nehta

Detailed Clinical Model Specification

Adverse Reaction
Version 3.1

22 December 2011

Approved for External Release

National E-Health Transition Authority Ltd

Level 25
56 Pitt Street
Sydney NSW 2000
Australia
www.nehta.gov.au

Document Information

Document owner

Document Owner
The National Clinical Terminology and Information Service

Change history

Version	Date	Comments
1.0	29 Jun 2007	Initial public release
1.1	29 Feb 2008	Minor typographical corrections and wording changes in Introduction
2.0	7 Sep 2009	Updated to incorporate changes made in the version 2.0 of the Discharge Summary Specification.
3.0	24 Aug 2011	New version created in accordance with the archetype from *NEHTA Clinical Knowledge Manager*[1].
3.1	22 Dec 2011	This version of the specification is published to support the Structured Content Specifications published (at the end of 2011) that use the versions of the DCMs included in this specification. Changes to the DCMs, included in this specification, are primarily to support the Consolidated View in the PCEHR.

Related documents

Name	Version/Release Date
NEHTA Acronyms, Abbreviations & Glossary of Terms	Version 1.2, Issued 25 May 2005
Participation Data Specification	Version 3.2, Issued 20 July 2011

Included Detailed Clinical Models

This specification contains the following Detailed Clinical Models:

1. Adverse Reaction, version 5.1
2. Exclusion Statement - Adverse Reactions, version 1.2

[1] http://dcm.nehta.org.au/ckm

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Acknowledgements

NEHTA would like to thank the following organisations and individuals for their contribution to these data specifications:

- Standards Australia;
- Members of the Australian DataTypes Project;
- Australian Institute of Health and Welfare; and
- Ocean Informatics.

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1 Introduction

1.1 Purpose and Scope

This detailed clinical model (DCM) specification forms part of a suite of data specifications that the National E-Health Transition Authority (NEHTA) is developing for the Australian health informatics community. The suite comprises specifications for a range of health topics (represented as data groups), which are considered to be the most critical to support the work programme given to NEHTA and to realise the benefits derived from Level 4 (semantic) interoperability[1] in the Australian healthcare setting.

NEHTA values your questions and comments about this document. Please direct your questions or feedback to *clinicalinformation@nehta.gov.au*.

1.2 Intended Audience

This document is intended to be read by jurisdictional information and communication technology (ICT) managers, clinicians involved in clinical information system specifications, software architects and developers, and implementers of clinical information systems in various healthcare settings.

It is reasonably technical in nature and expects the audience to be familiar with the language of health data specification and have some familiarity with health information standards and specifications. Definitions and examples are provided to clarify relevant terminology usage and intent.

1.3 Background

There are several e-health priority areas to be addressed by NEHTA specifications. One area of priority is identification of the data to be communicated and its structure. NEHTA is addressing this through data specifications, which detail the data elements (logically grouped) and their associated value domains.

Data specifications need to be independent of messaging formats. They are concerned with providing an information framework in which to achieve semantic interoperability.

Data specifications have been developed:

- Based on jurisdiction and clinician identified priorities;
- Specifically to suit the Australian model for a shared electronic health record (EHR);
- To define collections of related information, e.g. event summaries, data groups, data elements;
- To allow for expansion and extension as electronic systems mature;
- So they are human readable (with information enhanced by the hierarchical structure);
- Incorporating clinical examples of use to enhance utility and adoption; and
- To provide a set of clinical terminologies, specific to the requirements of the Australian healthcare system.

Whilst the Personally Controlled Electronic Health Record (PCEHR) System is referred to in these documents, the implementation of the PCEHR System is not dealt with here.

[1] Level 4 interoperability is described in [WALJ2005a].

1.4 Terminology

NEHTA, through the National Clinical Terminology and Information Service (NCTIS), is defining a national approach to clinical terminology. Consistent and accurate articulation and interpretation of clinical terms is critical to the process of safe exchange.

The Systematized Nomenclature of Medicine - Clinical Terms® (SNOMED CT® [2]) has been recommended by NEHTA and endorsed by the Australian, state and territory governments as the preferred clinical terminology for Australia, and is now freely available for e-health software developers to use in their Australian products under International Health Terminology Standards Development Organisation (IHTSDO) licensing arrangements.

While NEHTA's achievement of a national standard clinical terminology is based on SNOMED CT as the foundational resource, local variations and customisation of terms relevant to the Australian healthcare sector will be incorporated. SNOMED CT Australian Release (SNOMED CT-AU) is the Australian extension to SNOMED CT; the integrated national release of SNOMED CT for implementation in Australian deployed clinical IT systems. NEHTA is also developing the Australian Medicines Terminology (AMT) as the designated clinical terminology for medicines available in Australia. The AMT will provide a consistent approach to the identification and naming of medicines, to support medicines management and activity across the Australian healthcare domain. The AMT will be integrated with SNOMED CT-AU in the near future.

Reference sets listed as value domains within this document have been developed taking into account data element and data group definitions, as well as how they align and complement the SNOMED CT concept model. For further information regarding terminology and the development of reference sets please visit *http://www.nehta.gov.au/our-work/clinical-terminology* and direct your questions or feedback to *terminologies@nehta.gov.au*.

[2] SNOMED CT® is a registered trademark of the International Health Terminology Standards Development Organisation.

2 Adverse Reaction Detailed Clinical Model

This chapter describes version 5.1 of the Adverse Reaction Detailed Clinical Model.

2.1 Purpose

To record health information that will inform a clinical assessment of the propensity of an individual for a future reaction to a substance, class of substance or agent.

To record information about exposure events to a substance, building up a persisting and evolving summary over time.

To record information about any adverse reaction, including:

- immune mediated reactions Types I-IV (including allergic reactions and hypersensitivities), and
- non-immune mediated reactions (including pseudoallergic reactions, side effects, intolerances, drug toxicities (e.g. Gentamicin), drug-drug interactions, food-drug interactions, drug-disease interactions and idiosyncratic reactions).

2.2 Use

Use to record all information about adverse reactions (including allergic reactions) that are required to support direct clinical care of an individual, safe exchange of information about adverse reactions and to enable computerised knowledge-based activities such as clinical decision support and alerts.

Use to provide a single place within the health record to record a range of clinical statements about adverse reactions, including:

- record cumulative information about each exposure to a known substance, class of substance or agent; and
- record a clinician's opinion that administration of, or exposure to, a substance or agent is absolutely contraindicated.

Can also be used to record an individual's reflections on their adverse reactions.

Use to record the information about an adverse reaction that might be exchanged with other systems, including as part of an adverse reaction report sent to statutory authorities. It is likely that a formal adverse reaction report will require additional information that will be captured in the health record using other data groups, for example medication and problem/diagnosis etc.

This data group has been designed to allow recording of information about a more generic substance, class of substance or agent, and then allow more specific details to be recorded including identification of the specific substance on a per exposure basis, including links to other parts of the health record where further details may be located. Note: it is possible on second or subsequent exposures to a previously identified substance for a reaction not to occur and this data group allows for these events to be closely linked in a way that will assist in determining if the adverse reaction has been incorrectly identified.

In addition, it is anticipated that in some very specific clinical situations, such as immunologist assessment or for use in clinical trials, more information about the adverse reaction may be required. Additional details can be added as cluster data groups using the *Additional Exposure Detail* and *Additional Reaction Details*

slots. Similarly, additional details that are required only for reporting can be added using the *Reporting Details* slot.

The act of recording an adverse reaction in the health record implies there is a potential hazard for the individual if they are exposed to the same substance/agent in the future - a relative contraindication. If a clinician considers that it is not safe for the individual to be deliberately re-exposed to the substance/agent again, for example, following a manifestation of anaphylaxis, the *Absolute Contraindication* data flag should be recorded as True. Note: Conversely, a statement about severity of propensity (with possible values such as mild, moderate and severe) has deliberately not been modelled explicitly. Predicting or estimating the grade of possible severity of a future reaction is not safe to record and persist in data, except where it is absolutely clear that the risk of deliberate re-exposure is unacceptable and highly likely to cause significant harm, such as a previous manifestation of anaphylaxis, and in this case the *Absolute Contraindication* data flag should be used.

Valuable first-level information that could be presented to the clinician when they need to assess propensity for future reactions are:

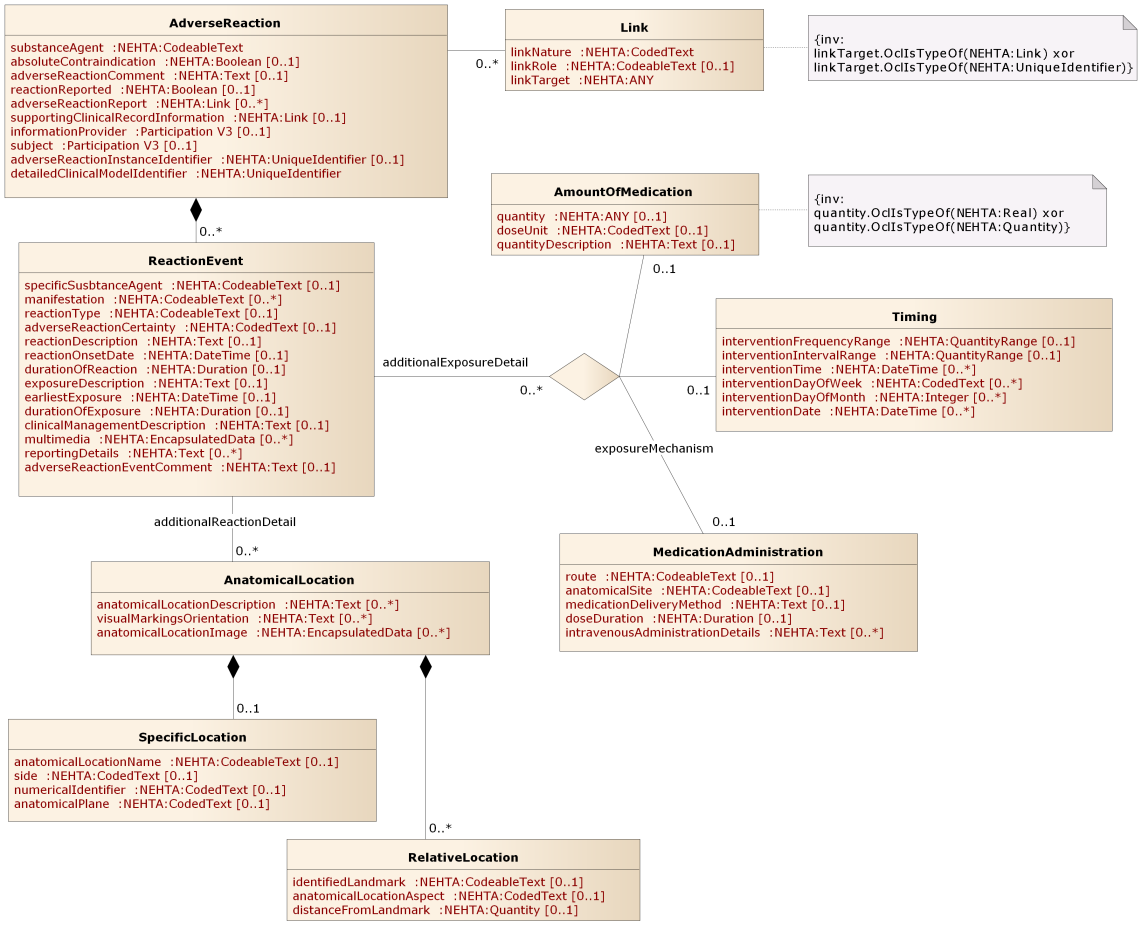
- statements about previous clinical manifestations following exposure,
- source of the information/reporter, and
- a flag for absolute contraindication.

Second-level information can be drawn from each exposure event and links to additional detailed information such as history, examination and diagnoses stored elsewhere in the record, if it is available.

2.3 Misuse

1. Not to be used for recording the absence (or negative presence) of a reaction to 'any substances' or to identified substances – use the EVALUATION.exclusion family of data groups to express a positive statement of exclusion.
2. Not to be used for recording that no information was able to be obtained about the adverse reaction status of a patient. Use the EVALUATION.absent_information family of data group to record a positive statement of absent information about adverse reactions was able to be obtained, for example, if a non-cooperative patient refuses to answer questions.
3. Not to be used to record adverse events, including failures of clinical process, interventions or products. For example: abnormal use or mistakes/errors made in administration of an agent or substance; mislabelling; harm or injury caused by an intervention or procedure; overdose, etc.
4. Not to be used for recording alerts.

