Australian Government
Australian Digital Health Agency

Adverse Reaction
Detailed Clinical Model Specification
Version 3.3

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Document Information

Key Information

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Product Version History

Product version	Date	Release 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.
3.2	18 Dec 2015	This specification is published to support the Structured Content Specifications published in the first half of 2015 that use the versions of DCMs included in this specification. Changes to the DCMs included in this specification are primarily to support the Shared Health Summary and Event Summary in the PCEHR.
3.3	5 Aug 2016	This version of the specification is published to support the Service Referral structured content specification. It includes rebranding for the Australian Digital Health Agency.

Related Documents

Name	Version/Release Date
Participation Data Specification	Version 3.2, Issued 20 July 2011

Included Detailed Clinical Models

This specification contains the following detailed clinical models:

- Adverse Reaction, version 5.3
- Exclusion Statement - Adverse Reactions, version 1.4

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

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Table of Contents

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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 Australian Digital Health Agency (the Agency) 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 the Agency and to realise the benefits derived from Level 4 (semantic) interoperability[1] in the Australian healthcare setting.

We value your questions and comments about this document. Please direct your questions or feedback to *help@digitalhealth.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.

This is a technical document; the audience should be familiar with the language of health data specification and also have some familiarity with health information standards and specifications. Definitions and examples are provided to clarify relevant terminology, usage, and intent.

1.3 Background

One area of priority for us is the identification of digital health data to be communicated and its structure. We are 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 priorities identified by jurisdictions and clinicians, incorporating clinical examples of use to enhance utility and adoption. These specifications are intended to:

- suit the Australian model for a shared electronic health record;
- define collections of related information, e.g. event summaries, data groups, data elements;
- be human readable (with information enhanced by the hierarchical structure);
- provide a set of clinical terminologies specific to the requirements of the Australian healthcare system; and
- allow for expansion and extension as electronic systems mature.

While the My Health Record system is referred to in these documents, implementation within the system is not dealt with here.

1.4 Terminology

Our National Clinical Terminology Service (NCTS) 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.

[1] Level 4 interoperability is described in *The Value Of Health Care Information Exchange And Interoperability [WALJ2005a]*.

We recommend the SNOMED CT as the preferred clinical terminology for Australia and this has been endorsed by the Australian, state and territory governments. SNOMED CT is considered to be the most comprehensive multilingual health terminology in the world. It is owned, maintained and distributed by the International Health Terminology Standards Development Organisation (IHTSDO).

Our NCTS is the Australian National Release Centre for SNOMED CT and is also responsible for managing, developing and distributing national clinical terminologies, such as SNOMED CT Australian Release (SNOMED CT-AU), the Australian Medicines Terminology (AMT), and related tools and services.

SNOMED CT-AU provides local variations and customisation of terms relevant to the Australian healthcare community. It includes the international resources, along with all Australian-developed terminology for implementation in Australian clinical information technology systems. The AMT provides a consistent approach to the identification and naming of medicines, and supports medicines management and activity across the Australian healthcare domain. The AMT is now included within SNOMED CT-AU, with even closer integration planned for the 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 with and complement the SNOMED CT concept model.

SNOMED CT-AU has been available for software developers to use in their Australian products since 1 July 2006. It is updated monthly and is freely available under a dual licensing arrangement – namely the SNOMED CT Affiliate License and Australian National Terminology License.

For further information regarding terminology and the development of reference sets, please visit http://-www.healthterminologies.gov.au. Email *help@digitalhealth.gov.au* with questions or feedback.

2 Adverse Reaction Detailed Clinical Model

This chapter describes version 5.3 of the *Adverse Reaction* Detailed Clinical Model.

2.1 Purpose

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

To record information about events of exposure 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 pseudo-allergic reactions, side-effects, intolerances, drug toxicities [e.g. Gentamicin induced ototoxicity], drug-drug interactions, food-drug interactions, drug-disease contraindications 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:

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

It 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; 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 use in clinical trials, more information about the adverse reaction may be required.

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 or 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 or 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 predisposition (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 predisposition for future reactions are:

- statements about previous clinical manifestations following exposure;
- source of the information or 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 available.

2.3 Misuse

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.

Not to be used for recording that no information could 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 could be obtained; for example, if a non-cooperative patient refuses to answer questions.

Not to be used to record adverse events, including failures of clinical process, interventions or products. For example: abnormal use or mistakes or errors made in administration of an agent or substance; mislabelling; harm or injury caused by an intervention or procedure; overdose, etc.

Not to be used for recording alerts.

2.4 UML Class Diagrams

The following figure represents the data hierarchy using 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 label names are represented as association role names. Association role names are only displayed if they differ from the associated class name. When a data element has a choice of data types, the data type of the attribute that represents it is an abstract interface class generalised from the individual data types. The diagram shows the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

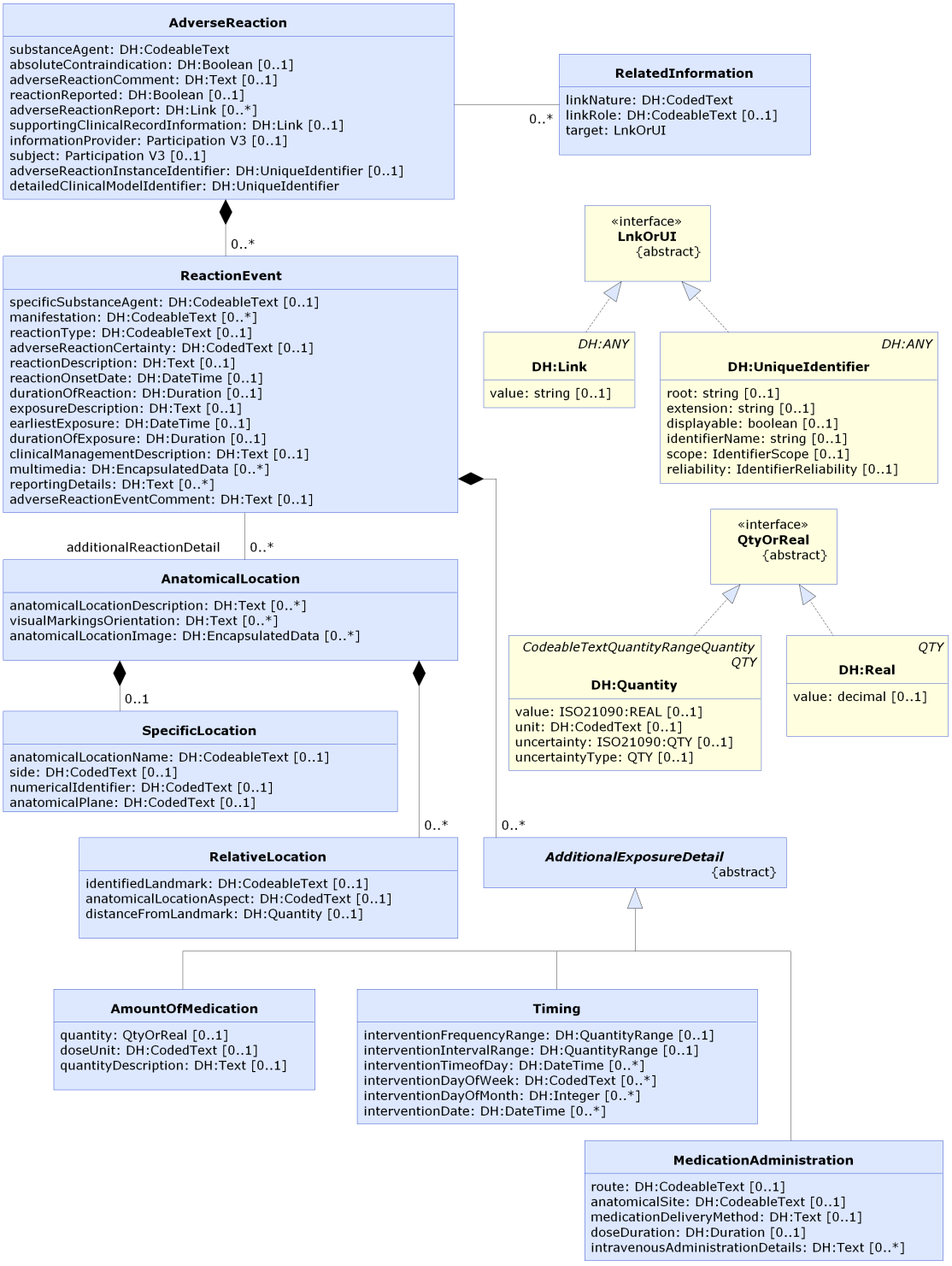

Figure 2.1. Adverse Reaction

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.
Definition Source	Australian Digital Health Agency
Synonymous Names	Reaction Allergy Intolerance Sensitivity Hypersensitivity
Scope	Substances and agents include medication at therapeutic or sub-therapeutic doses, food, plants, animals, venom from insect stings and glycoprotein from animals such as cats. Substances and agents exclude medication at above therapeutic doses.
Scope Source	Australian Digital Health Agency

