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# **Adverse Reactions**

## **Data Specifications**

Version 1.0 - 29/06/2007

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# Document information

## Change history

Version	Date	Comments
1.0	29.06.2007	Initial public release

# Acknowledgements

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- Standards Australia;
- Royal Australian College of General Practitioners;
- Society of Hospital Pharmacists of Australia;
- Members of the Australian DataTypes Project;
- Australian Institute of Health & Welfare; and
- Ocean Informatics.

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# 1 Introduction

## 1.1 Purpose and Scope

The Adverse Reaction data group specification forms part of a suite of data specifications that NEHTA is developing for the Australian Health Informatics Community. The suite comprises specifications for a range of health topics (represented as “data groups”), which are generally agreed to be of high priority to standardise in order to achieve the benefits brought about by Level 4 (semantic) interoperability in the Australian healthcare setting.

## 1.2 Intended Audience

This document is intended to be read by jurisdictional ICT managers, clinicians involved in Clinical Information System specifications, software architects and developers, and implementers of Clinical Information Systems in various healthcare settings.

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

## 1.3 Background

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

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

Data specifications have been developed:

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

Whilst shared EHR is referred to in these documents the implementation of the shared EHR is not dealt with here.

## 1.4 NEHTA Clinical Standards Metamodel

The NEHTA Event Summary and Clinical Data Standards metamodel is used to provide a high level overview of a family of structured documents which includes Adverse Reaction. Within this metamodel, clinical information is organised hierarchically into five levels:

- Event Summary;
- Section;
- Data Group;
- Data Element; and
- Value Domain.

Event summary collection in a shared EHR system shows the role and structure of an event summary in a shared EHR environment.