2.4 UML Class Diagram



The figure represents the data hierarchy of the Detailed Clinical Model as a UML 2.0 class diagram. The diagram displays data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes. Data groups are displayed as classes, their names are represented as association role names. Association role names are only displayed if they differ from the associated class name. The diagram shows the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

2.5 ADVERSE REACTION

Identification

Label	ADVERSE REACTION
Metadata Type	Data Group
Identifier	DG-15517
OID	1.2.36.1.2001.1001.101.102.15517

Definition

Definition	A harmful or undesirable effect associated with exposure to any substance or agent, including food, plants, animals, venom from animal stings or a medication at therapeutic or sub-therapeutic doses.
Definition Source	NEHTA
Synonymous Names	Reaction Allergy Allergic Adverse Event Effect Sensitivity Intolerance Hypersensitivity Side Effect Toxicity Interaction Drug Food Medication Agent Substance Immune Non-Immune Chemical

Data Hierarchy

	ADVERSE REACTION		
	001011001	Substance/Agent	1..1
		Absolute Contraindication	0..1
		Comment (Adverse Reaction Comment)	0..1
		REACTION EVENT	0..*

			Specific Substance/Agent			0..1
			Manifestation			0..*
			Reaction Type			0..1
			Certainty (Adverse Reaction Certainty)			0..1
			Reaction Description			0..1
			Onset of Reaction (Reaction Onset Date)			0..1
			Duration of Reaction			0..1
			Additional Reaction Detail (ANATOMICAL LOCATION)			0..*
				SPECIFIC LOCATION		0..1
					Name of Location (Anatomical Location Name)	0..1
					Side	0..1
					Numerical Identifier	0..1
					Anatomical Plane	0..1
				RELATIVE LOCATION		0..*
					Identified Landmark	0..1
					Aspect (Anatomical Location Aspect)	0..1
					Distance From Landmark	0..1
				Description (Anatomical Location Description)		0..*
				Visual Markings/Orientation		0..*
				Image (Anatomical Location Image)		0..*
			Exposure Description			0..1
			Earliest Exposure			0..1
			Duration of Exposure			0..1
			ADDITIONAL EXPOSURE DETAIL			0..*

				AMOUNT OF MEDICATION		0..1
					Quantity	0..1
					Dose Unit	0..1
					Quantity Description	0..1
				TIMING		0..1
					Frequency Range (Intervention Frequency Range)	0..1
					Interval Range (Intervention Interval Range)	0..1
					Time (Intervention Time)	0..*
					Day of Week (Intervention Day of Week)	0..*
					Day of Month (Intervention Day of Month)	0..*
					Date (Intervention Date)	0..*
				MEDICATION ADMINISTRATION		0..1
					Route	0..1
					Site (Anatomical Site)	0..1
					Delivery Method (Medication Delivery Method)	0..1
					Dose Duration	0..1
					Intravenous Details (Intravenous Administration Details)	0..*
			Clinical Management Description			0..1
			Multimedia			0..*
			Reporting Details			0..*
			Comment (Adverse Reaction Event Comment)			0..1
		Reaction Reported				0..1
		Adverse Reaction Report				0..*

		Supporting Clinical Record Information		0..1
		INFORMATION PROVIDER		0..1
		SUBJECT		0..1
		Adverse Reaction Instance Identifier		0..1
		LINK		0..*
			Link Nature	1..1
			Link Role	0..1
			Link Target	1..1
		Detailed Clinical Model Identifier		1..1

2.6 Substance/Agent

Identification

Label	Substance/Agent
Metadata Type	Data Element
Identifier	DE-15521
OID	1.2.36.1.2001.1001.101.103.15521

Definition

Definition	Identification of a substance, agent, or a class of substance, that is considered to be responsible for the adverse reaction.
Definition Source	NEHTA
Synonymous Names	Agent Substance
Notes	An agent can be a substance such as food, drug or an environmental allergen.
Data Type	CodeableText
Value Domain	Substance/Agent Values

Usage

Examples	1. Animal protein 2. Latex 3. Peanut 4. Penicillin 5. Bee venom

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	1..1

2.7 Substance/Agent Values

Identification

Label	Substance/Agent Values
Metadata Type	Value Domain
Identifier	VD-15521
OID	1.2.36.1.2001.1001.101.104.15521

Definition

Definition	The set of values for the agent/substance causing the adverse reaction experienced by the subject of care.
Definition Source	NEHTA

Value Domain

Source	NEHTA
Permissible Values	The permissible values are the members of the following 8 reference sets. From SNOMED CT-AU: • 32570211000036100 |*Substance foundation reference set*| From AMT: • 929360061000036106 |*Medicinal product reference set*| • 929360081000036101 |*Medicinal product pack reference set*| • 929360071000036103 |*Medicinal product unit of use reference set*| • 929360021000036102 |*Trade product reference set*| • 929360041000036105 |*Trade product pack reference set*| • 929360031000036100 |*Trade product unit of use reference set*| • 929360051000036108 |*Containered trade product pack reference set*|

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Substance/Agent	1..1

2.8 Absolute Contraindication

Identification

Label	Absolute Contraindication
Metadata Type	Data Element
Identifier	DE-16073
OID	1.2.36.1.2001.1001.101.103.16073

Definition

Definition	A flag indicating that a clinician has identified a propensity for a serious reaction upon further exposure to the substance/agent.
Definition Source	NEHTA
Synonymous Names	
Data Type	Boolean

Usage

Conditions of Use	Record as "true" if the clinician assesses that exposure to, or administration of, the agent should be avoided in future. False is not a valid value for this data element.
Conditions of Use Source	NEHTA
Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.9 Adverse Reaction Comment

Identification

Label	Comment
Metadata Type	Data Element
Identifier	DE-15590
OID	1.2.36.1.2001.1001.101.103.15590

Definition

Definition	Additional narrative about the adverse reaction not captured in other fields, including reason for flagging an absolute contraindication, instructions related to future exposure or administration of the substance/agent.
Definition Source	NEHTA
Synonymous Names	Reaction Note
Notes	Used to provide additional narrative information in relation to the adverse reaction such as finding site or route of administration.
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.10 REACTION EVENT

Identification

Label	REACTION EVENT
Metadata Type	Data Group
Identifier	DG-16474
OID	1.2.36.1.2001.1001.101.102.16474

Definition

Definition	Details about each adverse reaction event.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..*

Children

Data Type	Name	Occurrences
	Specific Substance/Agent	0..1
	Manifestation	0..*
	Reaction Type	0..1
	Certainty (Adverse Reaction Certainty)	0..1
	Reaction Description	0..1
	Onset of Reaction (Reaction Onset Date)	0..1
	Duration of Reaction	0..1
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..*

Data Type	Name	Occurrences
	Exposure Description	0..1
	Earliest Exposure	0..1
	Duration of Exposure	0..1
	ADDITIONAL EXPOSURE DETAIL	0..*
	Clinical Management Description	0..1
	Multimedia	0..*
	Reporting Details	0..*
	Comment (Adverse Reaction Event Comment)	0..1

2.11 Specific Substance/Agent

Identification

Label	Specific Substance/Agent
Metadata Type	Data Element
Identifier	DE-16349
OID	1.2.36.1.2001.1001.101.103.16349

Definition

Definition	Specific identification of the substance/agent considered to be responsible for the adverse reaction event.
Definition Source	NEHTA
Synonymous Names	
Notes	This may include a medication trade name.
Data Type	CodeableText
Value Domain	Substance/Agent Values

Usage

Examples	
Misuse	To record broad classes of substance such as "food" or "antibiotic".

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.12 Manifestation

Identification

Label	Manifestation
Metadata Type	Data Element
Identifier	DE-15564
OID	1.2.36.1.2001.1001.101.103.15564

Definition

Definition	Clinical manifestation of the adverse reaction expressed as a single word, phrase or brief description.
Definition Source	NEHTA
Synonymous Names	Reaction
Notes	The clinical manifestation (signs, symptoms, severity or certainty) of the adverse reaction are relevant as they contribute towards the decision as to the immediacy and extent of treatment to be provided, as determined by a healthcare provider. Given that an adverse reaction has occurred, it is important to determine the manifestations of that reaction.
Data Type	CodeableText
Value Domain	Clinical Manifestation Values

Usage

Examples	1. Itchy eyes 2. Dysphagia 3. Tinnitus 4. Nausea 5. Rash

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..*

2.13 Clinical Manifestation Values

Identification

Label	Clinical Manifestation Values
Metadata Type	Value Domain
Identifier	VD-15564
OID	1.2.36.1.2001.1001.101.104.15564
External Identifier	SNOMED CT-AU Concept ID: 32570071000036102

Definition

Definition	The *Clinical manifestation values reference set* provides the broadest possible terminology to support the recording of *Clinical Manifestation* of *Adverse Reaction* in Australian eHealth implementations.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU
Permissible Values	Not yet defined. Until it is defined use the *Clinical finding foundation reference set* (SNOMED CT-AU Concept ID: 32570071000036102). Please see Appendix A, *Known Issues*

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Manifestation	1..1

2.14 Reaction Type

Identification

Label	Reaction Type
Metadata Type	Data Element
Identifier	DE-15554
OID	1.2.36.1.2001.1001.101.103.15554

Definition

Definition	The type of reaction, as determined by the clinician.
Definition Source	NEHTA
Synonymous Names	
Context	This field is used to identify the type of adverse reaction as determined by: • the signs and/or symptoms experienced by the subject of care; • information provided by a relevant individual; • previously documented history; and/or • a clinical assessment by a healthcare provider.
Context Source	NEHTA
Notes	Examples include Immune mediated - Types I-IV (including allergy and hypersensitivity); Non-immune mediated - including pseudoallergic reaction, side effect, intolerance, drug toxicity, drug-drug interaction, food-drug interaction, drug-disease interaction and idiosyncratic reaction.
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[1] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1. Allergy 2. Idiosyncrasy 3. Interactions

[1] http://www.hl7.org/oid/index.cfm

4. Intolerance / sensitivity
5. Pseudoallergy / anaphylactoid reaction
6. Side effects

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	REACTION EVENT	0..1

2.15 Adverse Reaction Certainty

Identification

Label	Certainty
Metadata Type	Data Element
Identifier	DE-15568
OID	1.2.36.1.2001.1001.101.103.15568

Definition

Definition	Degree of certainty, as assessed by the clinician, that the specific substance/agent was the cause of the reaction.
Definition Source	NEHTA
Synonymous Names	
Notes	It is important to know the degree of certainty of an adverse reaction to an agent/substance as there may be instances where it is not clear whether it is the active agent or a secondary component causing the problem. For example, it may be the filler in a tablet that is the allergen rather than the active drug. Another example is where there is suspicion of a reaction that warrants recording but has not been confirmed objectively, or where a reaction has been recorded but is subsequently discounted following further observation or investigation.
Data Type	CodedText
Value Domain	Adverse Reaction Certainty Values

Usage

Examples	1. Certain 2. Probable 3. Unlikely

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.16 Adverse Reaction Certainty Values

Identification

Label	Adverse Reaction Certainty Values
Metadata Type	Value Domain
Identifier	VD-15568
OID	1.2.36.1.2001.1001.101.104.15568

Definition

Definition	The set of values for the degree of confidence that the agent/substance has caused the adverse reaction.
Definition Source	NEHTA

Value Domain

Source	WHO-UMC causality assessment system.	
Permissible Values	*Certain*	A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to agent exposure or administration, and which cannot be explained by concurrent disease or other agents or chemicals. The response to withdrawal of the agent (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure if necessary.
	Probable/Likely	A clinical event, including laboratory test abnormality, with a reasonable time relationship to agent exposure or administration, unlikely to be attributed to concurrent disease or other agents or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge) Rechallenge information is not required to fulfil this definition.
	Possible	A clinical event, including laboratory test abnormality, with a reasonable time relationship to agent exposure or administration, but which could also be explained by concurrent disease or other agents or chemicals. Information on agent withdrawal may be lacking or unclear.
	Unlikely	A clinical event, including laboratory test abnormality, with a temporal relationship to agent exposure or administration which makes a causal relationship improbable, and in which

		other agents, chemicals or underlying disease provide plausible explanations.
	Conditional/Unclassified	A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data are required for a proper assessment or the additional data are under examination.
	Unassessable/Unclassifiable	A reported adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.

Usage

Conditions of Use	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
Conditions of Use Source	Amended from: 1. [EDWA1994a] 2. The use of the WHO-UMC system for standardised case causality assessment [UMC2011a] Note: These sources specifically relate to drug adverse events or pharmacovigilance. Amendments were made to broaden the assessment to all agents that might cause or be suspected of causing an adverse event.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Certainty (Adverse Reaction Certainty)	1..1

2.17 Reaction Description

Identification

Label	Reaction Description
Metadata Type	Data Element
Identifier	DE-15563
OID	1.2.36.1.2001.1001.101.103.15563

Definition

Definition	Narrative description of the reaction.
Definition Source	NEHTA
Synonymous Names	Reaction
Data Type	Text

Usage

Examples	1. Itchy eyes 2. Dysphagia 3. Tinnitus

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	REACTION EVENT	0..1

2.18 Reaction Onset Date

Identification

Label	Onset of Reaction
Metadata Type	Data Element
Identifier	DE-15507
OID	1.2.36.1.2001.1001.101.103.15507

Definition

Definition	Record of the date or time (or both) of the onset of the reaction.
Definition Source	NEHTA
Synonymous Names	DateTime Started
Notes	The date or date and time that the specific reaction commenced. Sometimes, the date or age at which a person reacts to an agent is a relevant to understanding a condition, or to determining appropriate treatment. Often, this will be an approximate, self-reported age, date or datetime.
Data Type	DateTime

Usage

Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a date or time (or both).