Data Hierarchy

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

ADVERSE REACTION				
	Substance/Agent			1..1
	Absolute Contraindication			0..1
	Adverse Reaction Comment			0..1
	REACTION EVENT			0..*
		Specific Substance/Agent		0..1
		Manifestation		0..*
		Reaction Type		0..1

			Adverse Reaction Certainty			0..1
			Reaction Description			0..1
			Reaction Onset Date			0..1
			Duration of Reaction			0..1
			Additional Reaction Detail (ANATOMICAL LOCATION)			0..*
				SPECIFIC LOCATION		0..1
					Anatomical Location Name	0..1
					Side	0..1
					Numerical Identifier	0..1
					Anatomical Plane	0..1
				RELATIVE LOCATION		0..*
					Identified Landmark	0..1
					Anatomical Location Aspect	0..1
					Distance From Landmark	0..1
				Anatomical Location Description		0..*
				Visual Markings/Orientation		0..*
				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
					Intervention Frequency Range	0..1
					Intervention Interval Range	0..1
					Intervention Time of Day	0..*
					Intervention Day of Week	0..*
					Intervention Day of Month	0..*
					Intervention Date	0..*
				MEDICATION ADMINISTRATION		0..1
					Route	0..1
					Anatomical Site	0..1
					Medication Delivery Method	0..1
					Dose Duration	0..1
					Intravenous Administration Details	0..*
			Clinical Management Description			0..1
			Multimedia			0..*
			Reporting Details			0..*
			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
		RELATED INFORMATION				0..*
			Link Nature			1..1

			Link Role	0..1
			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	Australian Digital Health Agency
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
Exceptional Values	Absent values are **PROHIBITED**.

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 an agent or substance causing an adverse reaction.
Definition Source	Australian Digital Health Agency

Value Domain

Source	Australian Digital Health Agency
Permissible Values	The permissible values are the members of the following reference sets. From SNOMED CT-AU: • 142321000036106 |*Adverse reaction agent reference set*| • 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 predisposition for a serious reaction upon further exposure to the substance or agent.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Record as *true* if the clinician assesses that exposure to, or administration of, the agent should be avoided in future.
Data Type	Boolean

Usage

Conditions of Use	The value of this item **SHALL** be an implementation-specific value semantically equivalent to the default value.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Boolean.
Default Value	true
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.9 Adverse Reaction Comment

Identification

Label	Adverse Reaction 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 the reason for flagging an absolute contraindication, instructions related to future exposure, or administration of the substance or agent.
Definition Source	Australian Digital Health Agency
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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

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	Australian Digital Health Agency
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
	Adverse Reaction Certainty	0..1
	Reaction Description	0..1
	Reaction Onset Date	0..1
	Duration of Reaction	0..1
	Additional Reaction Detail (ANATOMICAL LOCATION)	0..*
	Exposure Description	0..1

Data Type	Name	Occurrences
	Earliest Exposure	0..1
	Duration of Exposure	0..1
	ADDITIONAL EXPOSURE DETAIL	0..*
	Clinical Management Description	0..1
	Multimedia	0..*
	Reporting Details	0..*
	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	Australian Digital Health Agency
Synonymous Names	
Notes	This may include a medication trade name.
Data Type	CodeableText
Value Domain	Substance/Agent Values

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.
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	Presentation or exhibition of signs and symptoms of the adverse reaction expressed as a single word, phrase or brief description.
Definition Source	Australian Digital Health Agency
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

Definition

Definition	The set of values for recording clinical manifestation of an adverse reaction.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU
Permissible Values	The permissible values are the members of the following SNOMED CT reference sets: • 142341000036103 |*Clinical manifestation reference set*| • 32570071000036102 |*Clinical finding foundation reference set*|

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	Australian Digital Health Agency
Synonymous Names	
Context	This field is used to identify the type of adverse reaction as determined by: • the signs and symptoms experienced by the subject; • information provided by a relevant individual; • previously documented history; and • clinical assessment by a healthcare provider.
Context Source	Australian Digital Health Agency
Data Type	CodeableText
Value Domain	Adverse Reaction Type Values

Usage

Examples	1) Allergic reaction 2) Drug interaction 3) Food intolerance 4) Hypersensitivity reaction 5) Medication side-effect

Relationships

Parents

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

2.15 Adverse Reaction Type Values

Identification

Label	Adverse Reaction Type Values
Metadata Type	Value Domain
Identifier	VD-15554
OID	1.2.36.1.2001.1001.101.104.15554
External Identifier	SNOMED CT-AU Concept Id: 11000036103 |*Adverse reaction type reference set*|

Definition

Definition	The set of values for the type of adverse reaction.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

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

2.16 Adverse Reaction Certainty

Identification

Label	Adverse Reaction 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	Australian Digital Health Agency
Synonymous Names	
Notes	It is important to know the degree of certainty that an adverse reaction is attributable to an agent or substance, as there may be instances where it is not clear whether it is the active agent or a secondary component that caused 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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodedText.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.17 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	Australian Digital Health Agency

Value Domain

Source	WHO-UMC	
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.

These values were developed from:

1) *Harmonisation in Pharmacovigilance [EDWA1994a]* and;

2) *The use of the WHO-UMC system for standardised case causality assessment [UMC2011a]*.

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)
	Adverse Reaction Certainty	1..1

2.18 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	Australian Digital Health Agency
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

2.19 Reaction Onset Date

Identification

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

Definition

Definition	Date, and optionally time, of the onset of the reaction event.
Definition Source	Australian Digital Health Agency
Synonymous Names	DateTime Started
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

2.20 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	Duration of the reaction.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Duration

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Duration.

Relationships

Parents

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

2.21 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	Australian Digital Health Agency
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..*
	Anatomical Location Description	0..*
	Visual Markings/Orientation	0..*
	Anatomical Location Image	0..*

2.22 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	Australian Digital Health Agency
Synonymous Names	

Relationships

Parents

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

Children

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

2.23 Anatomical Location Name

Identification

Label	Anatomical Location Name
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	Australian Digital Health Agency
Synonymous Names	
Data Type	CodeableText
Value Domain	Body Structure Foundation Reference Set

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

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

2.24 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	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

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

2.25 Side

Identification

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

Definition

Definition	Laterality of the anatomical location.
Definition Source	Australian Digital Health Agency
Synonymous Names	Laterality
Data Type	CodedText
Value Domain	Laterality Reference Set

Usage

Examples	1) Right 2) Left 3) Bilateral
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.26 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	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

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

2.27 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	Ordinal value used with anatomical site or part name to identify a specific anatomical site in a collection of enumerable sites, such as vertebrae or ribs.
Definition Source	Australian Digital Health Agency
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[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

Conditions of Use	This **SHALL** be an ordinal number between first and eighteenth.
Conditions of Use Source	Australian Digital Health Agency
Examples	1) First, as in 'first rib'. 2) Second, as in 'second toe'. 3) Third, as in 'third lumbar vertebra'.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

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

Relationships

Parents

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

2.28 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	Australian Digital Health Agency
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

Examples	1) Midline 2) Midclavicular 3) Midaxillary 4) Midscapular
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

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

2.29 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	Australian Digital Health Agency
Synonymous Names	
Notes	An example is: 5cm (distance) inferior (aspect) to the tibial tuberosity (landmark). More than one relative location may be 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
	Anatomical Location Aspect	0..1
	Distance From Landmark	0..1

2.30 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	Australian Digital Health Agency
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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

Relationships

Parents

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

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

2.31 Anatomical Location Aspect

Identification

Label	Anatomical Location 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	Australian Digital Health Agency
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[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	1) Medial to 2) Lateral to 3) Anterior to 4) Above
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

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

2.32 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	Australian Digital Health Agency
Synonymous Names	
Data Type	Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Quantity.

