	attribute meaning	Type changed from CV to CD.CV	
	attribute synthesised	Type changed from Boolean to BL	
	attribute sensitivity	Type changed from Integer to INT	
FOLDER	association compositions	Association compositions linking FOLDER and COMPOSITION (with qualifier rc_id) changed to attribute compositions of type SET<II>	This feature specifies a set that contains the identifiers of associated COMPOSITION instances, not the COMPOSITION instances themselves. This is confirmed by FOLDER XSD element <code>&lt;xs:element name="compositionsRcId" type="dt:II" minOccurs="0" maxOccurs="unbounded" /&gt;</code> . Although the use of the qualifier rc_id helps infer the referencing it is too ambiguous to be computable.
COMPOSITION	attribute territory	Type changed from String to CS	To conform to use of ISO 21090
ENTRY	attribute act_id	Type changed from String to II	To conform to use of ISO 21090
	attribute uncertainty_expressed	Type changed from Boolean to BL	
LINK	association target	Association target linking LINK and RECORD_COMPONENT (with qualifier rc_id) changed to attribute target of type II and	The model and schema appear to conflict with the definition and with the constraints expected for this type of construct. Currently



		cardinality changed from 1..* to 1..1.	the model and schema allow a RECORD_COMPONENT to have zero or more outbound LINK target instances (as expected) and for each target to reference one <b>or more</b> RECORD_COMPONENT instances (not expected). Section 6.2.17 states that the "LINK class defines the semantics of a non-containment relationship between two RECORD_COMPONENTs", however, the current model and schema specifies the LINK class as defining a relationship between a single RECORD_COMPONENT and one <b>or more</b> other RECORD_COMPONENT instances.
AUDIT_INFO	attribute reason_for_revision	Type changed from CV to CD.CV	To conform to use of ISO 21090
ATTESTATION_INFO	attribute reason_for_attestation	Type changed from CV to CD.CV	To conform to use of ISO 21090
	association target	Association target linking ATTESTATION_INFO and RECORD_COMPONENT (with qualifier rc_id) changed to attribute target of type SET<II>	This feature specifies a set that contains the identifiers of associated RECORD_COMPONENT instances, not the RECORD_COMPONENT

			instances themselves. This is confirmed by ATTESTATION_INFO XSD element <code>&lt;xs:element name="targetRcId" type="dt:II" minOccurs="1" maxOccurs="unbounded" /&gt;</code> . Although the use of the qualifier rc_id helps infer the referencing it is too ambiguous to be computable.
FUNCTIONAL_ROLE	attribute function	Type changed from CV to CD.CV	To conform to use of ISO 21090
	attribute service_setting	Type changed from CV to CD.CV	
RELATED_PARTY	attribute relationship	Type changed from TEXT to CD.CV	To conform to use of ISO 21090. The type change is from TEXT to CD.CV rather than to ED to make the attribute amenable to structured querying.
ITEM	attribute emphasis	Type changed from CV to CD.CV	To conform to use of ISO 21090.
ELEMENT	association value	Association value linking ELEMENT and DATA_VALUE changed to attribute value of type ANY	To conform to use of ISO 21090 and for representational consistency – i.e. all ISO 21090 data type instances are represented as attributes.

## **B Design Principles for SNOMED CT-Bound ELEMENT classes**

The following subsections describe the set of design principles used specify the set of SNOMED CT-bound ELEMENT classes described in this specification.

Care Component ELEMENT classes using SNOMED CT must:

- Be understandable, reproducible and useful
- Be consistent
- Support post-coordination as needed
- Be as resilient as possible with respect to terminology evolution
- Provide workarounds where gaps or errors exist in SNOMED CT, while minimising any strategic divergence with this standard.

### **A.1 Understandable, Reproducible and Useful**

A documented and clear requirements analysis process should enable an appropriate design approach to be selected to meet each information requirement.

- The results of the analysis should be reproducible. Any suitably trained person should reach the same conclusion by following the documented design steps.
- A key factor in meeting this principle is that the range of design choices should be restricted. Where choices need to be made the criteria for choosing a particular option should be expressed in a way that is clear and testable.