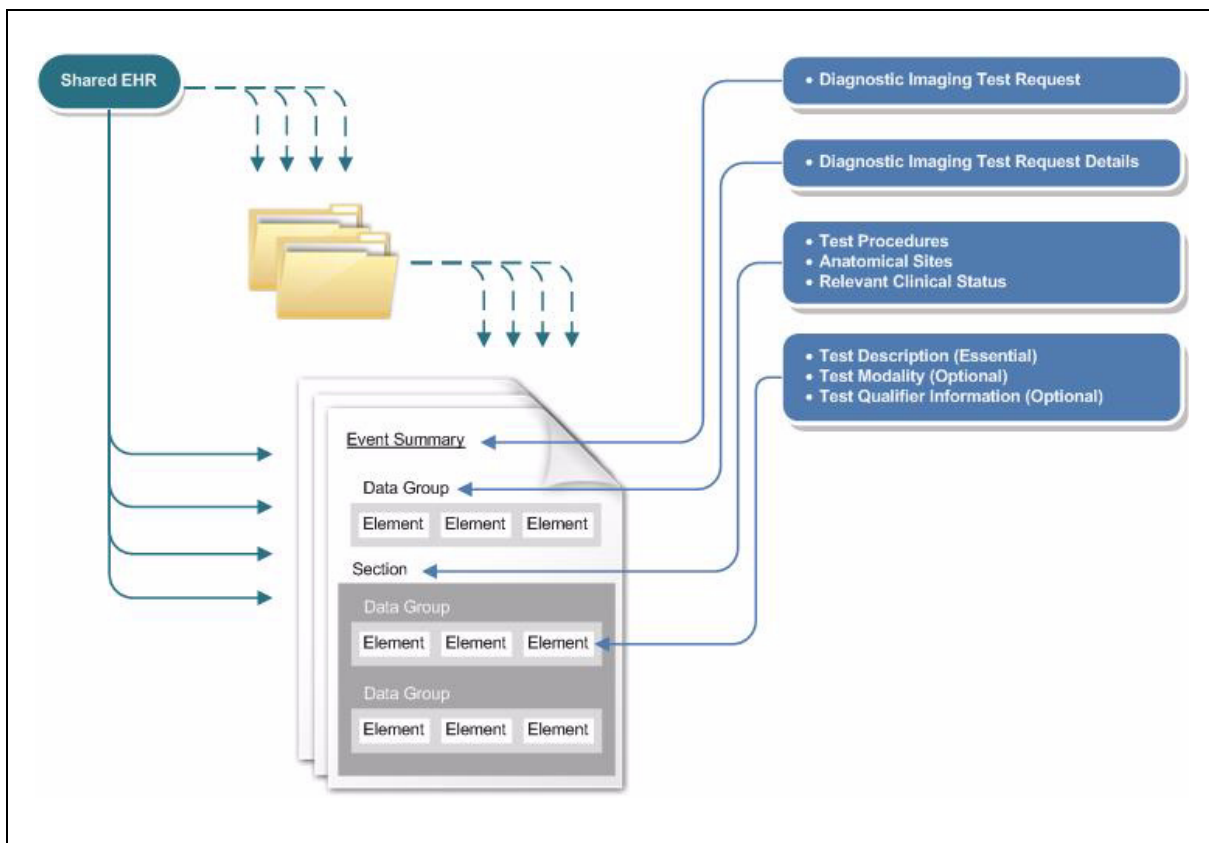


Table 1 Event summary collection in a shared EHR system

### 1.4.1 Event Summary

An event summary is a collection of health information pertinent to a subject of care and is derived from a healthcare event that is relevant to the ongoing care of that individual. The event summary (which is one of a family of care record summaries) is composed of one or more data groups and/or possibly data elements, which are organised into section(s) (see Section below).

Examples of commonly used care record summaries include Referral, Hospital Discharge and Diagnostic Imaging Results.

### 1.4.2 Section

The contents of an event summary may be organised into one or more sections. A section is an organising container. Its purpose is to organise information in the manner that is suitable for the primary purpose it is collected, and that is useful for healthcare providers. A section also provides a way to navigate through the data items within an event summary, thereby enabling more efficient querying to be made.

### 1.4.3 Data Group

A data group is a composite data structure (a collection of data elements or smaller data groups) for holding related items of information. Values of all the component data elements are often required to provide unambiguous meaning in a given context. A data group “organises” the data it holds. A data group can only be assigned values through the data elements that are contained within it. Examples of data groups are ADVERSE REACTION, ALERT, and MEDICATION.

### 1.4.4 Data Element

A data element is the smallest named unit of information in the model that can be assigned a value. Data elements are identified as being either simple or as a component.

A component data element is one that occurs as a member of a composite data structure. A data element that occurs in a segment outside the defined boundaries of a composite data structure is identified as a simple data element. The distinction between simple and component data elements is strictly a matter of context since a data element can be used in either capacity<sup>1</sup>.

The permissible values for a data element are constrained by a value domain (see Value Domain).

The same data element can be reused in any number of data groups; e.g. the "DateTime:Start" data element is used in both the ADVERSE REACTION and the ALERT data groups, however a data element may refer to different value domains depending on the context in which it is used.

### 1.4.5 Value Domain

A value domain constrains the permissible values for a data element. The value domain may specify the type of data value that is valid for a specific data element or be more specific about the coding system the values are drawn from or subset of codes. The values may be a subset of values based on a generic data type. Value domains are reusable components and therefore, the same value domain can be referred to by different data elements in different situations

Value domains constrain by either specifying a lower and/or upper bound on the range of permissible values or else specify a finite set of prescribed values. Such a set of prescribed values can be specified directly with the definition of the data element, or in a separate but associated specification or else by reference to one or more external vocabulary/terminology sets. Value domain examples (below) are shown below:

Data Element	Data Type	Example of Value Set	Example of Value Domain
Severity	Coded text	Code-set that describes severity of problem, diagnosis, or allergic reaction	"mild", "disabling", "life threatening"
Diagnosis	Coded text	Code set that describe diagnosis, problems, or issues	Valid SNOMED CT codes drawn from the disorders hierarchy

Table 2 Value domain examples

### 1.4.6 Classification Scheme

A classification scheme is a terminological system used to classify objects. It is organised in some specified structure, limited in content by a scope, and designed for assigning objects to concepts defined within it. Concepts are usually assigned to an object by linking the terms representing those concepts in the terminological system to the object. This process is called classification, and the terms assigned through classification are used for retrieval. In general, any terminological system is a classification scheme if its intent is for classifying objects<sup>2</sup>.