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.19 Duration of Reaction

Identification

Label	Duration of Reaction
Metadata Type	Data Element
Identifier	DE-16352
OID	1.2.36.1.2001.1001.101.103.16352

Definition

Definition	Length of duration of the reaction.
Definition Source	NEHTA
Synonymous Names	
Data Type	Duration

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.20 ANATOMICAL LOCATION

Identification

Label	Additional Reaction Detail
Metadata Type	Data Group
Identifier	DG-16150
OID	1.2.36.1.2001.1001.101.102.16150

Definition

Definition	Additional detail about the reaction, including anatomical location.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..*

Children

Data Type	Name	Occurrences
	SPECIFIC LOCATION	0..1
	RELATIVE LOCATION	0..*
	Description (Anatomical Location Description)	0..*
	Visual Markings/Orientation	0..*
	Image (Anatomical Location Image)	0..*

2.21 SPECIFIC LOCATION

Identification

Label	SPECIFIC LOCATION
Metadata Type	Data Group
Identifier	DG-16151
OID	1.2.36.1.2001.1001.101.102.16151

Definition

Definition	Specific and identified anatomical location.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..1

Children

Data Type	Name	Occurrences
	Name of Location (Anatomical Location Name)	0..1
	Side	0..1
	Numerical Identifier	0..1
	Anatomical Plane	0..1

2.22 Anatomical Location Name

Identification

Label	Name of Location
Metadata Type	Data Element
Identifier	DE-16153
OID	1.2.36.1.2001.1001.101.103.16153

Definition

Definition	The name of the anatomical location.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodeableText
Value Domain	Body Structure Foundation Reference Set

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

2.23 Body Structure Foundation Reference Set

Identification

Label	Body Structure Foundation Reference Set
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105

Definition

Definition	The set of values for named anatomical locations.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Name of Location (Anatomical Location Name)	1..1

2.24 Side

Identification

Label	Side
Metadata Type	Data Element
Identifier	DE-16336
OID	1.2.36.1.2001.1001.101.103.16336

Definition

Definition	The laterality of the anatomical location.
Definition Source	NEHTA
Synonymous Names	Laterality
Data Type	CodedText
Value Domain	Laterality Reference Set

Usage

Examples	1. Right 2. Left 3. Bilateral

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

2.25 Laterality Reference Set

Identification

Label	Laterality Reference Set
Metadata Type	Value Domain
Identifier	VD-16312
OID	1.2.36.1.2001.1001.101.104.16312
External Identifier	SNOMED CT-AU Concept Id: 32570611000036103

Definition

Definition	The set of values for identifying the laterality of an anatomical location.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Side	1..1

2.26 Numerical Identifier

Identification

Label	Numerical Identifier
Metadata Type	Data Element
Identifier	DE-16338
OID	1.2.36.1.2001.1001.101.103.16338

Definition

Definition	An ordinal number that identifies the specific anatomical site from multiple sites.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[2] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Conditions of Use	This **SHALL** be an ordinal number between first and eighteenth.
Conditions of Use Source	NEHTA
Examples	1. First, as in 'first rib'. 2. Second, as in 'second toe'. 3. Third, as in 'third lumbar vertebra'.

[2] http://www.hl7.org/oid/index.cfm

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	SPECIFIC LOCATION	0..1

2.27 Anatomical Plane

Identification

Label	Anatomical Plane
Metadata Type	Data Element
Identifier	DE-16340
OID	1.2.36.1.2001.1001.101.103.16340

Definition

Definition	Line describing the position of a vertical anatomical plane in the body.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[3] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1. Midline 2. Midclavicular 3. Midaxillary 4. Midscapular

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	SPECIFIC LOCATION	0..1

[3] http://www.hl7.org/oid/index.cfm

2.28 RELATIVE LOCATION

Identification

Label	RELATIVE LOCATION
Metadata Type	Data Group
Identifier	DG-16341
OID	1.2.36.1.2001.1001.101.102.16341

Definition

Definition	Qualifier(s) to identify a non-specific location.
Definition Source	NEHTA
Synonymous Names	
Notes	An example is: 5cm (distance) inferior (aspect) to the tibial tuberosity (landmark). There may be more than one relative location required to provide a cross reference.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..*

Children

Data Type	Name	Occurrences
	Identified Landmark	0..1
	Aspect (Anatomical Location Aspect)	0..1
	Distance From Landmark	0..1

2.29 Identified Landmark

Identification

Label	Identified Landmark
Metadata Type	Data Element
Identifier	DE-16343
OID	1.2.36.1.2001.1001.101.103.16343

Definition

Definition	Identified anatomical landmark from which to specify the relative anatomical location.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[4] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATIVE LOCATION	0..1

[4] http://www.hl7.org/oid/index.cfm

2.30 Anatomical Location Aspect

Identification

Label	Aspect
Metadata Type	Data Element
Identifier	DE-16345
OID	1.2.36.1.2001.1001.101.103.16345

Definition

Definition	Qualifier to identify which direction the anatomical location is in relation to the identified landmark.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[5] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1. Medial to: Relative location medial to the landmark. 2. Lateral to: Relative location lateral to the landmark. 3. Superior to: Relative location superior to the landmark. 4. Inferior to: Relative location inferior to the landmark. 5. Anterior to: Relative location anterior to the landmark. 6. Posterior to: Relative location posterior to the landmark. 7. Below: Relative location below the landmark. 8. Above: Relative location above the landmark. 9. Inferolateral to: Relative location inferior and lateral to the landmark. 10. Superolateral to: Relative location superior and lateral to the landmark. 11. Inferomedial to: Relative location inferior and medial to the landmark.

[5] http://www.hl7.org/oid/index.cfm

12 Superomedial to: Relative location superior and medial to the landmark.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	RELATIVE LOCATION	0..1

2.31 Distance From Landmark

Identification

Label	Distance From Landmark
Metadata Type	Data Element
Identifier	DE-16346
OID	1.2.36.1.2001.1001.101.103.16346

Definition

Definition	Distance of location from the identified landmark.
Definition Source	NEHTA
Synonymous Names	
Data Type	Quantity

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATIVE LOCATION	0..1

2.32 Anatomical Location Description

Identification

Label	Description
Metadata Type	Data Element
Identifier	DE-16319
OID	1.2.36.1.2001.1001.101.103.16319

Definition

Definition	Description of the anatomical location.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..*

2.33 Visual Markings/Orientation

Identification

Label	Visual Markings/Orientation
Metadata Type	Data Element
Identifier	DE-16407
OID	1.2.36.1.2001.1001.101.103.16407

Definition

Definition	Description of any visual markings used to orientate the viewer.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1. External reference points 2. Special sutures 3. Ink markings

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..*

2.34 Anatomical Location Image

Identification

Label	Image
Metadata Type	Data Element
Identifier	DE-16199
OID	1.2.36.1.2001.1001.101.103.16199

Definition

Definition	An image or images used to identify a location.
Definition Source	NEHTA
Synonymous Names	
Context	This element is intended to be an image, e.g. a photo of the anatomical site such as a wound on the leg.
Context Source	NEHTA
Data Type	EncapsulatedData

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..*

2.35 Exposure Description

Identification

Label	Exposure Description
Metadata Type	Data Element
Identifier	DE-16477
OID	1.2.36.1.2001.1001.101.103.16477

Definition

Definition	Description about exposure to the substance/agent.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.36 Earliest Exposure

Identification

Label	Earliest Exposure
Metadata Type	Data Element
Identifier	DE-16372
OID	1.2.36.1.2001.1001.101.103.16372

Definition

Definition	Record of the date or time (or both) of the earliest or initial exposure to the substance/agent.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a date or time (or both).

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.37 Duration of Exposure

Identification

Label	Duration of Exposure
Metadata Type	Data Element
Identifier	DE-16373
OID	1.2.36.1.2001.1001.101.103.16373

Definition

Definition	Length of duration of exposure.
Definition Source	NEHTA
Synonymous Names	
Notes	Used to describe the length of exposure to a substance/agent triggering a specific reaction event.
Data Type	Duration

Usage

Examples	

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	REACTION EVENT	0..1

2.38 ADDITIONAL EXPOSURE DETAIL

Identification

Label	ADDITIONAL EXPOSURE DETAIL
Metadata Type	Choice
Identifier	C-16478
OID	1.2.36.1.2001.1001.101.105.16478

Definition

Definition	Additional detail about exposure/s for this reaction event, including structured medication amount information.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..*

Children

Data Type	Name	Occurrences
	AMOUNT OF MEDICATION	0..1
	TIMING	0..1
	MEDICATION ADMINISTRATION	0..1

2.39 AMOUNT OF MEDICATION

Identification

Label	AMOUNT OF MEDICATION
Metadata Type	Data Group
Identifier	DG-16423
OID	1.2.36.1.2001.1001.101.102.16423

Definition

Definition	Additional detail about exposure/s for this reaction event, including structured medication amount information.
Definition Source	NEHTA
Synonymous Names	
Scope	Used to record additional details of exposure to a substance/agent that triggered the adverse reaction event.
Scope Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADDITIONAL EXPOSURE DETAIL	0..1

Children

Data Type	Name	Occurrences
	Quantity	0..1
	Dose Unit	0..1
	Quantity Description	0..1

2.40 Quantity

Identification

Label	Quantity
Metadata Type	Data Element
Identifier	DE-10145
OID	1.2.36.1.2001.1001.101.103.10145

Definition

Definition	The quantity, number or proportion.
Definition Source	NEHTA
Synonymous Names	
Notes	The number of doses or physical amount of the therapeutic good.
Data Type	Real Quantity

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	AMOUNT OF MEDICATION	0..1

2.41 Dose Unit

Identification

Label	Dose Unit
Metadata Type	Data Element
Identifier	DE-16524
OID	1.2.36.1.2001.1001.101.103.16524

Definition

Definition	The dose unit of this amount.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	Dose Unit Reference Set

Usage

Examples	1. Tablets 2. Capsules 3. Sachets 4. mg 5. mL

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	AMOUNT OF MEDICATION	0..1

2.42 Dose Unit Reference Set

Identification

Label	Dose Unit Reference Set
Metadata Type	Value Domain
Identifier	VD-16523
OID	1.2.36.1.2001.1001.101.104.16523
External Identifier	SNOMED CT-AU Concept Id: 32570641000036102

Definition

Definition	The set of values for dose unit.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Dose Unit	1..1

2.43 Quantity Description

Identification

Label	Quantity Description
Metadata Type	Data Element
Identifier	DE-16525
OID	1.2.36.1.2001.1001.101.103.16525

Definition

Definition	Free text description of the amount which may consist of the quantity and dose unit.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	AMOUNT OF MEDICATION	0..1

2.44 TIMING

Identification

Label	TIMING
Metadata Type	Data Group
Identifier	DG-16431
OID	1.2.36.1.2001.1001.101.102.16431

Definition

Definition	Details of the timing of the use or administration of the medicine, vaccine or other therapeutic good.
Definition Source	NEHTA
Synonymous Names	
Notes	It is for recording timing of exposure to the substance or agent, including medication or vaccine.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADDITIONAL EXPOSURE DETAIL	0..1

Children

Data Type	Name	Occurrences
	Frequency Range (Intervention Frequency Range)	0..1
	Interval Range (Intervention Interval Range)	0..1
	Time (Intervention Time)	0..*
	Day of Week (Intervention Day of Week)	0..*
	Day of Month (Intervention Day of Month)	0..*
	Date (Intervention Date)	0..*

2.45 Intervention Frequency Range

Identification

Label	Frequency Range
Metadata Type	Data Element
Identifier	DE-16547
OID	1.2.36.1.2001.1001.101.103.16547

Definition

Definition	The frequency as number of times per time period that the intervention is to take place.
Definition Source	NEHTA
Synonymous Names	
Notes	Includes details of variable upper and lower frequency e.g. 3-4 times a day.
Data Type	QuantityRange

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TIMING	0..1

2.46 Intervention Interval Range

Identification

Label	Interval Range
Metadata Type	Data Element
Identifier	DE-16548
OID	1.2.36.1.2001.1001.101.103.16548

Definition

Definition	The length of time between doses or interventions.
Definition Source	NEHTA
Synonymous Names	
Notes	8 Hourly is PT8H, monthly is P1M, every hour and a half is PT1H30M. Includes details of variable upper and lower intervals e.g. every 2-3 hours.
Data Type	QuantityRange

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TIMING	0..1

2.47 Intervention Time

Identification

Label	Time
Metadata Type	Data Element
Identifier	DE-16549
OID	1.2.36.1.2001.1001.101.103.16549

Definition

Definition	Specific time(s) during the day when the intervention should be applied.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Conditions of Use	This **SHALL NOT** contain a date component.
Conditions of Use Source	NEHTA
Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a time.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TIMING	0..*

2.48 Intervention Day of Week

Identification

Label	Day of Week
Metadata Type	Data Element
Identifier	DE-16551
OID	1.2.36.1.2001.1001.101.103.16551

Definition

Definition	The specific and repeating day(s) of the week.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[6] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	1. Monday 2. Wednesday 3. Friday 4. Sunday

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TIMING	0..*

[6] http://www.hl7.org/oid/index.cfm

2.49 Intervention Day of Month

Identification

Label	Day of Month
Metadata Type	Data Element
Identifier	DE-16552
OID	1.2.36.1.2001.1001.101.103.16552

Definition

Definition	The specific and repeating day(s) of the month.
Definition Source	NEHTA
Synonymous Names	
Notes	If it is required to give a dose on the 2nd day of each month, then the value is 2.
Data Type	Integer

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TIMING	0..*

2.50 Intervention Date

Identification

Label	Date
Metadata Type	Data Element
Identifier	DE-16553
OID	1.2.36.1.2001.1001.101.103.16553

Definition

Definition	Actual dates.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Examples	Please see DateTime in Appendix B, *Specification Guide for Use* for examples and usage information on specifying a date or time (or both).