Relationships

Parents

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

2.33 Anatomical Location Description

Identification

Label	Anatomical Location 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	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.34 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 orient the viewer.
Definition Source	Australian Digital Health Agency
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..*

2.35 Anatomical Location Image

Identification

Label	Anatomical Location 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	Australian Digital Health Agency
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	Australian Digital Health Agency
Data Type	EncapsulatedData

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for EncapsulatedData.

Relationships

Parents

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

2.36 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	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.37 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	Australian Digital Health Agency
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

2.38 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	Duration of exposure.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Used to describe the length of exposure to a substance/agent triggering a specific reaction event.
Data Type	Duration

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Duration.

Relationships

Parents

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

2.39 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	Australian Digital Health Agency
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

2.40 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	Details about the amount of the medicine, vaccine or other therapeutic good.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Used to record additional details of exposure to a substance/agent that triggered the adverse reaction event.
Scope Source	Australian Digital Health Agency

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

2.41 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	Australian Digital Health Agency
Synonymous Names	
Notes	The number of doses or physical amount of the therapeutic good.
Data Type	Real Quantity

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Real, and Quantity.

Relationships

Parents

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

2.42 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	Australian Digital Health Agency
Synonymous Names	
Data Type	CodedText
Value Domain	Dose Unit Reference Set

Usage

Examples	1) Tablet 2) Capsule 3) Sachet 4) mg 5) mL
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.43 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	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

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

2.44 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	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.45 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	Australian Digital Health Agency
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
	Intervention Frequency Range	0..1
	Intervention Interval Range	0..1
	Intervention Time of Day	0..*
	Intervention Day of Week	0..*
	Intervention Day of Month	0..*
	Intervention Date	0..*

2.46 Intervention Frequency Range

Identification

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

Definition

Definition	Frequency, expressed as the number of times per time period, that the intervention takes place.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Includes details of variable upper and lower frequency e.g. 3-4 times a day.
Data Type	QuantityRange

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for QuantityRange.

Relationships

Parents

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

2.47 Intervention Interval Range

Identification

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

Definition

Definition	Length of time between doses or interventions.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Includes details of variable upper and lower intervals e.g. 2-3 hours.
Data Type	QuantityRange

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for QuantityRange.

Relationships

Parents

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

2.48 Intervention Time of Day

Identification

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

Definition

Definition	Specific time during the day when the intervention is applied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Conditions of Use	This **SHALL NOT** contain a date component.
Conditions of Use Source	Australian Digital Health Agency
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..*

2.49 Intervention Day of Week

Identification

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

Definition

Definition	Day of the week when the intervention is applied.
Definition Source	Australian Digital Health Agency
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) Monday 2) Wednesday 3) Friday 4) Sunday
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

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

2.50 Intervention Day of Month

Identification

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

Definition

Definition	Day of the month when the intervention is applied.
Definition Source	Australian Digital Health Agency
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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Integer.

Relationships

Parents

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

2.51 Intervention Date

Identification

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

Definition

Definition	Date intervention is applied.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	DateTime

Usage

Conditions of Use	This **SHALL NOT** contain a time component.
Conditions of Use Source	Australian Digital Health Agency
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..*

2.52 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	Australian Digital Health Agency
Synonymous Names	
Scope	Used to describe the exposure mechanism to the substance or agent. This includes the route, anatomical site, and delivery methods of medications.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This data group is repeated for every instance of medication administration being recorded.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Route	0..1
	Anatomical Site	0..1
	Medication Delivery Method	0..1
	Dose Duration	0..1

Data Type	Name	Occurrences
	Intravenous Administration Details	0..*

2.53 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	Australian Digital Health Agency
Synonymous Names	Route of Administration
Notes	It is used to describe the path or channel by which the substance or agent is introduced or gains access into a patient's body. This includes the route by which medication is administered. Use “Unknown” only for retrospective data collection.
Data Type	CodeableText
Value Domain	Route of Administration Reference Set

Usage

Examples	1) Oral route 2) Subcutaneous route 3) Epidural route 4) Rectal route 5) Otic route

Relationships

Parents

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

2.54 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	Australian Digital Health Agency
Notes	Set of allowable values to describe the way through which a medication is administered.

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
001011001	Route	1..1

2.55 Anatomical Site

Identification

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

Definition

Definition	Description of the site of administration.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Location on or in the body where the substance or agent entered, or the therapeutic good was administered.
Data Type	CodeableText
Value Domain	Anatomical Location Name Values

Usage

Examples	1) Entire left thigh 2) Upper arm part 3) Entire left renal artery

Relationships

Parents

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

2.56 Anatomical Location Name Values

Identification

Label	Anatomical Location Name Values
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 |*Body structure foundation reference set*|

Definition

Definition	The set of values for named anatomical locations.
Definition Source	Australian Digital Health Agency

Value Domain

Source	SNOMED CT-AU

Relationships

Parents

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

2.57 Medication Delivery Method

Identification

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

Definition

Definition	Method by which medication is delivered to the subject.
Definition Source	Australian Digital Health Agency
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

2.58 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	Australian Digital Health Agency
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

2.59 Intravenous Administration Details

Identification

Label	Intravenous Administration 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	Australian Digital Health Agency
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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.60 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 of clinical management provided.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Used to describe clinical management provided to manage or treat the adverse reaction event.
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.61 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	Australian Digital Health Agency
Synonymous Names	
Notes	An example is a photo of a rash or presentation with angioneurotic oedema.
Data Type	EncapsulatedData

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for EncapsulatedData.

Relationships

Parents

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

2.62 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	Australian Digital Health Agency
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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.63 Adverse Reaction Event Comment

Identification

Label	Adverse Reaction Event 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	Australian Digital Health Agency
Synonymous Names	
Data Type	Text

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Text.

Relationships

Parents

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

2.64 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	Whether the adverse reaction was reported to a regulatory body.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	The value *true* means that the adverse reaction was reported to a regulatory body. One relevant regulatory body is the Australian Adverse Drug Reaction Reporting System (https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf).
Data Type	Boolean

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Boolean.

Relationships

Parents

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

2.65 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	Australian Digital Health Agency
Synonymous Names	
Data Type	Link

Usage

Examples	1) The TGA report *Report of suspected adverse reaction to medicines or vaccines form* (available from http://www.tga.gov.au/safety/problem-medicines-forms-bluecard.htm).

Relationships

Parents

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

2.66 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	Australian Digital Health Agency
Synonymous Names	
Notes	Examples of further information are presenting symptoms, examination findings, and diagnoses.
Data Type	Link

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Link.

Relationships

Parents

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

2.67 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	Source of the information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • an agent of a subject of care, e.g. parent, guardian; • a clinician; • a device or software; and • the subject of the DCM, when not the subject of care of the enclosing structured document.