A classification scheme is used to encompass terminologies and vocabularies used for various uses such as direct clinical use and statistical analysis. Classification schemes are referred to in NEHTA's data specifications where they exist externally and are required in value domains. Often these classifications schemes are underpinned by a set of codes, where each code maps to one or more entries in

1. Adapted from the Texas Department of State Health Services, *THCIC Hospital Discharge Data Collection*, THCIC 837\ Technical Specifications (version 13), November 19, 2004.  
 2. As defined by ISO/IEC 11179.

the classification scheme. Classification schemes are sometimes referred to as codesets.

A value domain may consist of permissible values sourced from zero or more existing, external classification schemes, depending upon the completeness and sufficiency of those classification schemes. Values that are not available in one classification scheme may be obtained from other classification schemes, or depending upon the context and/or local system requirements, a preferred classification scheme may be used from a selection of valid classification schemes for that value domain.

## **1.5 Terminology**

NEHTA is defining a national approach to clinical terminology. An interim licence with the College of American Pathology (CAP) for use of SNOMED CT® within Australia was in place from 2006. The International Health Terminology Standards Development Organisation (IHTSDO) was formed in April 2007 and Australia is one of the foundation member countries. New national SNOMED CT licence arrangements are now in place, managed by NEHTA.

Although SNOMED CT is a comprehensive clinical reference terminology it is recognised that this does not provide a total solution and will need to be supplemented by local extensions. NEHTA is therefore establishing a National Terminology Service to manage Australian extensions to SNOMED CT. The Australian Medicines Terminology will supply terms to populate the Vaccine Brand Name and Route.

## 2 Specifications




The objective of this specification is to provide detailed information regarding the data elements (and their associative hierarchies and value domains) relevant to the transfer of information within the Adverse Reactions domain.

The specification references other data group information, the details of which may be found in other NEHTA Specifications.

A Section can be thought of as an organisational heading. A data group is a collection of related data elements and/or data groups that can be treated as a single block, which might be subject to cardinality and obligation constraints.

### 2.1 Obligation Legend

In the following specifications, data obligation may be categorised as:

- Essential:**  Indicating that the data item is considered to be a core component of information and required in order for the entry to make sense, e.g. Alert without an Alert description does not make sense;
- Desirable:**  Indicating that the data item is considered worthy of being supplied where the data is known. The data item is deemed important in terms of providing additional or supplementary information in conjunction with essential data items. The data item should be supplied to provide as much context as possible for users to make informed decisions and/or to support various implementation requirements such as efficient indexing, querying and electronic decision support;
- Optional:**  Indicating that the data item may be supplied if required within a context and if the data is available, but it is not necessary for the data entry to make sense. It is recognised that for more complex or specialised healthcare provider settings, some items deemed optional may be viewed essential to them; or
- Conditional:** *a→b* Indicating that the data item is required on the condition of some other data item(s) being supplied, or based on the value(s) of another data item(s).

### 2.2 NEHTA Data Specifications ICON Legend







Icon	Metadata Types
	Event Summary
	Sections
	Packages
	Data Groups
	Data Elements
	Value Domains

Table 3 Metadata types





Icon	Explanation
	"Choice data group" - a single data group to be chosen from a set of data groups. Data groups of the same hierarchical depth within a hierarchical data group that make up a "choice set" are indicted using this icon.
	Multiple occurrences.*
	Externally sourced specifications.
	Externally sourced Data Group Specifications.

Table 4 Other Icons







Icon	Datatype	Explanation
	Text	Character strings (with optional language). Unless otherwise constrained by an implementation, can be any combination of alpha, numeric or symbols from the Unicode character set. (Sometimes referred to as free text).
	CodedText	Coded text <i>without</i> exceptions; text with code mappings.
	CodeableText	Coded text with exceptions; flexible datatype to support various ways of holding text, both free text, coded text and combinations of free + coded.
	DateTime	Used for specifying a single date and/or time. Has the ability to indicate a level of precision, as well as an indication that the date/time is estimated. String representations of known dates should conform to ISO 8601.
	Duration	The period of time during which something continues.  <b>Usage/Examples</b> Example (1) 3 hours. Example (2) 6 months. Example (3) 1 year.
	Number	A whole number or positive integer, and where (according to ISO 11404) - <i>integer</i> is the mathematical datatype comprising the exact integral values  <b>Usage/Examples</b> Example (1) 1. Example (2) 50. Example (3) 125.