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	TIMING	0..*

2.51 MEDICATION ADMINISTRATION

Identification

Label	MEDICATION ADMINISTRATION
Metadata Type	Data Group
Identifier	DG-10108
OID	1.2.36.1.2001.1001.101.102.10108

Definition

Definition	Details about the administration of the medicine, vaccine or other therapeutic good.
Definition Source	NEHTA
Synonymous Names	
Scope	Used to describe the exposure mechanism to the substance or agent. This includes the route, anatomical site, delivery methods of medications.
Scope Source	NEHTA

Usage

Conditions of Use	This data group is repeated for every instance of medication administration being recorded.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADDITIONAL EXPOSURE DETAIL	0..1

Children

Data Type	Name	Occurrences
	Route	0..1
	Site (Anatomical Site)	0..1
	Delivery Method (Medication Delivery Method)	0..1

Data Type	Name	Occurrences
	Dose Duration	0..1
	Intravenous Details (Intravenous Administration Details)	0..*

2.52 Route

Identification

Label	Route
Metadata Type	Data Element
Identifier	DE-10147
OID	1.2.36.1.2001.1001.101.103.10147

Definition

Definition	The route by which the medication is administered.
Definition Source	NEHTA
Synonymous Names	Route of Administration
Notes	It is used to describe the path or channel by which the substance/agent is introduced or gains access into a patient's body. This includes the route for which medication is administered.
Data Type	CodeableText
Value Domain	Route of Administration Reference Set

Usage

Conditions of Use	Use “Unknown” only for retrospective data collection.
Conditions of Use Source	NEHTA
Examples	1. Oral 2. Subcutaneous injection 3. Epidural 4. Rectal 5. Otic

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ADMINISTRATION	0..1

2.53 Route of Administration Reference Set

Identification

Label	Route of Administration Reference Set
Metadata Type	Value Domain
Identifier	VD-10147
OID	1.2.36.1.2001.1001.101.104.10147
External Identifier	SNOMED CT-AU Concept Id: 32570601000036100

Definition

Definition	A list of all possible routes of administration of medication.
Definition Source	NEHTA
Notes	Set of allowable values to describe the way through which a medication is administered to/by the subject of care.

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Route	1..1

2.54 Anatomical Site

Identification

Label	Site
Metadata Type	Data Element
Identifier	DE-10156
OID	1.2.36.1.2001.1001.101.103.10156

Definition

Definition	A description of the site of administration.
Definition Source	NEHTA
Synonymous Names	
Notes	Location on or in the body of the subject of care where the substance/agent entered the body or therapeutic good was administered.
Data Type	CodeableText
Value Domain	Body Structure Foundation Reference Set

Usage

Examples	1. Left thigh 2. Upper arm 3. Entire left renal artery

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ADMINISTRATION	0..1

2.55 Body Structure Foundation Reference Set

Identification

Label	Body Structure Foundation Reference Set
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105

Definition

Definition	The set of values for named anatomical locations.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Site (Anatomical Site)	1..1

2.56 Medication Delivery Method

Identification

Label	Delivery Method
Metadata Type	Data Element
Identifier	DE-16470
OID	1.2.36.1.2001.1001.101.103.16470

Definition

Definition	The method of delivery if this should be specified.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1. Delivery via nebuliser or spacer. 2. Delivery via syringe pump.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ADMINISTRATION	0..1

2.57 Dose Duration

Identification

Label	Dose Duration
Metadata Type	Data Element
Identifier	DE-16471
OID	1.2.36.1.2001.1001.101.103.16471

Definition

Definition	The length of time over which to administer each dose.
Definition Source	NEHTA
Synonymous Names	
Data Type	Duration

Usage

Examples	1. An intravenous injection may be administered over a period of 5 minutes.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ADMINISTRATION	0..1

2.58 Intravenous Administration Details

Identification

Label	Intravenous Details
Metadata Type	Data Element
Identifier	DE-16634
OID	1.2.36.1.2001.1001.101.105.16634

Definition

Definition	Details of intravenous administration.
Definition Source	NEHTA
Synonymous Names	
Notes	This free text data element is currently a placeholder for further structured data that is as yet undefined. See Appendix A, *Known Issues* for further information.
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	MEDICATION ADMINISTRATION	0..*

2.59 Clinical Management Description

Identification

Label	Clinical Management Description
Metadata Type	Data Element
Identifier	DE-16482
OID	1.2.36.1.2001.1001.101.103.16482

Definition

Definition	Description about the clinical management provided.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Conditions of Use	Used to describe details about clinical management provided to manage or treat the adverse reaction.
Conditions of Use Source	NEHTA
Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.60 Multimedia

Identification

Label	Multimedia
Metadata Type	Data Element
Identifier	DE-16376
OID	1.2.36.1.2001.1001.101.103.16376

Definition

Definition	Inclusion of any multimedia file to support the recording of the reaction event.
Definition Source	NEHTA
Synonymous Names	
Notes	An example is a photo of a rash or presentation with angioneurotic oedema.
Data Type	EncapsulatedData

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..*

2.61 Reporting Details

Identification

Label	Reporting Details
Metadata Type	Data Element
Identifier	DE-16631
OID	1.2.36.1.2001.1001.101.105.16631

Definition

Definition	Further details required for reporting to regulatory bodies.
Definition Source	NEHTA
Synonymous Names	
Notes	This free text data element is currently a placeholder for further structured data that is as yet undefined. See Appendix A, *Known Issues* for further information.
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	REACTION EVENT	0..*

2.62 Adverse Reaction Event Comment

Identification

Label	Comment
Metadata Type	Data Element
Identifier	DE-16483
OID	1.2.36.1.2001.1001.101.103.16483

Definition

Definition	Further comment about the reaction event.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	REACTION EVENT	0..1

2.63 Reaction Reported

Identification

Label	Reaction Reported
Metadata Type	Data Element
Identifier	DE-16379
OID	1.2.36.1.2001.1001.101.103.16379

Definition

Definition	Was the adverse reaction reported to a regulatory body?
Definition Source	NEHTA
Synonymous Names	
Data Type	Boolean

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.64 Adverse Reaction Report

Identification

Label	Adverse Reaction Report
Metadata Type	Data Element
Identifier	DE-16484
OID	1.2.36.1.2001.1001.101.103.16484

Definition

Definition	Link to an adverse reaction report sent to a regulatory body.
Definition Source	NEHTA
Synonymous Names	
Data Type	Link

Usage

Examples	

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	ADVERSE REACTION	0..*

2.65 Supporting Clinical Record Information

Identification

Label	Supporting Clinical Record Information
Metadata Type	Data Element
Identifier	DE-16485
OID	1.2.36.1.2001.1001.101.103.16485

Definition

Definition	Link to further information about the presentation and findings that exist elsewhere in the health record.
Definition Source	NEHTA
Synonymous Names	
Notes	Examples of further information are presenting symptoms, examination findings, diagnosis.
Data Type	Link

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.66 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Details pertinent to the identification of the source of the adverse reaction information.
Definition Source	NEHTA
Synonymous Names	
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • the subject of care; • a subject of care agent, e.g. parent, guardian; • the clinician; and • a device or software.

Usage

Conditions of Use	This **SHALL NOT** be used unless the provider of the information is not the *Composer/Author* of the enclosing Structured Document. This is a reuse of the *PARTICIPATION* `data group`, which is described in Participation Data Specification [NEHT2011v]. The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in Appendix B, *Specification Guide for Use*. • Participation Type **SHALL** have an implementation-specific value equivalent to “Information Provider”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or as a DEVICE.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.67 SUBJECT

Identification

Label	SUBJECT
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	The individual about whom the adverse reaction information is being recorded.
Definition Source	NEHTA
Synonymous Names	
Scope	Generally only used when the recorder needs to make it explicit. Otherwise, the subject of the enclosing Structured Document is assumed.
Scope Source	NEHTA

Usage

Conditions of Use	This **SHALL NOT** be used unless the subject of the information is not the *Subject of Care* of the enclosing Structured Document. This is a reuse of the *PARTICIPATION* `data group`, which is described in Participation Data Specification [NEHT2011v]. The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in Appendix B, *Specification Guide for Use*. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.68 Adverse Reaction Instance Identifier

Identification

Label	Adverse Reaction Instance Identifier
Metadata Type	Data Element
Identifier	DE-16697
OID	1.2.36.1.2001.1001.101.103.16697

Definition

Definition	A globally unique identifier for each instance of an *Adverse Reaction evaluation*.
Definition Source	NEHTA
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..1

2.69 LINK

Identification

Label	LINK
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	A link to an instance of another Detailed Clinical Model (DCM) or a document containing an instance of another DCM.
Definition Source	NEHTA
Synonymous Names	
Notes	Links may be to structures inside the enclosing document or inside other documents.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	0..*

Children

Data Type	Name	Occurrences
	Link Nature	1..1
	Link Role	0..1
	Link Target	1..1

2.70 Link Nature

Identification

Label	Link Nature
Metadata Type	Data Element
Identifier	DE-16698
OID	1.2.36.1.2001.1001.101.103.16698

Definition

Definition	The general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA
Synonymous Names	
Notes	This is one of two attributes which together communicate the semantics of the relationship between the source and target DCMs or document. This attribute is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver.
Data Type	CodedText
Value Domain	Link Nature Values

Usage

Examples	1. is related to 2. is confirmed by or authorised by 3. is related to the same problem or health issue

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	LINK	1..1

2.71 Link Nature Values

Identification

Label	Link Nature Values
Metadata Type	Value Domain
Identifier	VD-16698
OID	1.2.36.1.2001.1001.101.104.16698

Definition

Definition	The set of values for the general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA

Value Domain

Source	ISO 13606-3:2009	
Permissible Values	The permissible values are those specified in Termlist LINK_NATURE in ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]. They are listed here.	
	LINK-A0, is related to	A generic category for any Link, the details of which will be given by the value of Link Role.
	LINK-B0, is confirmed by or authorised by	The target link contains [an instance of a DCM or document] that acts as the legal or clinical basis for the activity documented in the source [DCM instance], or is a declaration of intent to provide (or not to provide) requested care. This Link is to be used to connect two [DCM instances or DCM and document], as opposed to the inclusion of a corroborating or authorising participant as an identified party within a single [DCM instance or document].
	LINK-C0, is related to the same problem or health issue	The target [instance of a DCM or document] documents health or health care that pertains to the same clinical situation as the source [DCM instance]. One of the two might be defining a problem for which the other is a manifestation, or the relationship might for example be cause and effect, stages in an evolving clinical history, a different interpretation of an observation, a clinical indication or contraindication.
	LINK-D0, is related to the same care plan, act or episode	The source and the target [instances of DCM or documents] are each documenting parts of the same care plan, act or episode. One of the

		two might be defining the same care plan, act or episode, or both might be related milestones.
	LINK-E0, is a related documentation	The target [instance of a DCM or document] is an alternative documentary form of the source [DCM instance], such as re-expression of the same clinical information or additional supplementary explanatory information.

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Link Nature	1..1

2.72 Link Role

Identification

Label	Link Role
Metadata Type	Data Element
Identifier	DE-16699
OID	1.2.36.1.2001.1001.101.103.16699

Definition

Definition	The detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA
Synonymous Names	
Notes	This is one of two attributes which together communicate the semantics of the relationship between the source and target DCMs. This attribute provides for a specific description of the actual role played by the target in relation to the source. This attribute may be populated from any suitable terminology, and therefore might support human readership better than interoperable automated processing.
Data Type	CodeableText
Value Domain	Link Role Values

Usage

Examples	1. unspecified link 2. suggests 3. endorses 4. evidence for 5. outcome 6. is documented by 7. excerpts

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	LINK	0..1

2.73 Link Role Values

Identification

Label	Link Role Values
Metadata Type	Value Domain
Identifier	VD-16699
OID	1.2.36.1.2001.1001.101.104.16699

Definition

Definition	The set of values for the detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA
Context	These values are used within the context of values from *Link Role*. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	NEHTA

Value Domain

Source	ISO 13606-3:2009
Permissible Values	Values **SHOULD** be from Termlist LINK_ROLE in ISO 13606-3:2009 [ISO2009a]. Values **MAY** be from any suitable terminology. Some values from Termlist LINK_ROLE in ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a] are:

LINK-A1, unspecified link	The term is used when no semantic information is available for this Link in the EHR system from which the EXTRACT has been created.
LINK-A2, suggests	The interpretation expressed in the target component is a possible cause or outcome of the findings documented in the source component.
LINK-B1, endorses	The interpretation expressed in the source component provides confirmatory evidence or a confirmatory opinion of the interpretation expressed in the target component.
LINK-C3, evidence for	The observation or interpretation documented in the source component provides confirmatory evidence of the interpretation expressed in the target component.
LINK-D1, outcome	The clinical situation documented in the target component is the direct outcome of the situation documented in the source component.