Usage

Conditions of Use	This **SHALL NOT** be used if the source of the information is 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]*. Further constraints on this data group that apply to this reuse of it are listed below. • 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. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

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

2.68 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	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This **SHALL NOT** be used if the subject of the information is 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]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

Relationships

Parents

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

2.69 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	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

2.70 RELATED INFORMATION

Identification

Label	RELATED INFORMATION
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	Information held elsewhere that is relevant to this instance of *Adverse Reaction*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Items of related information include, but are not limited to, documents, parts of documents, images and web pages. “Elsewhere” includes elsewhere in the same document. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. Links are only to be used between instances of DCMs or documents, i.e. between objects representing complete domain concepts. This is because relationships between sub-elements of whole concepts are not necessarily meaningful and may be confusing. When the item of related information is a complete document (including images) or a web page (or part thereof) an appropriate specialisation of the *Related Information* `data group` should be used. The document or other data component instance containing the *Related Information* `data group` is called the *source*. The related information is called the *target*.

Relationships

Parents

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

Children

Data Type	Name	Occurrences
	Link Nature	1..1

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

2.71 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 detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that 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
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

2.72 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
External Identifier	LINK_NATURE

Definition

Definition	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	Australian Digital Health Agency

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]*. The values are listed here with brief descriptions.

LINK-A0, is related to	The most general category of Link.
LINK-B0, is confirmed by or authorised by	The link target contains an instance of a DCM or document that is either a legal or authoritative basis for what is documented in the source DCM instance, or is a declaration of intent to provide (or not provide) requested care.
LINK-C0, is related to the same problem or health issue	The target instance of a DCM or document describes health or healthcare that concerns the same clinical situation as the source DCM instance.
LINK-D0, is related to the same care plan, act or episode	The source and the target instances of DCMs or documents both describe parts of the same care plan, act or episode.
LINK-E0, is a related documentation	The target instance of a DCM or document is an alternative documentary form of the source DCM instance. For example, a re-expression of the same clinical information or supplementary explanatory information.

Relationships

Parents

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

2.73 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 detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that 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)
	RELATED INFORMATION	0..1

2.74 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
External Identifier	LINK_ROLE

Definition

Definition	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	Australian Digital Health Agency
Context	These values are used within the context of the value of the *Link Nature* `data element`. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	Australian Digital Health Agency

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]*, together with brief descriptions, are: LINK-A1, unspecified link — This can be used to say explicitly “there is no semantic information available for this Link”. LINK-B1, endorses — The source endorses (agrees with, confirms or verifies) the situation (or interpretation) described in the target. LINK-C3, evidence for — The source describes evidence for the situation (or interpretation) described in the target. LINK-D1, outcome — The source describes an outcome of the situation (or interpretation) that the target describes. LINK-E1, documented by — The source is a less formal description of the situation (or interpretation) documented by the target. LINK-E4, excerpts — The source is an extract (copy) of part or all of the information contained within the target. LINK-E5, derived from — The source contains information that has been derived (e.g. calculated) from information in the target.

Usage

Conditions of Use	Each of the values in LINK_ROLE from ISO 13606-3:2009 identifies a subcategory of a corresponding value in *Link Nature Values*. That correspondence is indicated by the first letter after the code string “LINK-”. For example, 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 for *Link Nature Values*.
Conditions of Use Source	ISO 13606-3:2009

Relationships

Parents

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

2.75 Target

Identification

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

Definition

Definition	The “linked to” or identified information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Link, and UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	1..1

2.76 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	A globally unique identifier for this detailed clinical model.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be either the default value or a semantically equivalent value from an appropriate code system.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.15517
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

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 1.4 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 Detailed Clinical Model (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 about adverse reactions to a substance.

3.3 UML Class Diagrams

The following figure represents the data hierarchy using 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 label names are represented as association role names. Association role names are only displayed if they differ from the associated class name. When a data element has a choice of data types, the data type of the attribute that represents it is an abstract interface class generalised from the individual data types. The diagram shows the data hierarchy excluding the details of participation. The default multiplicity is 1..1.

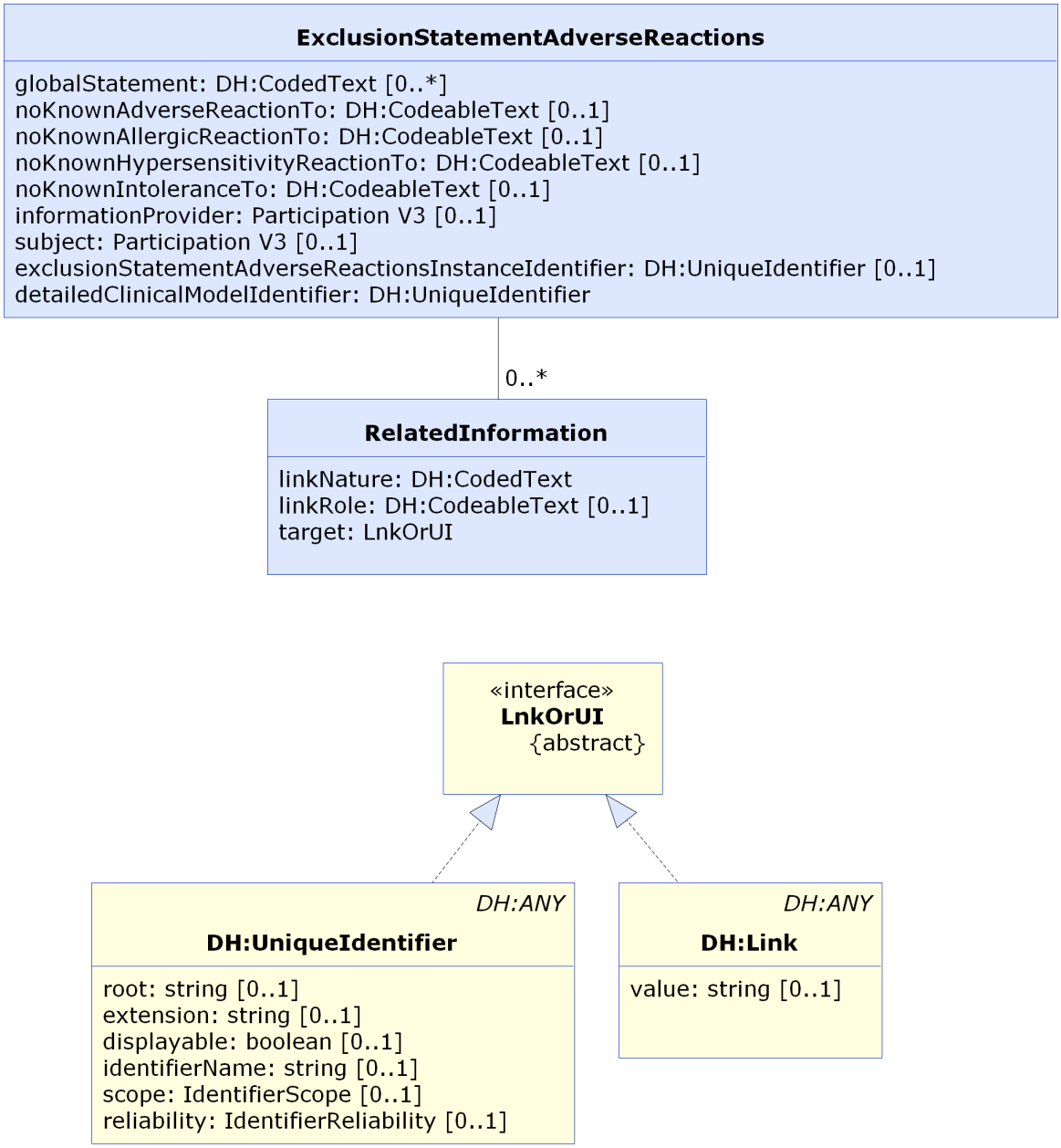

Figure 3.1. Exclusion Statement for Adverse Reaction

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

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

	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

		RELATED INFORMATION		0..*
			Link Nature	1..1
			Link Role	0..1
			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.
Context Source	Australian Digital Health Agency
Data Type	CodedText
Value Domain	Global Statement Values

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodedText.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

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	Australian Digital Health Agency	
Permissible Values	01, None known	No information about adverse reactions to any substance is known.
	02, Not asked	No information about adverse reactions to any substance is available because the patient was not asked or was not able to be asked.
	03, 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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

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	Please see Appendix B, *Specification Guide for Use* for examples and usage information for CodeableText.