Table 5 Datatypes






Icon	Datatype	Explanation
	Boolean	A value of true or false.  <b>Usage/Example</b> Example (1) An actual value entered by the user might be "yes" or could be chosen by a mouse click on an icon such as <input checked="" type="checkbox"/>
<b>ID</b>	UniqueIdentifier	A general unique identifier to identify a physical or virtual object or concept.
	TimeInterval	Two Date/Time values that define the initial and later points in time.  <b>Usage/Examples</b> Example (1) 12:00 – 18:00. Example (2) 1:30 a.m. – 6:00 p.m.
	Quantity	Used for recording many real world measurements and observations. Consists of the property being recorded, the magnitude value, and the units. It may also include precision and number of decimal places.  <b>Usage/Examples</b> Example (1) Property = width. Example (2) Units = centimetres. Example (3) Value = 100.
	QuantityRange	Two <i>Quantity</i> values that define the minimum and maximum values, i.e. lower and upper bounds. This is typically used for defining the valid range of values for a particular measurement or observation.  <b>Usage/Examples</b> Example (1) Temperature range of -20 to 100 °C Example (2) 30-50 mg of a prescribed drug.
	EncapsulatedData	Used to specify how to supply metadata such as the type of data encapsulated (such as JPEG images, HTML, etc. using RFC 1521 MIME types), whether the data is inline or passed by reference, what character set is used to encode the data, any low resolution "thumbnail" representation included, any compression algorithm or integrity check information included.

Table 5 Datatypes


Icon	Datatype	Explanation
	Link	<p>This is a general link, reference or pointer to an object, data, or application that exists logically or stored electronically in a computer system.</p> <p><b>Usage/Examples</b></p> <p>Example (1) 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 – “<a href="http://www.google.com">http://www.google.com</a>”.</p> <p>Example (2) An absolute or relative path within a file/directory structure – e.g. in Windows operating system, the ‘link’ or absolute path to a particular letter (Word document) may be - “C:\Documents and Settings\guestUser\My Documents\Letter.doc”.</p>
A:B	Ratio	<p>The relative magnitudes of two Quantity values (usually expressed as a quotient).</p> <p><b>Usage/Examples</b></p> <p>Example (1) 1/3. Example (2) 1:3.</p>
a,b,c...	Sequence	<p>Ordered collection of items.</p> <p><b>Usage/Example</b></p> <p>Example (1) A person’s given names, e.g. “David Phillip Andrew” would be held as 3 items grouped in order to form a single entity.</p>
{b,a,c}	Set	<p>Unordered collection of items with values that must be unique within the set.</p>

Table 5 Datatypes

# ADVERSE REACTION

## Identification




<b>Name</b>	ADVERSE REACTION	
<b>Metadata Type</b>	Data Group	
<b>Identifier</b>	DG-017	<i>External Identifier</i>
<b>Version</b>	1.0	

## Definition

<b>Definition</b>	<p>A harmful or undesirable response to an agent/substance.</p> <p>An adverse reaction may occur within a variable timeframe after exposure to an agent/ substance and may range from minor reactions like a skin rash to serious and life-threatening events such as anaphylaxis. Exposure may be by ingestion, inhalation, injection or direct contact.</p> <p>An adverse reaction includes allergies, intolerances and sensitivities. An adverse reaction does not include poisoning, medical errors or mishaps that may occur during surgical or medical care, as these are generally classified as an adverse event.</p>
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	Allergic reaction, Allergy, Intolerance, Sensitivity.
<b>Scope</b>	<p>The collection of the presence or absence of an adverse reaction to a specific substance/agent. The Adverse Reaction data group is used to capture the body's response to the effect of an agent or substance whereas the Alert data group notifies a healthcare provider of any special considerations that may need to be known, such as infectious disease carrier, pregnant or elite athlete.</p> <p>The process of identifying adverse reactions is a critical element of good clinical practice and is essential for safety and quality.</p>
<b>Scope Source</b>	NEHTA
<b>Assumptions</b>	

## Hierarchical Structure

ADVERSE REACTION	Obligation
T <sub>010</sub> Adverse Reaction Presence	!
T/T <sub>010</sub> Information Provided By	0
T <sub>010</sub> Agent Type	✓
T/T <sub>010</sub> Agent Description	!
DateTime of Exposure	0
T <sub>010</sub> Agent Description Certainty	✓
T <sub>010</sub> Adverse Reaction Type	✓
REACTION DETAILS	✓ ↻
T/T <sub>010</sub> Reaction Description	✓
T <sub>010</sub> Severity	✓
DateTime Started	0
T <sub>010</sub> Adverse Reaction Status	✓
T/T <sub>010</sub> Adverse Reaction Outcome	0
T Adverse Reaction Note	0

 ADVERSE REACTION	Obligation
 REPORTER IDENTIFICATION	!
 DateTime Reported	!