	LINK-E1, documented by	A clinical situation documented in the source component is more formally documented in the target component.
	LINK-E4, excerpts	The source component is an extract (copy) of part or all of the information contained within the target component.

Usage

Conditions of Use	Each of the link terms in LINK_ROLE from ISO 13606-3:2009 is a sub-category of a corresponding term in *Link Nature Values*, where that correspondence is indicated by the first letter after the code string “LINK-” e.g. the term LINK-A1 is a subcategory of term LINK-A0. If a term in this list is used for the *Link Role* `data element`, the appropriate corresponding value **SHALL** be used from *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Link Role	1..1

2.74 Link Target

Identification

Label	Link Target
Metadata Type	Data Element
Identifier	DE-16700
OID	1.2.36.1.2001.1001.101.103.16700

Definition

Definition	The logical “to” object in the link relation, as per the linguistic sense of the *Link Nature* `data element` (and, if present, the *Link Role* `data element`).
Definition Source	NEHTA
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	LINK	1..1

2.75 Detailed Clinical Model Identifier

Identification

Label	Detailed Clinical Model Identifier
Metadata Type	Data Element
Identifier	DE-16693
OID	1.2.36.1.2001.1001.101.103.16693

Definition

Definition	The NEHTA OID for the *Adverse Reaction* concept represented by this DCM.
Definition Source	NEHTA
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	
Default Value	1.2.36.1.2001.1001.101.102.15517
Default Value Conditions of Use	The value of this item is fixed and **SHALL** be the default value.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	ADVERSE REACTION	1..1

3 Exclusion Statement - Adverse Reactions Detailed Clinical Model

This chapter describes version 1.2 of the Exclusion Statement - Adverse Reactions Detailed Clinical Model.

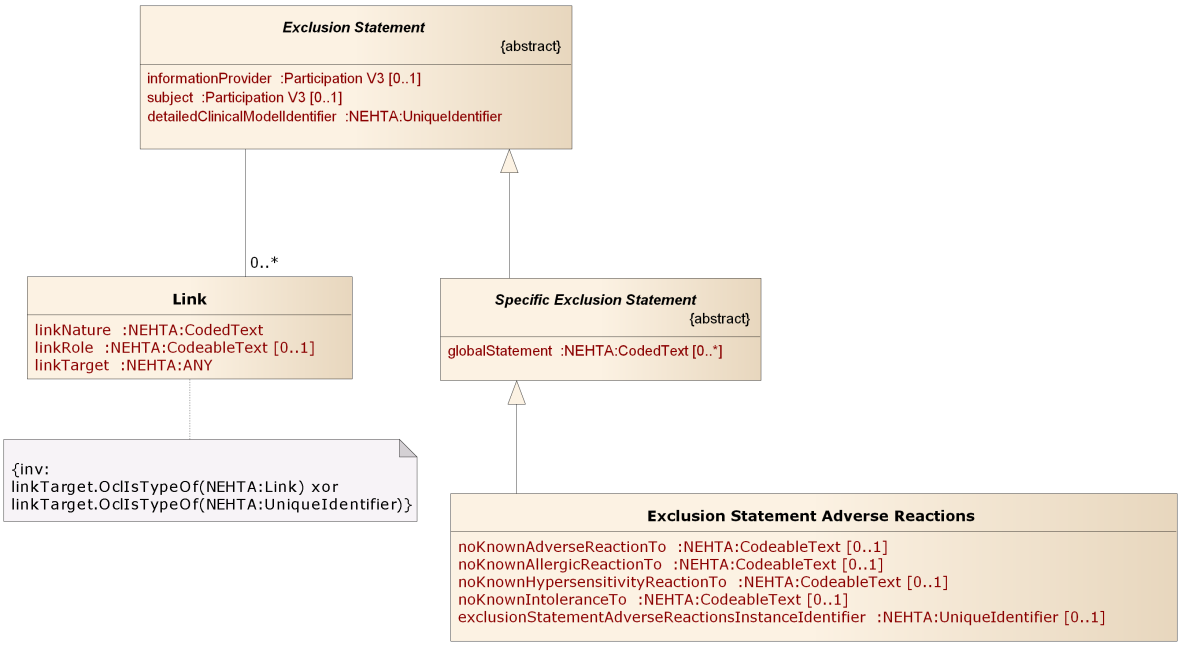
3.1 Purpose

To positively record the absence or exclusion of any adverse reactions within the health record.

3.2 Use

Use to record the positive exclusion or absence of adverse reactions within the health record. This DCM avoids the need to use terminology to express negation about any item within the health record. It is important to note that the Exclusion Statement information is time-specific. Its validity may not extend beyond the point in time when the information is recorded. The patient should always be asked to verify previous statements on adverse reaction to a substance.

3.3 UML Class Diagram



The figure represents the data hierarchy of the Detailed Clinical Model as a UML 2.0 class diagram. The diagram displays data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes. Data groups are displayed as classes, their names are represented as association role names. Association role names are only displayed if they differ from the associated class name. The diagram shows the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

3.4 EXCLUSION STATEMENT - ADVERSE REACTIONS

Identification

Label	EXCLUSION STATEMENT - ADVERSE REACTIONS
Metadata Type	Data Group
Identifier	DG-16137
OID	1.2.36.1.2001.1001.101.102.16137

Definition

Definition	Statements about adverse reactions that need to be positively recorded as absent or excluded.
Definition Source	openEHR Foundation
Scope	To positively record the absence or exclusion of any adverse reactions within the health record.
Scope Source	openEHR Foundation

Data Hierarchy

	EXCLUSION STATEMENT - ADVERSE REACTIONS		
		Global Statement	0..*
		No Known Adverse Reaction to	0..1
		No Known Allergic Reaction to	0..1
		No Known Hypersensitivity Reaction to	0..1
		No Known Intolerance to	0..1
		INFORMATION PROVIDER	0..1
		SUBJECT	0..1
		Exclusion Statement - Adverse Reactions Instance Identifier	0..1
		LINK	0..*
		Link Nature	1..1

			Link Role	0..1
			Link Target	1..1
		Detailed Clinical Model Identifier		1..1

3.5 Global Statement

Identification

Label	Global Statement
Metadata Type	Data Element
Identifier	DE-16302
OID	1.2.36.1.2001.1001.101.103.16302

Definition

Definition	The statement about the absence or exclusion.
Definition Source	openEHR Foundation
Synonymous Names	
Context	This can be used to capture any information that is needed to be explicitly recorded as being absent or excluded within the record.
Context Source	openEHR Foundation
Data Type	CodedText
Value Domain	Global Statement Values

Usage

Conditions of Use	Captures any information that is needed to be explicitly recorded as being absent or excluded within the record.
Conditions of Use Source	openEHR Foundation
Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..*

3.6 Global Statement Values

Identification

Label	Global Statement Values
Metadata Type	Value Domain
Identifier	VD-16299
OID	1.2.36.1.2001.1001.101.104.16299

Definition

Definition	The set of values for the global statements about the exclusion.
Definition Source	openEHR Foundation

Value Domain

Source	NEHTA	
Permissible Values	*Not asked*	No information about adverse reactions to any substance is available because the patient was not asked or not able to be asked.
	None known	No information about adverse reactions to any substance is known.
	None supplied	No information about adverse reactions to any substance is supplied.
	Please see Appendix A, *Known Issues*	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Global Statement	1..1

3.7 No Known Adverse Reaction to

Identification

Label	No Known Adverse Reaction to
Metadata Type	Data Element
Identifier	DE-16305
OID	1.2.36.1.2001.1001.101.103.16305

Definition

Definition	Positive statement about adverse reactions to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[1] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

[1] http://www.hl7.org/oid/index.cfm

3.8 No Known Allergic Reaction to

Identification

Label	No Known Allergic Reaction to
Metadata Type	Data Element
Identifier	DE-16306
OID	1.2.36.1.2001.1001.101.103.16306

Definition

Definition	Positive statement about allergic reactions to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[2] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

[2] http://www.hl7.org/oid/index.cfm

3.9 No Known Hypersensitivity Reaction to

Identification

Label	No Known Hypersensitivity Reaction to
Metadata Type	Data Element
Identifier	DE-16307
OID	1.2.36.1.2001.1001.101.103.16307

Definition

Definition	Positive statement about hypersensitivity reactions to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[3] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

[3] http://www.hl7.org/oid/index.cfm

3.10 No Known Intolerance to

Identification

Label	No Known Intolerance to
Metadata Type	Data Element
Identifier	DE-16308
OID	1.2.36.1.2001.1001.101.103.16308

Definition

Definition	Positive statement about intolerances to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	*Not specified.* In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the *HL7 code set registration procedure*[4] with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

[4] http://www.hl7.org/oid/index.cfm

3.11 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	Details pertinent to the identification of the source of the adverse reaction information.
Definition Source	NEHTA
Synonymous Names	
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • the subject of care; • a subject of care agent, e.g. parent, guardian; • the clinician; and • a device or software.

Usage

Conditions of Use	This **SHALL NOT** be used unless the provider of the information is not the *Composer/Author* of the enclosing Structured Document. This is a reuse of the *PARTICIPATION* `data group`, which is described in Participation Data Specification [NEHT2011v]. The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in Appendix B, *Specification Guide for Use*. • Participation Type **SHALL** have an implementation-specific value equivalent to “Information Provider”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON or as a DEVICE.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

3.12 SUBJECT

Identification

Label	SUBJECT
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	The individual about whom the adverse reaction information is being recorded.
Definition Source	NEHTA
Synonymous Names	
Scope	Generally only used when the recorder needs to make it explicit. Otherwise, the subject of the enclosing Structured Document is assumed.
Scope Source	NEHTA

Usage

Conditions of Use	This **SHALL NOT** be used unless the subject of the information is not the *Subject of Care* of the enclosing Structured Document. This is a reuse of the *PARTICIPATION* `data group`, which is described in Participation Data Specification [NEHT2011v]. The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in Appendix B, *Specification Guide for Use*. • Participation Type **SHALL** have an implementation-specific value equivalent to "Subject". • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

3.13 Exclusion Statement - Adverse Reactions Instance Identifier

Identification

Label	Exclusion Statement - Adverse Reactions Instance Identifier
Metadata Type	Data Element
Identifier	DE-16712
OID	1.2.36.1.2001.1001.101.103.16712

Definition

Definition	A globally unique object identifier for each instance of an *Exclusion Statement - Adverse Reactions* evaluation.
Definition Source	NEHTA
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1

3.14 LINK

Identification

Label	LINK
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	A link to an instance of another Detailed Clinical Model (DCM) or a document containing an instance of another DCM.
Definition Source	NEHTA
Synonymous Names	
Notes	Links may be to structures inside the enclosing document or inside other documents.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..*

Children

Data Type	Name	Occurrences
	Link Nature	1..1
	Link Role	0..1
	Link Target	1..1

3.15 Link Nature

Identification

Label	Link Nature
Metadata Type	Data Element
Identifier	DE-16698
OID	1.2.36.1.2001.1001.101.103.16698

Definition

Definition	The general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA
Synonymous Names	
Notes	This is one of two attributes which together communicate the semantics of the relationship between the source and target DCMs or document. This attribute is intended to be a coarse-grained category that can be used to enable interoperability between sender and receiver.
Data Type	CodedText
Value Domain	Link Nature Values

Usage

Examples	1. is related to 2. is confirmed by or authorised by 3. is related to the same problem or health issue

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	LINK	1..1

3.16 Link Nature Values

Identification

Label	Link Nature Values
Metadata Type	Value Domain
Identifier	VD-16698
OID	1.2.36.1.2001.1001.101.104.16698

Definition

Definition	The set of values for the general semantic category of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA

Value Domain

Source	ISO 13606-3:2009	
Permissible Values	The permissible values are those specified in Termlist LINK_NATURE in ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a]. They are listed here.	
	LINK-A0, is related to	A generic category for any Link, the details of which will be given by the value of Link Role.
	LINK-B0, is confirmed by or authorised by	The target link contains [an instance of a DCM or document] that acts as the legal or clinical basis for the activity documented in the source [DCM instance], or is a declaration of intent to provide (or not to provide) requested care. This Link is to be used to connect two [DCM instances or DCM and document], as opposed to the inclusion of a corroborating or authorising participant as an identified party within a single [DCM instance or document].
	LINK-C0, is related to the same problem or health issue	The target [instance of a DCM or document] documents health or health care that pertains to the same clinical situation as the source [DCM instance]. One of the two might be defining a problem for which the other is a manifestation, or the relationship might for example be cause and effect, stages in an evolving clinical history, a different interpretation of an observation, a clinical indication or contraindication.
	LINK-D0, is related to the same care plan, act or episode	The source and the target [instances of DCM or documents] are each documenting parts of the same care plan, act or episode. One of the