### **A.2 Consistency**

The logical representation of similar types of information should follow the same general pattern.

- The representation of the same information with different levels of additional detail should follow the same pattern with appropriate restrictions to allow added detailed to be specified without mandating any detail that may reasonably not be recorded during the care process.
- A key factor in meeting this principle is that the ability to add additional attributes or subsidiary elements to a unit of information must be sufficient to meet requirements but must be restricted in ways that preclude or limit alternative approaches to representing the same facet of information.

### **A.3 SNOMED CT Post-Coordination Support**

The model should assume full support for the SNOMED CT Concept Model and associated post-coordinated expressions.

- The model should not include accommodation for alternative coded and structured representations of meanings that fall within the scope of SNOMED CT as adopted by the LRA

- This does not preclude workarounds for defects in SNOMED CT coverage within the agreed scope but such accommodations should be explicitly declared and revised once the defect is addressed in the Standard.
- Implemented care record systems may represent information in different ways, but should be able to map or translate and process care records data queries and responses based on SNOMED CT expressions as specified by the LRA.

## A.4 Resilience to Terminology Evolution

The model must be resilient to changes in the SNOMED CT Concept Model.

- Terminology binding constraints may need to be revised to account for some changes. However, there should be no need to add or remove classes or attributes to the structural model to support such changes.
- A key effect of this is to preclude or limit the use of separate attributes within an information unit that repeat or replace facets of information that are represented by the Concept Model.

This principle does not necessarily preclude all need for the LRA to be sensitive to SNOMED CT concept model changes. If, despite the cautionary measures taken above, concept model changes impact the LRA, this will be managed with concept model version referencing within, and version controlling of, the LRA.

## A.5 Workarounds Without Divergence

The model must provide mechanisms for specifying workarounds to address issues arising from missing SNOMED CT Concepts or inadequacies in the SNOMED Concept Model. It should also, however, be designed to encourage and accommodate the use of more robust approaches when these SNOMED defects are remedied.

- The model should not require or anticipate the addition of any SNOMED CT Concepts that are contrary to SNOMED CT's editorial policy or that would result in an unsustainable combinatorial explosion of SNOMED CT content.

## C Component Relationship Vocabulary

The scope of the LRA component vocabulary must be clear as there must not be duplication of representation between the Link relationship and other aspects of the reference or participations model, or other conceptual representations (although some overlap is impossible to avoid here.)

This is a work in progress and this section is included as an informative resource. A separate process for review and comment on information in this appendix will be arranged.

In scope:

- Referents and referent tracking
- Lists of semantically similar entities managed as multiple entities
- Assertions of causation, attribution

- Record threading
- Planning and execution
- Instance relationships<sup>13</sup>

Out of scope:

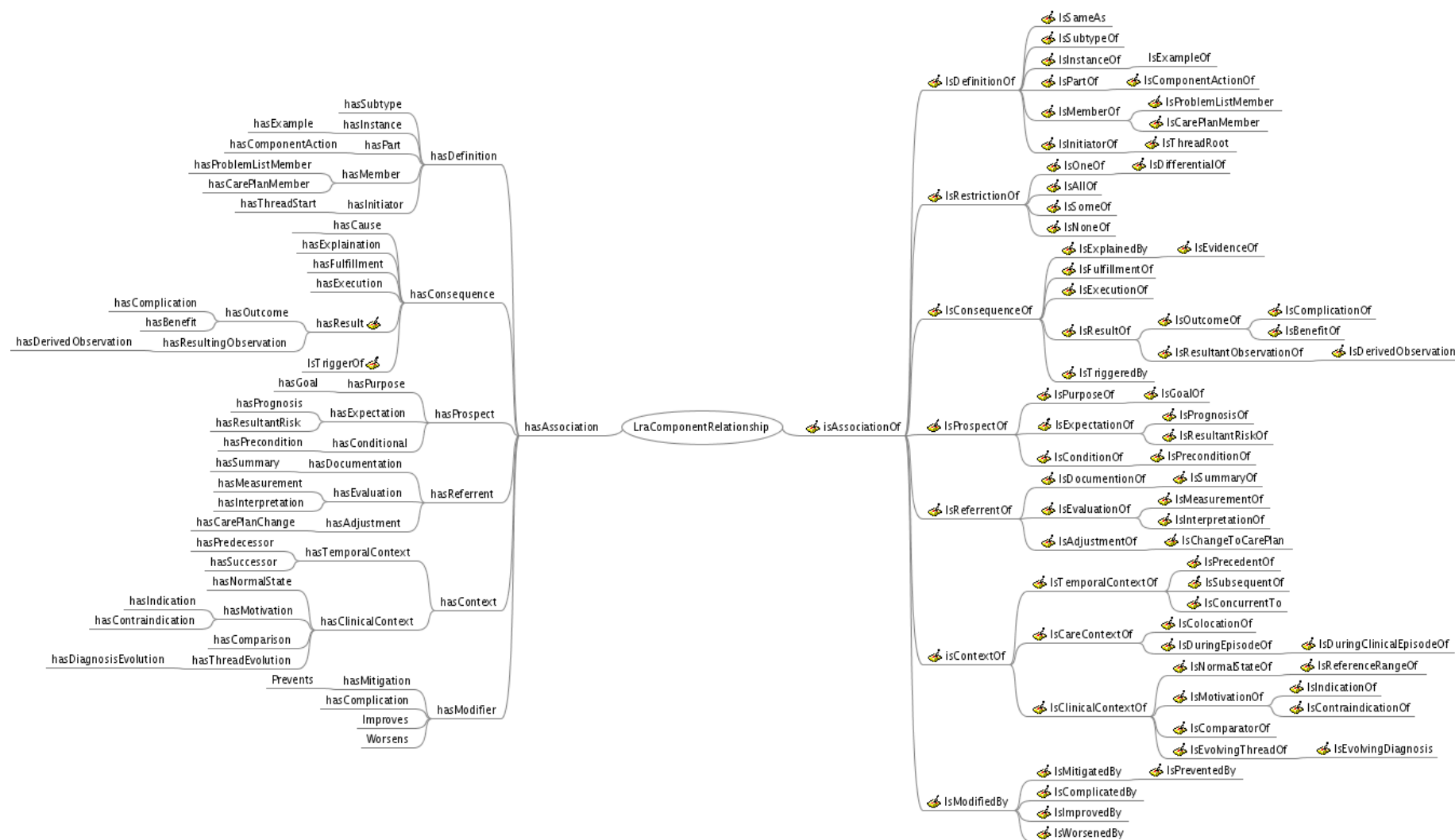
- Record versioning relationships
- Structural lists of data point series managed as a single entity.
- Record access, information governance audit
- Provenance, attestation, participation
- Structural headings, record display structure
- Conceptual relationships

An initial attempt to characterise the vocabulary has focussed on an amalgamation of HL7, UMLS, SNOMED CT and EN13606 link assertion vocabularies. This has been re-factored in an attempt to organise the information in a conceptual hierarchy of relationship types, rather than functionally, although a specific effort has been to cover elements of those vocabularies deemed to be in scope.

This effort has resulted in the following vocabulary here shown as a hierarchy plus part the text of the associated definitions:

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<sup>13</sup> <https://www.portal.nss.cfh.nhs.uk/sites/idsp/LRACollaboration/LRAWiki/Concept%20versus%20instance%20relationships.aspx>