### Usage














<b>Conditions of Use</b>	This data group is repeated for every instance of an adverse reaction. An adverse reaction to an immunisation is to be recorded here.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	Recording an alert.

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Children

Data Type	Name	Version	Obligation	Condition	Occurrence
 T <sub>010</sub>	Adverse Reaction Presence	1.0	Essential		Single
 T/T <sub>010</sub>	Information Provided By	1.0	Optional		Single
 T <sub>010</sub>	Agent Type	1.0	Desirable		Single
 T/T <sub>010</sub>	Agent Description	1.0	Essential		Single
	DateTime of Exposure	1.0	Optional		Single
 T <sub>010</sub>	Agent Description Certainty	1.0	Desirable		Single
 T <sub>010</sub>	Adverse Reaction Type	1.0	Desirable		Single
	REACTION DETAILS	1.0	Desirable		Multiple
 T <sub>010</sub>	Adverse Reaction Status	1.0	Desirable		Single
 T/T <sub>010</sub>	Adverse Reaction Outcome	1.0	Optional		Single
 T	Adverse Reaction Note	1.0	Optional		Single
	REPORTER IDENTIFICATION	1.0	Essential		Single
	DateTime Reported	1.0	Essential		Single

## Adverse Reaction Presence

### Identification

<b>Name</b>	Adverse Reaction Presence		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-152	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	An indication that the subject of care has or has not experienced an adverse reaction to an agent/substance, as determined by a healthcare provider.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	The result of an act of enquiry by a healthcare provider. It may be equally important to have, in some situations, specific information that a subject of care does not have a reaction to a specific agent/substance, e.g. 'not allergic to penicillin'.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	CodedText
<b>Value Domain</b>	Adverse Reaction Presence values

### Usage


<b>Conditions of Use</b>	To record whether or not an adverse reaction has occurred as determined by a healthcare provider, following a clinical assessment.
<b>Conditions of Use Source</b>	
<b>Examples</b>	Example 1) Present. Example 2) Absent. Example 3) Nil known.
<b>Misuse</b>	

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Essential		Single

## VD Adverse Reaction Presence values

### Identification

<b>Name</b>	Adverse Reaction Presence values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-053
<b>Version</b>	1.0

### Definition

<b>Definition</b>	An indication of the existence or non existence of a harmful or undesirable response to an agent/substance.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Absent; Present; and Nil known.

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
T <sub>010</sub>	Adverse Reaction Presence	1.0

## Adverse Reaction Type

### Identification

<b>Name</b>	Adverse Reaction Type		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-158	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The type of reaction experienced by the subject of care to an agent/substance, as determined by a healthcare provider.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	This field is used to identify the type of adverse reaction as determined by: (a) the signs and/or symptoms experienced by the subject of care; (b) information provided by a relevant individual; (c) previously documented history; and/or (d) a clinical assessment by a healthcare provider.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	CodedText
<b>Value Domain</b>	Adverse Reaction Type values

### Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Examples</b>	Example 1) Allergy. Example 2) Intolerance. Example 3) Sensitivity.
<b>Misuse</b>	

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Desirable		Single

## VD Adverse Reaction Type values

### Identification

<b>Name</b>	Adverse Reaction Type values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-054
<b>Version</b>	1.0

### Definition

<b>Definition</b>	An indication of the type of reaction experienced to an agent/substance.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Allergy; Intolerance; and Sensitivity.