	LINK-E0, is a related documentation	two might be defining the same care plan, act or episode, or both might be related milestones. The target [instance of a DCM or document] is an alternative documentary form of the source [DCM instance], such as re-expression of the same clinical information or additional supplementary explanatory information.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	Link Nature	1..1

3.17 Link Role

Identification

Label	Link Role
Metadata Type	Data Element
Identifier	DE-16699
OID	1.2.36.1.2001.1001.101.103.16699

Definition

Definition	The detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA
Synonymous Names	
Notes	This is one of two attributes which together communicate the semantics of the relationship between the source and target DCMs. This attribute provides for a specific description of the actual role played by the target in relation to the source. This attribute may be populated from any suitable terminology, and therefore might support human readership better than interoperable automated processing.
Data Type	CodeableText
Value Domain	Link Role Values

Usage

Examples	1. unspecified link 2. suggests 3. endorses 4. evidence for 5. outcome 6. is documented by 7. excerpts

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	LINK	0..1

3.18 Link Role Values

Identification

Label	Link Role Values
Metadata Type	Value Domain
Identifier	VD-16699
OID	1.2.36.1.2001.1001.101.104.16699

Definition

Definition	The set of values for the detailed semantic description of the relationship between this instance of this DCM, i.e. the source, and the target DCM instance or target document.
Definition Source	NEHTA
Context	These values are used within the context of values from *Link Role*. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	NEHTA

Value Domain

Source	ISO 13606-3:2009
Permissible Values	Values **SHOULD** be from Termlist LINK_ROLE in ISO 13606-3:2009 [ISO2009a]. Values **MAY** be from any suitable terminology. Some values from Termlist LINK_ROLE in ISO 13606-3:2009 Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists [ISO2009a] are:

LINK-A1, unspecified link	The term is used when no semantic information is available for this Link in the EHR system from which the EXTRACT has been created.
LINK-A2, suggests	The interpretation expressed in the target component is a possible cause or outcome of the findings documented in the source component.
LINK-B1, endorses	The interpretation expressed in the source component provides confirmatory evidence or a confirmatory opinion of the interpretation expressed in the target component.
LINK-C3, evidence for	The observation or interpretation documented in the source component provides confirmatory evidence of the interpretation expressed in the target component.
LINK-D1, outcome	The clinical situation documented in the target component is the direct outcome of the situation documented in the source component.

	LINK-E1, documented by	A clinical situation documented in the source component is more formally documented in the target component.
	LINK-E4, excerpts	The source component is an extract (copy) of part or all of the information contained within the target component.

Usage

Conditions of Use	Each of the link terms in LINK_ROLE from ISO 13606-3:2009 is a sub-category of a corresponding term in *Link Nature Values*, where that correspondence is indicated by the first letter after the code string “LINK-” e.g. the term LINK-A1 is a subcategory of term LINK-A0. If a term in this list is used for the *Link Role* `data element`, the appropriate corresponding value **SHALL** be used from *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

Data Type	Name	**Occurrences** (child within parent)
	Link Role	1..1

3.19 Link Target

Identification

Label	Link Target
Metadata Type	Data Element
Identifier	DE-16700
OID	1.2.36.1.2001.1001.101.103.16700

Definition

Definition	The logical “to” object in the link relation, as per the linguistic sense of the *Link Nature* `data element` (and, if present, the *Link Role* `data element`).
Definition Source	NEHTA
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

Examples	

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	LINK	1..1

3.20 Detailed Clinical Model Identifier

Identification

Label	Detailed Clinical Model Identifier
Metadata Type	Data Element
Identifier	DE-16693
OID	1.2.36.1.2001.1001.101.103.16693

Definition

Definition	The NEHTA OID for the *Exclusion Statement - Adverse Reactions* concept represented by this DCM.
Definition Source	NEHTA
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	
Default Value	1.2.36.1.2001.1001.101.102.16137
Default Value Conditions of Use	The value of this item is fixed and **SHALL** be the default value.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	EXCLUSION STATEMENT - ADVERSE REACTIONS	1..1

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Appendix A. Known Issues

This appendix lists known issues with this specification at the time of publishing. NEHTA is working on solutions to these issues, and we encourage comments to further assist with the development of these solutions.

Reference	Description
Data Hierarchy	Only the parts of these DCMs required for current Structured Content Specifications have been mapped to HL7 CDA. Mapping the remaining parts to CDA may reveal inconsistencies in the data hierarchies, requiring normative change.
Clinical Manifestation Values	The Clinical Manifestation Values has not been defined. Until it is defined use the *Clinical finding foundation reference set* (SNOMED CT-AU Concept ID: 32570071000036102).
Quantity Data Element	The correctness of the solution presented in this specification is uncertain; this data element needs to be able to cater for quantities of non-medications.
Anatomical Site Data Element	In the future this data element needs to be updated in order to cater for administration of non-medications.
Global Statement Values Data Element	The list of permissible values is a sample set to initiate discussion and collaboration to develop the correct set of values.
Exclusion Statement	The Exclusion Statement DCMs are the subject of ongoing development and review and may well change in the future.
Undefined Value Domains	The following data elements lack a defined value domain: *Numerical Identifier*, *Anatomical Plane*, *Anatomical Location Aspect*, *Reaction Type*, *Identified Landmark*, *Intervention Day of Week*, *No Known Adverse Reaction to*, *No Known Allergic Reaction to*, *No Known Hypersensitivity Reaction to*, and *No Known Intolerance to*. NEHTA is in the process of developing national code sets for these items. In the meantime, you are free to use your own code set(s), providing any code set used **SHALL** be registered, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and **SHALL** be publicly available. Note that when national standard code set(s) do become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.
Undefined Data Structures	The following data elements lack a defined data structure: *Intravenous Administration Details* and *Reporting Details*. A free-text data element is currently used as an interim solution.

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Appendix B. Specification Guide for Use

B.1 Overview

Each Detailed Clinical Model (DCM) and Structured Content Specification (SCS) is designed to be a shared basis for data interpretation. It specifies rigorous business and technical definitions of data which systems may need to share. It is intended to be a logical specification of the data to be persisted within or communicated between systems. It is also the foundation for conformance, compliance and accreditation testing of implemented systems. NEHTA's CDA implementation guides are guides to the implementation of HL7 CDA R2 messages based upon these DCMs and SCSs.

Each DCM specifies all of the data components required for any use of a clinical concept, for instance an entry in a medical record such as a procedure or an imaging test. As such, they are maximal data sets. DCMs are building blocks which are trimmed to size for use in the construction of SCSs.

Each SCS specifies the data for a single type of clinical document or information exchange, such as a discharge summary. It is assembled using DCMs that have been constrained to eliminate data components not relevant to the particular context. For example, *Procedure* in a discharge summary uses only some of the data components required by *Procedure* in a specialist report.

B.2 The Structured Content Specification Metamodel

The NEHTA Structured Content Specification Metamodel (see Figure 1) is used to specify the overall structure of a Structured Content Specification.

A DCM can be regarded as a data group with no parent.

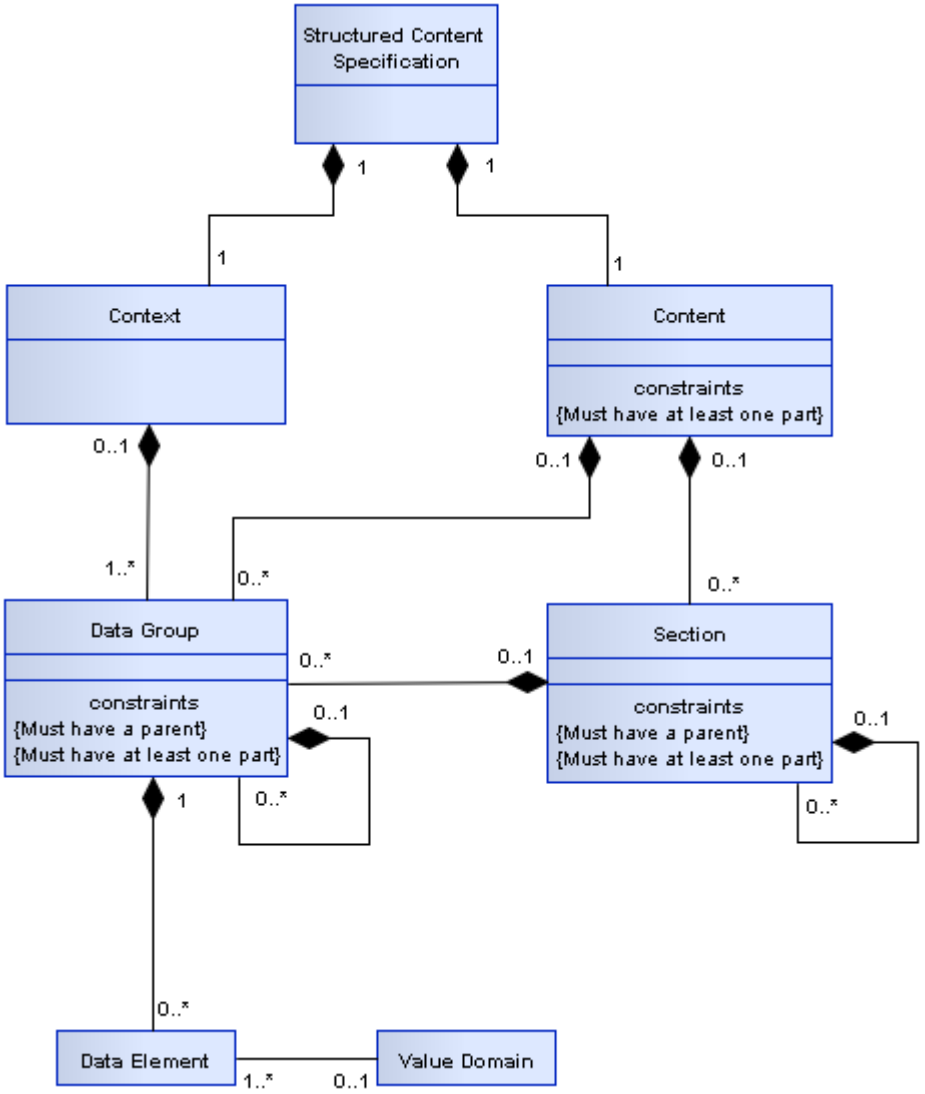

Figure 1: SCS Metamodel

There are two main components used to organise information within an SCS as follows:

Context: This contains information related to the overall context of the document.

Content: This contains information that changes between different SCSs, but is always structured as shown, and consists of the following components:

- Section
- Data Group
- Data Element
- Value Domain

These components are described in more detail below.

Context

The purpose of the context is to identify and classify the document and to provide subjects of care and involved healthcare providers with the information related to the relevant healthcare events.

Content

Content contains a collection of personal information and health information pertinent to a subject of care which is derived from the healthcare event described in the document. The detail is organised into one or more data groups which are optionally grouped into sections.

Section

A section is composed of other sections, data groups, or both. It is an organising container that gives the reader a clue as to the expected content. The primary purpose of a section is to organise information in a manner that is suitable for the primary purpose for which it is collected, and to provide a way to navigate through the data components within the document, thereby enabling more efficient querying. It is recommended that the section support safe reuse for secondary purposes, e.g. clinical coding or inclusion in a summarised form in an electronic health record. A section is context-specific to the document in which it resides.

Data Group

Each data group is used to represent one concept. A data group consists of other data groups or data elements (or both). Some data groups are reused across DCMs.

Every instance of a data group **SHALL** have at least one child data component instantiated.

Participation

Participation is a special case of a data group that is based on a data group template, which is reused throughout the DCMs and SCSs. Participations are an amalgam of the Actors (see below) operating within a defined healthcare domain and the Roles they are playing within that domain.

A Participant has been defined to align with the concepts of the NEHTA interoperability framework [NEHT2007b]. It equates to an *Entity* that is related to the action described in an SCS as an *Actor*. A participant can be a human, an organisation or an IT system.

[NEHT2011v] defines the full Participation specification.

Choice

Choice represents a decision to be made at run-time between a disjunctive mandatory set of data groups defined at design-time, i.e. one and only one member of the set is chosen for each instance of the choice.

For example, at design time a Healthcare Provider provides a service but it is not until run-time that a decision can be made as to whether the provider is a person or an organisation. Hence when a Healthcare Provider Participant is instantiated, it will contain either an instance of the *Person* data group or an instance of the *Organisation* data group.

Data Element

A data element is the smallest named unit of information in the model that can be assigned a value. For example, *DateTime of Observation* and *Observation Note*. Data elements are bound to data types (see Data Types Legend). Some data elements are reused in different data groups.