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	Source of the information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency
Notes	This does not have to be a person and, in particular, does not have to be a healthcare provider. Types of sources include: • an agent of a subject of care, e.g. parent, guardian; • a clinician; • a device or software; and • the subject of the DCM, when not the subject of care of the enclosing structured document.

Usage

Conditions of Use	This **SHALL NOT** be used if the source of the information is 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]*. Further constraints on this data group that apply to this reuse of it are listed below. • 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. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

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	Australian Digital Health Agency
Synonymous Names	
Scope	Only used when the recorder needs to make it explicit. Otherwise, it is assumed to be the subject of care of the enclosing structured document.
Scope Source	Australian Digital Health Agency

Usage

Conditions of Use	This **SHALL NOT** be used if the subject of the information is 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]*. Further constraints on this data group that apply to this reuse of it are listed below. • Participation Type **SHALL** have an implementation-specific value equivalent to “Subject”. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON. Terms used in obligation and occurrence constraints are explained in Appendix B, *Specification Guide for Use*.
Conditions of Use Source	Australian Digital Health Agency

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	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

3.14 RELATED INFORMATION

Identification

Label	RELATED INFORMATION
Metadata Type	Data Group
Identifier	DG-16692
OID	1.2.36.1.2001.1001.101.102.16692

Definition

Definition	Information held elsewhere that is relevant to this instance of *Exclusion Statement - Adverse Reactions*.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	Items of related information include, but are not limited to, documents, parts of documents, images and web pages. “Elsewhere” includes elsewhere in the same document. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. 1:1 and 1:N relationships between instances of DCMs can be expressed by using one, or more than one, respectively, links. Chains of links can be used to see problem threads or other logical groupings of items. Links are only to be used between instances of DCMs or documents, i.e. between objects representing complete domain concepts. This is because relationships between sub-elements of whole concepts are not necessarily meaningful and may be confusing. When the item of related information is a complete document (including images) or a web page (or part thereof) an appropriate specialisation of the *Related Information* `data group` should be used. The document or other data component instance containing the *Related Information* `data group` is called the *source*. The related information is called the *target*.

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
	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 detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that 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
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	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
External Identifier	LINK_NATURE

Definition

Definition	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	Australian Digital Health Agency

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]*. The values are listed here with brief descriptions.	
	LINK-A0, is related to	The most general category of Link.
	LINK-B0, is confirmed by or authorised by	The link target contains an instance of a DCM or document that is either a legal or authoritative basis for what is documented in the source DCM instance, or is a declaration of intent to provide (or not provide) requested care.
	LINK-C0, is related to the same problem or health issue	The target instance of a DCM or document describes health or healthcare that concerns the same clinical situation as the source DCM instance.
	LINK-D0, is related to the same care plan, act or episode	The source and the target instances of DCMs or documents both describe parts of the same care plan, act or episode.
	LINK-E0, is a related documentation	The target instance of a DCM or document is an alternative documentary form of the source DCM instance. For example, a re-expression of the same clinical information or 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 detailed clinical model (DCM), i.e. the source, and the target DCM instance or target document.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Notes	This is one of two attributes that 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)
	RELATED INFORMATION	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
External Identifier	LINK_ROLE

Definition

Definition	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	Australian Digital Health Agency
Context	These values are used within the context of the value of the *Link Nature* `data element`. They provide greater specificity and may be selected more for human readership than for interoperable automated processing.
Context Source	Australian Digital Health Agency

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]*, together with brief descriptions, are:

LINK-A1, unspecified link	This can be used to say explicitly “there is no semantic information available for this Link”.
LINK-B1, endorses	The source endorses (agrees with, confirms or verifies) the situation (or interpretation) described in the target.
LINK-C3, evidence for	The source describes evidence for the situation (or interpretation) described in the target.
LINK-D1, outcome	The source describes an outcome of the situation (or interpretation) that the target describes.
LINK-E1, documented by	The source is a less formal description of the situation (or interpretation) documented by the target.
LINK-E4, excerpts	The source is an extract (copy) of part or all of the information contained within the target.
LINK-E5, derived from	The source contains information that has been derived (e.g. calculated) from information in the target.

Usage

Conditions of Use	Each of the values in LINK_ROLE from ISO 13606-3:2009 identifies a subcategory of a corresponding value in *Link Nature Values*. That correspondence is indicated by the first letter after the code string “LINK-”. For example, 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 for *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 Target

Identification

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

Definition

Definition	The “linked to” or identified information.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	Link UniqueIdentifier

Usage

Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for Link, and UniqueIdentifier.

Relationships

Parents

Data Type	Name	Occurrences (child within parent)
	RELATED INFORMATION	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	A globally unique identifier for this detailed clinical model.
Definition Source	Australian Digital Health Agency
Synonymous Names	
Data Type	UniqueIdentifier

Usage

Conditions of Use	The value of this item **SHALL** be either the default value or a semantically equivalent value from an appropriate code system.
Conditions of Use Source	Australian Digital Health Agency
Examples	Please see Appendix B, *Specification Guide for Use* for examples and usage information for UniqueIdentifier.
Default Value	1.2.36.1.2001.1001.101.102.16137
Exceptional Values	Absent values are **PROHIBITED**. Abnormal values are **PROHIBITED**.

Relationships

Parents

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

Appendix A. Known Issues

This appendix lists known issues with this specification at the time of publishing. We are working on solutions to these issues and encourage comments to help us develop these solutions.

Reference	Description
Links to external resources	Certain combinations of web browsers and PDF readers have problems opening URL links (usually found in reference sections) that span more than one line.
Data Hierarchies	Only the parts of these detailed clinical models (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.
Undefined Value Domains	The following data elements lack a defined value domain: *Identified Landmark*, *No Known Adverse Reaction to*, *No Known Allergic Reaction to*, *No Known Hypersensitivity Reaction to*, and *No Known Intolerance to*. We are in the process of developing national code sets for these items. In the meantime, you are free to use your own code sets, 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 sets do become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.
Provisional Value Domains	The following defined value domains are provisional: *Numerical Identifier*, *Anatomical Plane*, *Anatomical Location Aspect*, *Intervention Day of Week*. We are in the process of developing national code sets for these items. In the meantime, you are free to use your own code sets, 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 sets do become available, they **SHALL** be used and the non-standard code sets **SHALL** be deprecated.
Undefined Data Structures	The following data components lack a defined data structure: *Intravenous Administration Details* and *Reporting Details*. A free text data element is currently used as an interim solution.
Information Provider	We are considering making *Information Provider* one of a pair of data components: *Information Provider* for the source of the information, typically the subject of care of the enclosing structured document and *Reporter* for the author of the information, typically the author of the enclosing structured document. *Reporter* has not been added to this DCM. More investigation is needed to make a decision.
Quantity	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 Value Domain	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.
Timing	Definitions of the data elements within this data group need to be improved.

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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 that 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 the compliance, conformance, and declaration process. Our 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 describes a template of a Structured Document. It 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

Our metamodel for structured content specifications (see Figure 1) is used to specify the overall structure of a structured content specification. The structure is a tree, so every item in the tree, other than the root node, has a parent node. For an SCS, the root node is a Structured Document. For a DCM, the root node is a Data Group.