<b>text</b>	<b>description</b>
isAssociationOf	The subject has some logical connection with the object
IsDefinitionOf	The subject is in some way defined by the object.
IsSameAs	The subject is same as the object. It is equivalent and is interchangeable or could be merged. The subject and object statement must describe the same thing, have the same provenance and attestation, and be semantically equivalent. This is intended to be rarely used in the circumstance where a unique instance acquires more than one globally unique identifier.
IsSubtypeOf	The subject is a more specific example of the object. In instance healthcare data there is expected to be limited use for this construct.
IsInstanceOf	The subject is an a concrete example of an abstract object. E.g. an instance entry describing abstract condition concepts such as "Patient has angina" may be linked to specific occurrences of that group, such as "This episode of angina". The distinction here is between recognised clinical conditions and the specific elements.
IsExampleOf	
IsPartOf	A general partitive relationship. The subject is part of the object.
IsComponentActionOf	The subject is a sub-action of an overall action. This may be nested to document complex actions, which may be performed by different people, occurring as part of a whole action under an individuals responsibility. The sequencing of such actions into a care plan is not included in this.
IsMemberOf	The subject is an element in a set of things that share a common feature.
IsProblemListMember	The subject is in a set of things that are regarded as a problem by the patient or a healthcare professional
IsCarePlanMember	The subject is part of a planned sequence of activities defined by the object
IsInitiatorOf	The subject is the starting event or condition for the object
IsThreadRoot	The subject is the initiating event or condition of a health issue. This will in most events be assigned retrospectively, and may change over time.
IsRestrictionOf	These relationships are basic set building relationships that are included for the technical design modelling. It is not expected that end users will be interacting directly with this kind of relationship but rather that the end user applications will be mapping some of their structured data representations into the form.
IsOneOf	The subject is one of a number of possible alternative objects. The object here must refere to a statement of a list or set of alternatives, that are

	stated as a single entry - in most events this will be a cluster. An alternative representation to this is to use this directly between subject and multiple objects.
IsDifferentialOf	The specific use case for one of relationships and ordered lists is the expression of differential diagnosis lists, where individual elements express a choice that may be true. From decision support purposes a list of differential diagnoses must be considered as all true until superceded by a more specific diagnosis.
IsAllOf	The subject is an aggregation of all of the objects (see Is one of for various patterns)
IsSomeOf	The subject is some of the object(s)
IsNoneOf	The subject is not any of the object(s). It is disjoint from
IsConsequenceOf	The subject is a consequence of the object. This consequence may be causative or by intention.
IsExplainedBy	The subject event or condition can be explained by the object event or condition.
IsEvidenceOf	The subject event or condition is both explained by the object event or condition but also affirms the presence of the object event.
IsFulfillmentOf	The subject intervention has occurred to meet an object goal.
IsExecutionOf	The subject intervention occurs to complete an object planned intervention
IsResultOf	Synonymous for IsCausedBy. The subject was caused by a object, event, intervention or condition. In this case the object was a necessary cause that has an understood patho-physiological link to the subject occurrence.
IsOutcomeOf	The subject event or condition is an outcome of an object intervention.
IsComplicationOf	The subject is an outcome event or condition of an object intervention that has subjectively negative consequences for the patient
IsBenefitOf	The subject is an outcome event or condition of an object intervention that has subjectively positive consequences for the patient
IsResultantObservationOf	The subject is an observation which has occurred as the result of an intervention procedure, such as a diagnostics procedure or a patient examination, or from a calculation.
IsDerivedObservation	The subject is an observation that has been derived directly from an object calculation and input observations.
IsTriggeredBy	Same as hasTrigger. A subject event or condition is triggered by an object event or condition in the medical sense. Triggered does not imply that there is a patho-physiological mechanism but rather that the object is an initiating event without which the subject would not have occurred. This does not imply that the event could not have occurred.