Whilst all data elements are constrained by their data type, some data elements are further constrained by value domains (see Value Domain below).

Value Domain

A value domain constrains the permissible values for a data element. The values are often a subset of values based on a generic data type.

Value domains are reusable components and therefore, the same value domain can be referred to by different data elements in different contexts. Value domains are often specified as a reference set. A reference set (or a subset) is a constrained list of SNOMED CT-AU, AMT or LOINC concepts that are appropriate to a particular context. It is noted that many of these reference sets have been developed specifically for the context in which they appear. It is recommended that an assessment of fitness for purpose be undertaken before using any of the reference sets in another context.

Value domains constrain by either specifying a lower or upper bound (or both) on the range of permissible values or else by specifying a finite set of prescribed values. Such a set of prescribed values can be specified directly within the definition of the data element, or in a separate but associated specification or else by reference to one or more vocabulary/terminology reference sets. The table below provides some examples of value domains.

Table 1: Value Domain Examples

<table>
<tr><th>Data Element</th><th>Data Type</th><th>Example of Value Domain</th></tr>
<tr><td>Sex</td><td>CodedText</td><td>[SA2006a] and [SA2006b] derive their values from METeOR 270263 which includes values such as:
<table><tr><th>Value</th><th>Meaning</th></tr><tr><td>1</td><td>Male</td></tr><tr><td>2</td><td>Female</td></tr><tr><td>3</td><td>Intersex or Indeterminate</td></tr><tr><td>9</td><td>Not Stated/Inadequately Described</td></tr></table></td></tr>
<tr><td>Diagnosis</td><td>CodeableText</td><td>A SNOMED CT-AU reference set which references concepts such as ‘Bronchitis’ (Concept ID: 32398004).</td></tr>
<tr><td>Therapeutic Good Identification</td><td>CodeableText</td><td>An AMT reference set which references concepts such as ‘Ibuprofen Blue (Herron) (ibuprofen 200 mg) tablet: film-coated, 1 tablet’ (Concept ID: 54363011000036107).</td></tr>
<tr><td>Individual Pathology Test Result Name</td><td>CodeableText</td><td>A LOINC subset which references concepts such as ‘Cholesterol [Moles/volume] in Serum or Plasma’ (ID: 14647-2).</td></tr>
</table>

B.3 Icon Legend

These legends describe all icons that are used within the various NEHTA information specifications.

Metadata Types Legend

The following table explains each of the icons used to represent the metadata types within DCMs and SCSs.

Table 2: Metadata Types Legend

Icon	Metadata Types
	Structured Document
	Section
	Data Group
	Participation
	Choice

Data Types Legend

The following table explains each of the icons used to represent the data types bound to each data element in the SCSs. These data types are a profile of the **ISO 21090-2011** data types as specified in [NEHT2010c].

Table 3: Data Types Legend

Icon	Data type	Explanation
	Boolean (ISO 21090: BL)	A primitive data type, sometimes called the logical data type, having one of two values: *true* and *false*. Many systems represent true as *non-zero* (often 1, or -1) and false as *zero*. **Usage/Examples** • An actual value entered by a user might be “yes” or could be chosen by a mouse click on an icon such as ☑.

CodeableText

(ISO 21090: CD)

Coded text *with* exceptions; a flexible data type to support various ways of holding text, both free text and coded text. Commonly used to support compliance for early adopters of the Structured Content Specifications. While it is recommended that the values in this data type come from the bound value domain, it allows other value domains to also be used (with or without translations to the bound value domain) or free text alternatives. This is a recognition that it may not be possible to define an entire value domain for a complex concept (e.g. *Diagnosis*) or that there may be competing code sets in existence. Note that within exchange specifications or message profiles this data type **MAY** be constrained to mandate compliance with the bound value domain.

Usage/Examples

- AIHW Separation Mode specifies the status at separation of a person from an organisation. An early adopter **MAY** have a similar concept (coded or otherwise) that maps to this data element but does not strictly comply with the AIHW values.
- A SNOMED CT-AU coded/complex expression that embodies single or multiple concepts. The SNOMED CT-AU concepts behind these CodeableText components are specified in the Structured Content Specification value domains.

CodedText

(ISO 21090: CD)

Coded text *without* exceptions; text with code mappings. Values in this data type **SHALL** come from the bound value domain, with no exceptions. Often used for reference sets with only a small number of applicable values, e.g. Gender and Document Status.

Usage/Examples

[SA2006b] specifies the following value domain representing a type of address:

Value	Meaning
1	Business
2	Mailing or Postal
3	Temporary Accommodation
4	Residential (permanent)
9	Not Stated/Unknown/Inadequately Described

DateTime

(ISO 21090: TS)

Used for specifying a single date or time (or both). Has the ability to indicate a level of precision, but not whether the date or time is estimated. String representations of known dates **SHALL** conform to the nonextended format within the **ISO 21090-2011** standard, i.e. YYYYMMDDHHMMSS.UUUU[+]-ZZzz.

Usage/Examples

- Partial dates: 2008, 20081001.
- To indicate 1:20 pm on May the 31st, 1999 for a time zone which is 5 hours behind Coordinated Universal Time (UTC): 19990531132000-0500.

 Duration (ISO 21090: PQ.TIME)	The period of time during which something continues. Consists of a value and a unit which represents the time value, e.g. hours, months. Compound durations are not allowed, e.g. 10 days 3 weeks 5 hours. **Usage/Examples** • 3 hours • 6 months • 1 year
 Any (ISO 21090: ANY)	Represents a data element where the data type to be used is conditional on another data component. The values that can be required will vary considerably depending on the context. Note that this is an abstract data type that is the basis for all data types and **SHOULD NOT** be used in an actual implementation.
 EncapsulatedData (ISO 21090: ED)	Data that is primarily intended for human interpretation or for further machine processing outside the scope of this specification. This includes unformatted or formatted written language, multimedia data, or structured information as defined by a different standard (e.g. XML signatures). **Usage/Examples** • JPEG images • HTML documents • [RFC1521] MIME types
 Integer (ISO 21090: INT)	The mathematical data type comprising the exact integral values (according to [NEHT2010c]). **Usage/Examples** • 1 • -50 • 125
 Link (ISO 21090: TEL)	This is a general link, reference or pointer to an object, data or application that exists logically or is stored electronically in a computer system. **Usage/Examples** • URL (Uniform Resource Locator) – the World Wide Web address of a site on the internet, such as the URL for the Google internet search engine – *http://www.google.com*. • An absolute or relative path within a file or directory structure – e.g. in the Windows® operating system, the “link” or absolute path to a particular letter could be *C:\Documents and Settings\GuestUser\MyDocuments\letter.doc*

 Quantity (ISO 21090: PQ)	Used for recording many real world measurements and observations. Includes the magnitude value and the units. **Usage/Examples** • 100 centimetres • 25.5 grams
 QuantityRatio (ISO 21090: RTO)	The relative magnitudes of two *Quantity* values (usually expressed as a quotient). **Usage/Examples** • 25 mg/500 ml • 200 mmol per litre
 QuantityRange (ISO 21090: IVL)	Two *Quantity* values that define the minimum and maximum values, i.e. lower and upper bounds. This is typically used for defining the valid range of values for a particular measurement or observation. Unbounded quantity ranges can be defined by not including a minimum and/or a maximum quantity value. **Usage/Examples** • -20 to 100 Celsius • 30-50 mg • >10 kg
 Real (ISO 21090: REAL)	A computational approximation to the standard mathematical concept of real numbers. These are often called floating-point numbers. **Usage/Examples** • 1.075 • -325.1 • 3.14157
 Text (ISO 21090: ST)	Character strings (with optional language). Unless otherwise constrained by an implementation, can be any combination of alpha, numeric or symbols from the Unicode character set. Sometimes referred to as free text. **Usage/Examples** “The patient is a 37 year old man who was referred for cardiac evaluation after complaining of occasional palpitations, racing heart beats and occasional dizziness.”
 TimeInterval (ISO 21090:TS)	An interval in time, with (optionally) a start date/time and (optionally) an end date/time and/or a duration/width. **Usage/Examples** • 01/01/2008 – 31/12/2008 • 1:30 a.m. – 6:00 p.m., duration/width = 16.5 hours

	UniqueIdentifier (ISO 21090: II)	A general unique value to identify a physical or virtual object or concept. In using this data type, the attributes of the UniqueIdentifier data type **SHOULD** be populated from the identifiers as defined in AS 4846 (2006) [SA2006a] and AS 5017 (2006) [SA2006b] as follows: • *root*: a globally unique object identifier that identifies the combination of geographic area, issuer and type. If no such globally unique object identifier exists, it **SHALL** be created. • *extension*: a unique identifier within the scope of the root that is directly equivalent to the identifier designation element. • *identifierName*: a human readable name for the namespace represented by the root that is populated with the issuer or identifier type values, or a concatenation of both, as appropriate. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used for that purpose. • *identifierScope*: the geographic span or coverage that applies to or constrains the identifier. It is directly equivalent to the geographic area element. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used as such. Also, the following constraints apply on the UniqueIdentifier data type: 1. The *root* attribute **SHALL** be used. 2. For an entity identifier, the *root* attribute **SHALL** be an OID that consists of a node in a hierarchically-assigned namespace, formally defined using the ITU-T's ASN.1 standard. 3. For an entity identifier, the *root* attribute **SHALL NOT** be a UUID. 4. The *extension* attribute **SHALL** be used. **Usage/Examples** IHIs, HPI-Is, HPI-Os and patient hospital medical record numbers are examples of identifiers that **MAY** be carried by this data type.

Keywords Legend

Where used in this document and in DCMs and SCSs, the keywords **SHALL, SHOULD, MAY, SHALL NOT** and **SHOULD NOT** are to be interpreted as described in [RFC2119].

The following table defines these keywords.

Table 4: Keywords Legend

Keyword	Interpretation
SHALL	This word, or the term ‘required’, means that the statement is an absolute requirement of the specification.
SHOULD	This word, or the adjective ‘recommended’, means that there **MAY** exist valid reasons in particular circumstances to ignore a particular component, but the full implications **SHALL** be understood and carefully weighed before choosing a different course.

MAY	This word, or the adjective 'optional', means that a component is truly optional. One implementer may choose to include the component because a particular implementation requires it, or because the implementer determines that it enhances the implementation, while another implementer may omit the same component. An implementation that does not include a particular option **SHALL** be prepared to interoperate with another implementation that does include the option, perhaps with reduced functionality. In the same vein, an implementation that does include a particular option **SHALL** be prepared to interoperate with another implementation that does not include the option (except of course, for the feature the option provides).
SHALL NOT	This phrase means that the statement is an absolute prohibition of the specification.
SHOULD NOT	This phrase, or the phrase 'not recommended' means that there **MAY** exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications **SHOULD** be understood and the case carefully weighed before implementing any behaviour described with this label.

Obligation Legend

Obligation in DCMs or SCSs specifies whether or not a data component **SHALL** be populated in the logical record architecture of a message. NEHTA intends that all data components will be implemented.

Implementation guides specify the rules and formats for implementing and populating data components in specific messaging formats.

The following table defines the obligations.

Table 5: Obligations Legend

Keyword	Interpretation
ESSENTIAL	Indicates that the data component is considered a mandatory component of information and **SHALL** be populated. **Usage/Examples:** The Participant component for a Subject of Care **SHALL** include an Entity Identifier data component in order to hold the IHI.
OPTIONAL	Indicates that the data component is not considered a mandatory component of information and **MAY** be populated. **Usage/Examples:** This is only needed when a DCM incorrectly asserts that a data component is **ESSENTIAL**. It will be used with a note stating that the DCM needs revision.
PROHIBITED	Indicates that the data component is considered a forbidden component of information and **SHALL NOT** be populated. **Usage/Examples:** Within a Participation data group depicting a Subject of Care, the Participation Healthcare Role **SHALL NOT** be completed.

CONDITIONAL	Indicates that a data component is considered **ESSENTIAL** only on satisfaction of a given condition. Individual data components specify the obligation of the data component when the condition is not met. When a condition is met, the data component is considered to be **ESSENTIAL** and **SHALL** be populated. When a condition is not met, the data component may be considered as **PROHIBITED**, or the data component may be considered **OPTIONAL**. **Usage/Examples:** Within a Pathology Result Report, the *Specimen Detail* `data group` is **ESSENTIAL** if the requested test is to be performed on a specimen, otherwise it **SHALL NOT** be populated.

Where **ESSENTIAL** child data components are contained within **OPTIONAL** parent data components, the child data components only need to be populated when the parent is populated.

B.4 Information Model Specification Parts Legends

This section illustrates the format and parts used to define each section, data group and data element within NEHTA's information model specifications and identifies when each part is applicable.

Data Hierarchy

The top-level component contains a data hierarchy. Each row contains information about a single data component. The entries are nested to represent inclusion of one component in another. Each entry contains at least three occupied cells. The left-most cell contains an icon to indicate the entry's data type. The next cell to the right contains the label and description of the component (if the label is different from the name, the name is displayed in brackets after the label). The next cell to the right contains the multiplicity range for the data component.