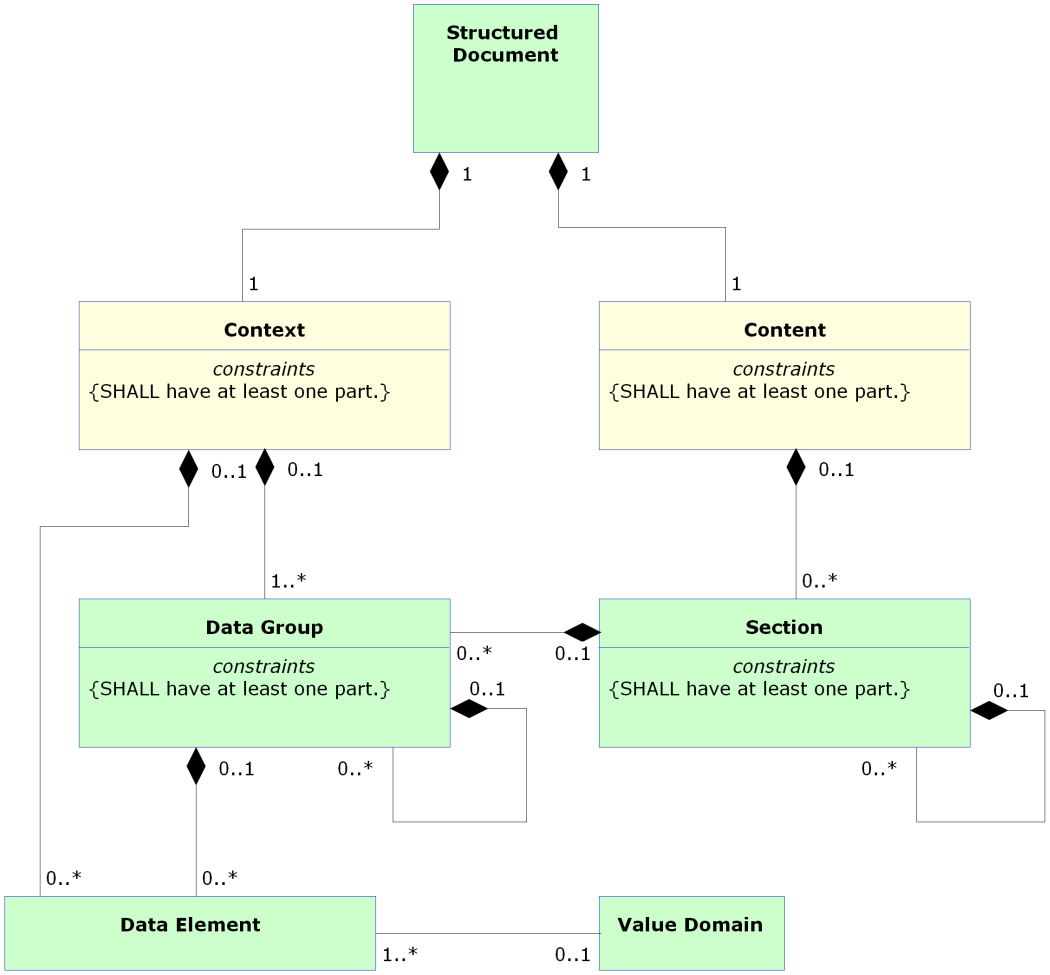

Figure 1: SCS Metamodel

There are two main items 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 in Figure 1, and consists of the following data components:

- Section
- Data Group
- Data Element
- Value Domain

These data components are described in more detail below.

Structured Document

A structured document is a collection of health information about a subject of care that is relevant to the ongoing care of that person. They are composed of one or more data groups and data elements that are organised into

sections. Examples of structured documents are *Discharge Summary*, *Shared Health Summary*, and *Advance Care Directive Custodian Record*.

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 that 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 data groups, other sections, or both. It is an organising container that cues the reader about expected content. A section organises information in a manner suitable for the primary purpose for which it is collected and provides 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, 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 Agency's *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.

Our *Participation Data Specification [NEHT2011v]* defines the full Participation specification.

Choice

Choice represents a selection, to be made at run-time, of a single member from a set of data groups, where the set is 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.

While 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 items, therefore the same value domain can be referred to by different data elements in different contexts. Value domains are often specified with reference to a *reference set*. A reference set is a constrained list of SNOMED CT-AU concepts that are appropriate to a particular context or use. Since 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 either by specifying a lower or upper bound (or both) on the range of permissible values or 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 or 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>Standards Australia AS 4846 (2006) – Health Care Provider Identification [SA2006a] and Standards Australia AS 5017 (2006) – Health Care Client Identification [SA2006b] derive their values from METeOR 287316, 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 that references concepts such as “Bronchitis” (Concept ID: 32398004).</td></tr>
<tr><td>Therapeutic Good Identification</td><td>CodeableText</td><td>An AMT reference set that 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 that 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 in the Agency's DCMs and SCSs.

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 *Data Types in NEHTA Specifications: A Profile of the ISO 21090 Specification [NEHT2010c]*.

Table 3: Data Types Legend

Icon	Data type	Explanation
	Any (ISO 21090: ANY)	Use of this icon indicates that instances of the data element can be of any concrete data type. There are no limitations on the data type of the data element. The values that can be required will vary considerably depending on the context. This is an abstract data type that is the basis for all data types and **SHOULD NOT** be used in an actual implementation.
	Boolean (ISO 21090: BL)	A data type, sometimes called the logical data type, having one of the 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; supports various ways of holding text, both free text and coded text.

Often 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 useful when it is not possible to define an entire value domain for a complex concept (e.g. *Diagnosis*) and when there are 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

- The Australian Institute of Health and Welfare (AIHW) defines a data element concept *Episode of admitted patient care-separation mode* (the status at separation of a subject of care and the place to which they are released). An early adopter could 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 data elements 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

Standards Australia AS 5017 (2006) – Health Care Client Identification [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)

A single date, optionally with a time of day.

Has the ability to indicate a level of precision, but not whether the date or time is estimated. Cannot represent a time alone.

String representations of known dates **SHALL** conform to the format within the **ISO 21090-2011** standard without the use of extensions, i.e. YYYY[MM[DD[HH[MM[SS[.U[U[U[U]]]]]]]]][+|-ZZzz].

Usage/Examples

- Partial dates: 2008, 20081001.
- To indicate 1:20 pm on May the 31st, 1999 for a time zone that is 10 hours ahead of Coordinated Universal Time (UTC): 19990531132000+1000.

Duration (ISO 21090: PQ.TIME)	The period of time during which something continues. Consists of a value and a unit that 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
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. **Usage/Examples** • 1 • -50 • 125
Link (ISO 21090: TEL)	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)	A magnitude value with a unit of measurement. This is used for recording many real world measurements and observations. As the default unit of measure is 1, even counts of items can be recorded with *Quantity*. **Usage/Examples** • 100 centimetres • 25.5 grams • 3 per month

QuantityRange

(ISO 21090: IVL)

A range of *Quantity* values.

It may be identified using a combination of an optional minimum *Quantity* and an optional maximum *Quantity* (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 identified by not including a minimum or a maximum *Quantity* value.

Usage/Examples

- -20 to 100 Celsius
- 30-50 mg
- >10 kg
- 2-3 hours

QuantityRatio

(ISO 21090: RTO)

A relative magnitude of two *Quantity* values.

Usually recorded as numerator and denominator.

Usage/Examples

- 25 mg / 500 ml
- 200 mmol per litre

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)

A character string (with optional language) containing any combination of alpha, numeric, or symbols from the Unicode character set. Also 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:IVL)

An interval in time.

It is identified using a combination of an optional start *DateTime*, an optional end *DateTime*, and an optional *Duration*.

Usage/Examples

- 20080101+1000 - 20081231+1000
- 200801010130+1000 - 200801011800+1000
- 200801010130+1000, duration=16.5 hours

UniqueIdentifier (ISO 21090: II)	A unique value used 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) – Health Care Provider Identification [SA2006a]* and *AS 5017 (2006) – Health Care Client Identification [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** Australian health identifiers (e.g. IHI, HPI-I and HPI-O) and patient hospital medical record numbers are examples of identifiers that may be carried by data elements of 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 *Key Words for Use in RFCs to Indicate Requirement Levels [RFC2119]*. Our specifications use the terms **SHALL** in place of “MUST” and **SHALL NOT** in place of “MUST NOT”. The key word definitions in RFC 2119, adjusted to remove the key words not used in the Agency specifications, are presented in the following table.