IsProspectOf	The subject is a future circumstance that has some association with the of the object.
IsPurposeOf	The subject goal, event or condition is the purpose of a specific object intervention
IsGoalOf	The subject goal is the specific target of an intervention
IsExpectationOf	The subject is a reasonably probable circumstance or occurrence that will arise associated with the object circumstance
IsPrognosisOf	The subject is an event or condition that is likely as a result of the object event or circumstance.
IsResultantRiskOf	The subject is a risk of an event, or propensity for a condition, that is expected to be present as the result of a object event or condition
IsConditionOf	The subject is must occur in association with any intended or expected occurrence of the subject event or condition.
IsPreconditionOf	The subject must occur before any expected or intended occurrence of the object event or condition
IsReferrentOf	The subject record is a documentation, assessment or interpretation of an object record, occurrence or circumstance
IsDocumentionOf	The subject document refers to the object event or circumstance.
IsSummaryOf	The subject document summarises a set of occurrences or circumstances or a more detailed documentation object.
IsEvaluationOf	The subject is an assessment of the quantity, quality or nature of some object circumstance or occurrence
IsMeasurementOf	the subject is some assessment of the quantity or quality of some object circumstance or occurrence
IsInterpretationOf	The subject is some assessment of the nature of the object circumstance or occurrence
IsAdjustmentOf	A subject record is some alteration to an object record, strategy or plan
IsChangeToCarePlan	The subject plan is a change to some object care plan
isContextOf	The subject circumstance describes the background of some object circumstance or situation
IsTemporalContextOf	The subject circumstance describes or constrains the time of the object circumstance through a specified time based relationship
IsPrecedentOf	The subject circumstance occurs preceding the object circumstance and in some way defines the timing of the object circumstance
IsSubsequentOf	The subject circumstance occurs subsequent to the object circumstance and in some way constraint the occurrence of the object

IsConcurrentTo	The subject circumstance occurs in the same time span as the object circumstance and the object is in some way constrained to occur within this time span
IsCareContextOf	The subject circumstance defines the care delivery circumstance of the object circumstance
IsColocationOf	The subject circumstance happens in the same place as the object circumstance, and the location of the object is in some way determined by the subject circumstance
IsDuringEpisodeOf	The subject circumstance occurs in the same episode of responsibility of care provision as the object circumstance.
IsDuringClinicalEpisodeOf	The subject occurs within a specific bounded clinical episode. Such clinical episodes are defined as periods of responsibility of care that have a specific clinical objective. This might include a maternal delivery episode, for example, and the definition is based on the requirements for decision support based on occurrences bound by specific clinical contexts. The population of such contexts within a health record may be derived from the activity context of a specific medical record, and is unlikely to be directly asserted in the originating EHR.
IsClinicalContextOf	The subject circumstance describes an aspect of the background on which the object circumstance must be interpreted.
IsNormalStateOf	The subject defines a range of hypothetical normal states that an object observation or interpretation is to be compared against
IsReferenceRangeOf	The subject defines a set of normal quantitative ranges that the object can be compared against
IsMotivationOf	The subject defines a background circumstance that defines the rationale for an object decision
IsIndicationOf	The subject defines a circumstance that provides the background for a decision to perform an object intervention or planned intervention
IsContraindicationOf	The subject defines a circumstance that provides the background for a decision to abandon an intervention or a planned intervention
IsComparatorOf	The subject circumstance defines an index circumstance that the object circumstance can be compared against
IsEvolvingThreadOf	The subject is a situation or occurrence that is part of the same health record thread as the object situation or occurrence
IsEvolvingDiagnosis	The subject is a diagnosis which is an update of, or modification to an original object presumed or provisional diagnosis or differential diagnosis list.
IsModifiedBy	The subject occurrence or circumstance is changed in nature as a result of the object occurrence or circumstance.

IsMitigatedBy	The subject occurrence or circumstance is deemed to be less severe in nature than it may otherwise be due to the object circumstance or occurrence
IsPreventedBy	The subject risk or goal is avoided due to the presence of a object occurrence or circumstance.
IsComplicatedBy	A subject occurrence or circumstance has a detrimental interaction with a object occurrence or circumstance. The interaction between the two leads to a current and ongoing detrimental interaction effect such that the two occurrences or circumstances are perceived as more negative than expected given the two individual occurrences or circumstances
IsImprovedBy	The subject occurrence or circumstance is subjectively made better, or less severe, by the object occurrence or circumstance.
IsWorsenedBy	The subject occurrence or circumstance is subjectively made better, or less severe, by the object occurrence or circumstance.

The inverses of the relationships are not described here.