The right-hand side of the data hierarchy may contain one or more columns under the heading "Core Requirement". Each column contains information for one document exchange scenario. A cell that is empty indicates that the data component on that row is **OPTIONAL** to implement. That is, software that creates documents made in conformance with this specification **MAY** exclude the data component; and software that reads documents made in conformance with this specification **MAY** ignore the data component. All other components **SHALL** be implemented.

In an SCS, a component may be prohibited, that is, it occurs in the referenced DCM but it **SHALL NOT** be included in documents created according to the SCS. This is represented by a multiplicity range of 0..0. The text of the entry is also in a ~~strike through~~ font and it has a grey background.

Chapter Name

Each section, data group, data element, value domain or choice has its own eponymous chapter. The chapter name is used in all data hierarchies.

Identification Section Legend

The following table illustrates the layout of the Identification section and describes the various parts of the section.

Table 6: Identification Section Legend

Label	A suggested display name for the component. (Source NEHTA.)
Metadata Type	The type of the component, e.g. section, data group or data element. (Source NEHTA.)
Identifier	A NEHTA assigned internal identifier of the concept represented by the component. (Source NEHTA.)
OID	An object identifier that uniquely identifies the concept represented by the data component. (Source NEHTA.)
External Identifier	An identifier of the concept represented by the data component that is assigned by an organisation other than NEHTA. (Source NEHTA.)

Definition Section Legend

The following table illustrates the layout of the Definition section and describes the various parts of the section.

Table 7: Definition Section Legend

Definition	The meaning, description or explanation of the data component. (Source NEHTA.) For data groups used in a particular context, the definition **MAY** be a refinement of the generic data group definition.
Definition Source	The authoritative source for the Definition statement.
Synonymous Names	A list of any names the data component **MAY** also be known as. (Source NEHTA.) Implementers **MAY** prefer to use synonymous names to refer to the component in specific contexts.
Scope	Situations in which the data component may be used, i.e. the extent and capacity within which this data component may be used, including the circumstances under which the collection of specified data is required or recommended. For example, Medication Instruction (data group) has a scope which includes all prescribable therapeutic goods, both medicines and non-medicines. This attribute is not relevant to data elements or value domains. (Source NEHTA.)
Scope Source	The authoritative source for the Scope statement.
Context	The environment in which the data component is meaningful, i.e. the circumstance, purpose and perspective under which this data component is defined or used.

	For example, Street Name has a context of Address. (Source NEHTA.)
Assumptions	Suppositions and notions used in defining the data component. (Source NEHTA.)
Assumptions Source	The authoritative source for the Assumptions statement.
Notes	Informative text that further describes the data component, or assists in the understanding of how the data component can be used. (Source NEHTA.)
Notes Source	The authoritative source for the Notes statement.
Data Type	The data type of the data element, e.g. DateTime or Text. (Source NEHTA.) The data type is applicable only to data elements. The valid data types are specified in the Data Types Legend.
Value Domain	The name and identifier of the terminologies, code sets and classifications to define the data element value range, or a statement describing what values to use in the absence of a defined value domain for the related data element. In the absence of national standard code sets, the code sets used **SHALL** be registered code sets, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and **SHALL** be publicly available. When national standard code sets become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated. (Source NEHTA.) The Value Domain is applicable only to CodedText and CodeableText data elements.

Value Domain Section Legend

The following table illustrates the layout of the Value Domain section and describes the various parts of the section.

Table 8: Value Domain Section Legend

Source	The name of the terminology or vocabulary from which the value domain's permissible values are sourced, e.g. SNOMED CT-AU, LOINC.
Version Number	Version number of the value domain source.
Permissible Values	List of permissible values in the value domain.

Usage Section Legend

The following table illustrates the layout of the Usage section and describes the various parts of the section.

Table 9: Usage Section Legend

Examples	One or more demonstrations of the data that is catered for by the data element. (Source NEHTA.)

	Where a data element has an associated value domain, examples representative of that domain are used where possible. Where the value domain is yet to be determined, an indicative example is provided. Implementation guides **MAY** contain specific examples for how data elements **SHALL** be populated and how they relate to each other. The Value Domain is applicable only to CodedText and CodeableText data elements.
Conditions of Use	Prerequisites, provisos or restrictions for use of the component. (Source NEHTA.)
Conditions of Use Source	The authoritative source for the Conditions of Use statement.
Misuse	Incorrect, inappropriate or wrong uses of the component. (Source NEHTA.)
Default Value	A common denomination, or at least a usable denomination, from the Value Domain where available or applicable, typically assigned at the creation of an instance of the component. (Source NEHTA.)

Relationships Section Legend

The Relationships section specifies the cardinality and conditionality between parent and child data components. Note that if no components in either table have any conditions, then the condition column will be omitted for that table.

The following table illustrates the layout of the Parent relationships table. Note that the occurrences and conditions in the relationships described by this table are from the parent to the child component, i.e. from the component listed in the table to the component described by the section.

Table 11: Parent Legend

Data Type	Name	Occurrences (child within parent)	Condition
The icon illustrating the metadata type or data type.	Parent Component Name	The minimum and maximum number of instances of the component described on this page that **SHALL** occur.	The conditions that **SHALL** be met to include the data element. Only applicable for elements with a conditional obligation.

The following table illustrates the layout of the Children relationships table.

Table 10: Children Legend

Data Type	Name	Occurrences	Condition
The icon illustrating the metadata type or data type.	Child Component Name	The minimum and maximum number of instances of the component described on this page that **SHALL** occur.	The conditions that **SHALL** be met to include this child data element. Only applicable for elements with a conditional obligation.

Appendix C. Change History

C.1 Changes Introduced in this Version

Preliminary Pages

Added the section “Included Detailed Clinical Models” to provide identification of the version of each DCM included in this specification.
Corrected “Australian Institute of Health & Welfare” to “Australian Institute of Health and Welfare”.

Chapter 1 Introduction

This chapter has been revised through editorial review, a number of editorial and typographical errors have been corrected.
Added footnote to 1.1 Purpose and Scope to provide a reference defining the concept “Level 4 (semantic) interoperability”.

Chapter 2 Adverse Reaction Detailed Clinical Model

Added a sentence identifying the version of the DCM.
Corrected presentation of data component names in text throughout the chapter.
Added standard examples text for all data components of type *DateTime*.
Corrected “eg Gentamycin” to “e.g. Gentamicin” in 2.1 Purpose.
Corrected over capitalisation in 2.2 Use and 2.3 Misuse.
Amended 2.2 Use to include a further sentence of explanatory text and replaced “contra-indication” with “contraindication”.
Added a comma (,) to the 3rd list item in 2.3 Misuse.
The Adverse Reaction UML Class Diagram has been moved to this chapter and updated to reflect changes to the included data components; the explanative text has been slightly reworded.
Primarily to support the Consolidated View in the PCEHR the following data components (sourced from the openEHR Reference Model) have been added: a. Adverse Reaction Instance Identifier b. LINK i. Link Nature ii. Link Role iii. Link Target c. Detailed Clinical Model Identifier

The structure of the tables within the relationships sections of each data component has been modified to remove the condition column and change the title of the “Occurrences” column in the Parents table to “Occurrences (child within parent)”.
Corrected the case of the synonymous names and the OID and identifier of ADVERSE REACTION.
Corrected the presentation of permissible values and replaced “patient” with “subject of care” in the definition of Substance/Agent Values .
Replaced “True” with “ ‘true’ ” in the conditions of use of Absolute Contraindication.
Renamed *Clinical Manifestation Values Reference Set* to Clinical Manifestation Values, and included explanative text for permissible values.
Corrected “Idiosyncracy” to “Idiosyncrasy” in the examples of Reaction Type.
Inserted “the” in the definition, replaced “may be” with “is ” and “reaction which warrants” with “reaction that warrants” in the notes of Adverse Reaction Certainty.
Corrected presentation of the usage section for Adverse Reaction Certainty Values.
Renamed *ADDITIONAL REACTION DETAIL* (Label: Additional Reaction Detail) to ANATOMICAL LOCATION (Label: Additional Reaction Detail).
Corrected the use of “and/or” in: a. Manifestation b. Adverse Reaction Certainty c. Reaction Onset Date d. Earliest Exposure e. Quantity
Corrected the article to “the” in the definition of: a. Anatomical Location Name b. Identified Landmark c. Anatomical Location Description d. Side e. Laterality Reference Set

Corrected presentation of examples for: a. Manifestation b. Reaction Type c. Adverse Reaction Certainty d. Reaction Description e. Dose Unit f. Route g. Medication Delivery Method h. Side i. Numerical Identifier j. Anatomical Plane k. Visual Markings/Orientation
Corrected “Bilalteral” to “Bilateral” in the examples of Side.
Replaced “Identify the specific anatomical site out of multiple sites” with “An ordinal number that identifies the specific anatomical site from multiple sites” in the definition of Numerical Identifier.
Inserted an “a” and replaced “Qualifiers” with “Qualifier(s)”in the Definition of RELATIVE LOCATION.
Corrected “medial” to “lateral” in the examples of Anatomical Location Aspect.
Replaced “Image” with “An image” in the definition of Anatomical Location Image.
Made each of the children of the ADDITIONAL EXPOSURE DETAIL choice optional to align with the correct representation of choices.
Amended the scope of AMOUNT OF MEDICATION.
Changed the data types of Quantity from (*Real*, *QuantityRatio*) to (*Real*, *Quantity*).
Corrected “Mg” to “mg” in the examples of Dose Unit.
Removed the notes from of Dose Unit Reference Set.
Inserted a “the” in the notes of TIMING.
Added a condition of use to Intervention Time.
Amended the note of Intervention Day of Month.
Changed the label of MEDICATION ADMINISTRATION from “Exposure Mechanism” to “MEDICATION ADMINISTRATION”.
Corrected “neubliser” to “nebuliser” in the examples of Medication Delivery Method.
Corrected the case for synonymous names and improved the wording of the note in Route.
Corrected the representation of the Intravenous Administration Details data component to be a *Text* data element and corrected its OID and identifier.
Corrected the OID and identifier of Reporting Details.
Amended wording of the example in Dose Duration.
Corrected “Link to further information about about the presentation …” to “Link to further information about the presentation…” in the definition of Supporting Clinical Record Information and amended the note.

All instances of “have a fixed value of” have been replaced with “have an implementation-specific value equivalent to”.
Amended the note of INFORMATION PROVIDER.

Chapter 3 Exclusion Statement – Adverse Reactions Detailed Clinical Model

Added a sentence identifying the version of the DCM.
Added 3.1 Purpose and 3.2 Use.
Corrected the definition and removed usage in toto from EXCLUSION STATEMENT - ADVERSE REACTIONS.
The Exclusion Statement - Adverse Reactions UML Class Diagram has been moved to this chapter and updated to reflect the changes in the data components; the explanative text has been slightly reworded.
Primarily to support the Consolidated View in the PCEHR the following data components (sourced from the openEHR Reference Model) have been added: a. Exclusion Statement - Adverse Reactions Instance Identifier b. LINK i. Link Nature ii. Link Role iii. Link Target c. Detailed Clinical Model Identifier
The structure of the tables within the relationships sections of each data component has been modified to remove the condition column and change the title of the “Occurrences” column in the Parents table to “Occurrences (child within parent)”.
Corrected the list of permissible values for Global Statement.
Amended the note of INFORMATION PROVIDER.
All instances of “have a fixed value of” have been replaced with “have an implementation-specific value equivalent to”.

Chapter 4 UML Class Diagram

Chapter 4 removed and the content moved to Chapter 2 and Chapter 3 as appropriate.

Appendix A Known Issues

Removed entry for 'Intervention Day of Week' data element in line with the decision to define a value domain for this data element.
Corrected the entry for ‘Undefined Value Domains’ to include all applicable data components.
Added entry for clinical manifestation values.

Amended entry for 'Quantity' data element to take into account changes to the data element.
Added undefined data structures entry to indicate the data elements that lack a defined data structure.

Appendix B Guide for Use

This appendix has revised through editorial review, a number of editorial and typographical errors have been corrected.
In 'Value Domain' in B.2 “To Be Advised” replaced with “Individual Pathology Test Result Name”.
Added ‘Obligation Legend’ in B.3.
Reworked ‘Data Hierarchy’ in B.4 to explain 'Core Requirement'.
Reworked ‘Relationships Section Legend’ in B.4 to include further explanative text, and improved tables.

Appendix C Change History

This is a new appendix included to provide detailed information of the changes between the previous version of this specification and the current version of this specification.

Reference List

This chapter has been moved to after the appendices.
Added entry for reference cited in footnote added to section 1.1.
Added entry for Harmonisation in Pharmacovigilance.
Added entry for The use of the WHO-UMC system for standardised case causality assessment.
Added entry for ISO 13606-3:2009.
Added entry for NEHTA Interoperability Framework.
Removed entry for Data Specifications and Structured Document Templates - Guide for Use, Version 1.2 which is replaced by Appendix B, *Specification Guide for Use*.
Corrected the titles of AS 4846 and AS 5017.

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