Table 4: Keywords Legend

Keyword	Definition
SHALL	This word means that the statement is an absolute requirement of the specification.
SHOULD	This word means that there may exist valid reasons in particular circumstances to ignore a particular data component, but the full implications must be understood and carefully weighed before choosing a different course.

MAY	This word means that a data component is truly optional. One implementer may choose to include the data component because a particular implementation requires it, or because the implementer determines that it enhances the implementation, while another implementer may omit the same data 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 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

In DCMs and SCSs obligations on a data component specify whether or not it **SHALL** be populated in the logical record architecture of a message. We intend that all data components that are not **PROHIBITED** will be implemented.

Obligations in statements about values specify whether or not certain values are permitted.

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 item of information and **SHALL** be populated. **Usage/Examples:** The Participant data 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 item of information and **MAY** be populated. **Usage/Examples:** Such data components will be implemented, only inclusion and population are optional. 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	On a data component this indicates that the data component is considered a forbidden item of information and **SHALL NOT** be included. In a statement about values this indicates that the use of the specified values is considered forbidden and they **SHALL NOT** be used. **Usage/Examples:** Within a Participation data group depicting a Subject of Care, the Participation Healthcare Role **SHALL NOT** be populated.

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 **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 included.

Obligations follow the usual scope rules: where **ESSENTIAL** child data components are contained within **OPTIONAL** parent data components, the child data components **SHALL NOT** be included when the parent is not included.

B.4 Exceptional Values

Occasionally a data element will have an exceptional value: an abnormal value (i.e. the value cannot be described using the expected set of values) or an absent value (i.e. no value is provided). Some abnormal values are only relevant to data elements of certain data types (e.g. positive infinity is relevant to numbers but not Booleans).

Unless otherwise specified, all data elements are permitted to have exceptional values. Constraints on the use of exceptional values are contained in the Exceptional Values row of the Usage section, except for instances of Participation, when they are in the Conditions of Use row. The most common statements constraining exceptional values are:

- Absent values are **PROHIBITED**.
- Abnormal values are **PROHIBITED**.

The commonly used implementation specifications ISO 21090 and HL7 CDA R2 use *nullFlavor* to manage abnormal and absent values.

The following table provides a classification of nullFlavor values as abnormal or absent.

Table 6: Classification of ISO 21090 nullFlavor values as absent or abnormal

Level	Code	Term	Abnormal	Absent
1	NI	No information		Absent
2	INV	Invalid	Abnormal	
3	OTH	Other	Abnormal	
4	PINF	Positive infinity	Abnormal	
4	NINF	Negative infinity	Abnormal	
3	UNC	Unencoded	Abnormal	
3	DER	Derived	Abnormal	
2	UNK	Unknown		Absent
3	ASKU	Asked but unknown		Absent
4	NAV	Temporarily unavailable		Absent
3	NASK	Not asked		Absent
3	QS	Sufficient quantity	Abnormal	

Level	Code	Term	Abnormal	Absent
3	TRC	Trace	Abnormal	
2	MSK	Masked		Absent
2	NA	Not applicable		Absent

B.5 Information Model Specification Parts Legends

This section illustrates the format and parts used to define each section, data group and data element within the Agency's DCMs and SCSs, and identifies when each part is applicable.

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 7: Identification Section Legend

Label	A suggested display name for the data component.
Metadata Type	The type of the data component, e.g. section, data group or data element.
Identifier	An Agency-assigned internal identifier of the data component. Note that if one data component is used twice (e.g. *Therapeutic Good Identification* is used in both *Medication Instruction* and *Medication Action*), both uses of the data component will have the same identifier. A data component identifier identifies a data component, not a **use** of a data component.
OID	An object identifier equivalent to the data component identifier.
External Identifier	An identifier of the concept represented by the data component that is assigned by an organisation other than the Agency.

Definition Section Legend

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

Table 8: Definition Section Legend

Definition	The meaning, description or explanation of the data component. 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.

	Implementers may prefer to use synonymous names to refer to the data component in specific contexts.
Scope	Situations in which the data component may be used, including the Scope circumstances where specified data are required or recommended. For example, Medication Instruction (data group) has a scope that includes all prescribable therapeutic goods, both medicines and non-medicines. This item is not relevant to data elements or value domains.
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. This item is applicable only to data elements.
Assumptions	Suppositions and notions used in defining the data component.
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.
Data Type	The data type (or data types) of the data element, e.g. DateTime or Text. The valid data types are specified in the Data Types Legend. This item is applicable only to data elements.
Value Domain	The name of the Value Domain used to define the range of values of the data element, or a statement describing what values to use in the absence of a defined value domain for the related data element. The statement is: 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. This item is applicable only to data elements with data type CodedText or CodeableText.

Data Hierarchy

The top-level data components (a Structured Document in an SCS or Data Groups in a DCM) contain a data hierarchy. Each row contains information about a single data component. The entries are nested to represent inclusion of one data 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 of the data 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.

If a row is shaded grey, this indicates that the data component **SHOULD NOT** be used. This will be because analysis of requirements either did not find reasons to use it or found reasons to not use it.

If the text in a row is in a ~~strike through~~ font and the multiplicity is 0..0, this indicates that the data component **SHALL NOT** be used. This will be because analysis of requirements found reasons to prohibit the use of it.

In some documents the right-hand side of the data hierarchy contains 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 data components **SHALL** be implemented.

Sample SCS Data Hierarchy

Note

Items below whose text is lighter (mid-blue and mid-grey) are technical identifiers whose purpose is to facilitate interoperability, sharing of data and secondary use. Typically, such identifiers will be generated internally by systems and not displayed to users since they rarely have clinical significance.

Items below with a grey background are data components that are included in the relevant detailed clinical model specification, but whose use is discouraged in this particular scenario.

	SPECIALIST LETTER			
CONTEXT				
		SUBJECT OF CARE		1..1
		DOCUMENT AUTHOR		1..1
		ENCOUNTER		1..1
			DateTime Subject of Care Seen (DateTime Health Event Started)	1..1
			DateTime Health Event Ended	0..0
			HEALTHCARE FACILITY	0..0
		Document Instance Identifier		0..1
		RELATED INFORMATION		0..0
		Document Type		1..1
CONTENT				
		RESPONSE DETAILS		1..1
			Diagnosis (PROBLEM/DIAGNOSIS)	0..*
			Diagnosis Name (Problem/Diagnosis Identification)	1..1
			Clinical Description	0..0
	and more			

Value Domain Section Legend

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

Table 9: 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	A specification of the permissible values in the value domain. This may be a list of codes. (Each code is typically presented as a triple with code values, text equivalent, and description) for example: 1, Registered No result yet available. This may be a conformance statement (e.g. "The permissible values are the members of the following seven AMT reference sets: ...").

Usage Section Legend

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

Table 10: Usage Section Legend

Examples	Sample values for the data element, with or without notes about sample values. 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, indicative examples are provided. Implementation guides may contain specific examples of how data elements may be populated and how they relate to each other. This item is applicable only to data elements.
Conditions of Use	Prerequisites, provisos or restrictions for use of the data component.
Conditions of Use Source	The authoritative source for the Conditions of Use statement.
Misuse	Incorrect, inappropriate or wrong uses of the data component.
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 data component.
Exceptional Values	A statement of limitations on the use of exceptional values, see Exceptional Values. Unless otherwise specified, all data elements are permitted to have exceptional values. The most common statements constraining exceptional values are: • Abnormal values are **PROHIBITED**. • Absent values are **PROHIBITED**. This item is applicable only to data elements.

Relationships Section Legend

The Relationships section specifies the cardinality between parent and child data components.

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

Table 11: Parent Legend

Data Type	**Name**	**Occurrences** (child within parent)
The icon illustrating the metadata type or data type.	Parent Data Component Name	The minimum and maximum number of instances of the data component described on this page that **SHALL** occur.

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

Table 12: Children Legend

Data Type	**Name**	**Occurrences**
The icon illustrating the metadata type or data type.	Child Data Component Name	The minimum and maximum number of instances of the data component described on this page that **SHALL** occur.

Appendix C. Change History

A summary of changes from one document version to the next. Changes to the change history are excluded.

C.1 Changes Since Version 3.2 - 18 December 2015

Generic changes

Various changes to rebrand the document from the National E-Health Transition Authority (NEHTA) to the Australian Digital Health Agency (the Agency):

- Definition Source, Scope Source, Context Source, Condition of Use Source and Value Domain Source updated from “NEHTA” to “Australian Digital Health Agency”;
- references to “National E-Health Transition Authority” and “NEHTA” have been replaced with references to the “Australian Digital Health Agency” and “the Agency” respectively; and
- all NEHTA URLs have been updated to redirect to the Agency website.

Preliminary Pages

Document Information section has been changed to include the latest release details.

Chapter 1 Introduction

Various editorial changes to presentation and wording, including replacing the expression “PCEHR” with “My Health Record”.

Chapter 2 Adverse Reaction Detailed Clinical Model

The version has changed from 5.2 to 5.3.

In 2.1 Purpose, 2.2 Use and 2.3 Misuse, there are various editorial changes to wording.

In 2.4 UML Diagrams, the class diagram has been updated.

In 2.5 ADVERSE REACTION, some synonymous names have been removed. A statement has been added to scope indicating that “Substances and agents exclude medication at above therapeutic doses”

In 2.5 ADVERSE REACTION, Data Hierarchy the following data elements have had their labels changed to match their names:

- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > TIMING > Intervention Frequency Range*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > TIMING > Intervention Interval Range*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > TIMING > Intervention Day of Week*;

- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > TIMING > Intervention Day of Month*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > TIMING > Intervention Date*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > MEDICATION ADMINISTRATION > Anatomical Site*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > MEDICATION ADMINISTRATION > Medication Delivery Method*; and
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > MEDICATION ADMINISTRATION > Intravenous Administration Details*.

In 2.5 ADVERSE REACTION, Data Hierarchy *Intervention Time* has been renamed *Intervention Time of Day*.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *ADVERSE REACTION > Substance/Agent*;
- *ADVERSE REACTION > Absolute Contraindication*;
- *ADVERSE REACTION > REACTION EVENT > Adverse Reaction Certainty*;
- *ADVERSE REACTION > REACTION EVENT > ANATOMICAL LOCATION > SPECIFIC LOCATION > Side*;
- *ADVERSE REACTION > REACTION EVENT > ANATOMICAL LOCATION > SPECIFIC LOCATION > Numerical Identifier*;
- *ADVERSE REACTION > REACTION EVENT > ANATOMICAL LOCATION > SPECIFIC LOCATION > Anatomical Plane*;
- *ADVERSE REACTION > REACTION EVENT > ANATOMICAL LOCATION > RELATIVE LOCATION > Anatomical Location Aspect*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > AMOUNT OF MEDICATION > Dose Unit*;
- *ADVERSE REACTION > REACTION EVENT > ADDITIONAL EXPOSURE DETAIL > TIMING > Intervention Day of Week*;
- *ADVERSE REACTION > Adverse Reaction Instance Identifier*;
- *ADVERSE REACTION > RELATED INFORMATION > Link Nature*; and
- *ADVERSE REACTION > Detailed Clinical Model Identifier*.

In 2.7 Substance/Agent Values, there was an editorial change to the definition.

In 2.8 Absolute Contraindication, the term “propensity” has been replaced with “predisposition”. The definition and usage have been rewritten to be easier to understand.

In 2.14 Reaction Type, the term “subject of care” has been replaced with “subject”.

In 2.16 Adverse Reaction Certainty, there are editorial changes to the definition and usage.

In 2.17 Adverse Reaction Certainty Values, there are editorial changes to the value domain and usage.

In 2.19 Reaction Onset Date, the wording of the definition has been revised and the notes have been removed.

In 2.20 Duration of Reaction, the wording of the definition has been revised.

In 2.27 Numerical Identifier, the wording of the definition has been revised.

In 2.29 RELATIVE LOCATION, the wording of the notes has been revised.

In 2.31 Anatomical Location Aspect, the list of examples has been shortened and the explanations of each example have been removed.

In 2.34 Visual Markings/Orientation, the wording of the definition has been revised.

In 2.38 Duration of Exposure, the wording of the definition has been revised.

In 2.40 AMOUNT OF MEDICATION, the wording of the definition has been revised.

In 2.42 Dose Unit, editorial changes have been made to the examples.

In 2.46 Intervention Frequency Range, the wording of the definition has been revised. The label has changed.

In 2.47 Intervention Interval Range, the wording of the definition has been revised. The notes have been corrected. The label has changed.

In 2.48 Intervention Time of Day, the name has changed. The wording of the definition has been revised. The label has changed.

In 2.49 Intervention Day of Week, the wording of the definition has been revised. The label has changed.

In 2.50 Intervention Day of Month, the wording of the definition has been revised. The label has changed.

In 2.51 Intervention Date, the wording of the definition has been revised. An intended data constraint, stating that a time component shall not be included, has been made explicit. The label has changed.

In 2.53 Route, there are editorial changes to the notes and examples.

In 2.54 Route of Administration Reference Set, there are editorial changes to the notes.

In 2.55 Anatomical Site, there are editorial changes and the label has changed. The value domain has changed to “Anatomical Location Name Values”.

In 2.56 Anatomical Location Name Values, the name of the value domain has changed from “Body Structure Foundation Reference Set”.

In 2.57 Medication Delivery Method, there are editorial changes to the definition and the label has changed.

In 2.59 Intravenous Administration Details, there are minor changes to the text of the examples and label has changed.

In 2.60 Clinical Management Description, there are editorial changes, such that the note has been moved into a condition of use.

In 2.62 Reporting Details, there are minor changes to the text of the examples.

In 2.64 Reaction Reported, there are editorial changes. A clarifying note has been added.

In 2.65 Adverse Reaction Report, an example has been added.

In 2.67 INFORMATION PROVIDER, this follows current design for specifying Information Provider.

In 2.68 SUBJECT, there are editorial changes to the scope and conditions of use.

In 2.70 RELATED INFORMATION, there are editorial changes.

In 2.72 Link Nature Values, there are editorial changes.

In 2.73 Link Role, there are editorial changes.

In 2.74 Link Role Values, the permissible values have been updated.

In 2.76 Detailed Clinical Model Identifier, there are editorial changes.

Chapter 3 Exclusion Statement - Adverse Reactions Detailed Clinical Model

The version has changed from 1.3 to 1.4.

Guidance on data elements with exceptional values has been added. This affects all uses of the following data elements:

- *EXCLUSION STATEMENT - ADVERSE REACTIONS* > *Global Statement*;
- *EXCLUSION STATEMENT - ADVERSE REACTIONS* > *Exclusion Statement - Adverse Reactions Instance Identifier*;
- *EXCLUSION STATEMENT - ADVERSE REACTIONS* > *RELATED INFORMATION* > *Link Nature*; and
- *EXCLUSION STATEMENT - ADVERSE REACTIONS* > *Detailed Clinical Model Identifier*.

In 3.5 Global Statement, a condition of use has been removed.

In 3.6 Global Statement Values, there are editorial changes.

In 3.11 INFORMATION PROVIDER, this follows current design for specifying Information Provider.

In 3.12 SUBJECT, there are editorial changes to the scope and conditions of use.

In 3.14 RELATED INFORMATION, there are editorial changes.

In 3.16 Link Nature Values, there are editorial changes.

In 3.17 Link Role, there are editorial changes.

In 3.18 Link Role Values, the permissible values have been updated.

In 3.20 Detailed Clinical Model Identifier, there are editorial changes.

Appendix A. Known Issues

Various changes.

Appendix B. Specification Guide for Use

Various editorial changes.

Renamed the section B.4 “Abnormal and Absent Values” to “Exceptional Values” and updated explanatory text throughout accordingly.

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This page is intentionally left blank.

Index

E

G

I

L

M

N

Q

R

S

T

V

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