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	<p>The value domain options are mutually exclusive and cannot be used in conjunction with each other.</p> <p>Allergy: An irritating or harmful response to a foreign agent/substance that is harmless to most people.</p> <p>Sensitivity: A reaction to an agent/substance, which is an exaggeration of a normal side effect produced by that agent/substance.</p> <p>Intolerance: Unpleasant symptoms occurring after exposure to an agent/substance e.g. food substances which the body cannot handle as it does not possess sufficient quantities of a particular enzyme/chemical needed to break down the agent/substance.</p>
<b>Conditions of Use Source</b>	<p><a href="http://www.internethealthlibrary.com">http://www.internethealthlibrary.com</a> (modified)</p> <p><a href="http://www.allergyuk.org/allergy_intol.html">www.allergyuk.org/allergy_intol.html</a> (modified)</p>
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
<b>T</b> <sub>010</sub>	Adverse Reaction Type	1.0

## Agent Description

### Identification

<b>Name</b>	Agent Description		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-021	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The agent/substance causing the adverse reaction, as determined by a healthcare provider.		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>	Knowledge of a problematic agent/substance is essential for good clinical practice and for the prevention of subsequent harm.		
<b>Context Source</b>	NEHTA		
<b>Assumptions</b>			
<b>Data Type</b>	CodeableText		
<b>Value Domain</b>	Agent Description values		

### Usage


<b>Conditions of Use</b>			
<b>Conditions of Use Source</b>			
<b>Examples</b>	Example 1) Egg. Example 2) Penicillin. Example 3) Bee sting.		
<b>Misuse</b>			

### Data Flow

<b>Sender Type</b>	Either system or human.		
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.		
<b>Recipient Type</b>	Either system or human.		
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.		

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Essential		Single

## VD Agent Description values

### Identification

<b>Name</b>	Agent Description values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-102
<b>Version</b>	1.0

### Definition

<b>Definition</b>	The specific agent/substance causing the adverse reaction.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
<b>T/T<sub>010</sub></b>	Agent Description	1.0

## DateTime of Exposure

### Identification

<b>Name</b>	DateTime of Exposure		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-15506	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The date or date and time that the exposure to the agent/substance occurred. <i>The date and time could be automatically generated the system, or could be entered or overridden by a user if required.</i>		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>			
<b>Data Type</b>	DateTime		
<b>Value Domain</b>			

### Usage


<b>Conditions of Use</b>	Where possible, exact dates should be used. Incomplete dates should generally only be used for retrospective data collection.
<b>Conditions of Use Source</b>	NEHTA
<b>Examples</b>	Example 1) 31/03/2004. Example 2) 03/2004. Example 3) 2004. Example 4) 31/03/2004 13:10.
<b>Misuse</b>	Entering approximate dates when an exact date is available.

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Optional		Single

# DE Agent Description Certainty

## Identification

<b>Name</b>	Agent Description Certainty		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-068	<i>External Identifier</i>	
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	Used to indicate the degree of confidence that the agent/substance referred to in the agent description has caused the adverse reaction, as determined by a healthcare provider.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	It is important to know the degree of certainty of an adverse reaction to an agent/substance. There may be instances where it is not clear whether it is the active agent or a secondary component causing the problem. For example, it may be the filler in a tablet that may be the allergen rather than the active drug. Another example is where there is suspicion of a reaction which warrants recording but it has not been confirmed objectively, or where a reaction has been recorded but is subsequently discounted following further observation and/or investigation.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	CodedText
<b>Value Domain</b>	Agent Description Certainty values

## Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Examples</b>	<p>Example 1) Certain.</p> <p>Example 2) Probable.</p> <p>Example 3) Possible.</p> <p>Example 4) Unlikely.</p> <p>Example 5) Conditional/Unclassified.</p> <p>Example 6) Unassessible/Unclassifiable.</p>
<b>Misuse</b>	

## Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

## Relationships

### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Desirable		Single

## VD Agent Description Certainty values

### Identification

<b>Name</b>	Agent Description Certainty values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-033
<b>Version</b>	1.0

### Definition

<b>Definition</b>	Indicates the degree of confidence that the agent/substance has caused the adverse reaction.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	WHO-UMC causality assessment system.
<b>Version Number</b>	
<b>Permissible Values</b>	Certain; Conditional/Unclassified; Possible; Probably/Likely; Unassessible/Unclassifiable; and Unlikely.

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	<p>The value domain options are mutually exclusive and cannot be used in conjunction with each other.</p> <p><b>Certain:</b> 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.</p> <p><b>Probably/Likely:</b> 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.</p> <p><b>Possible:</b> A clinical event, including laboratory test abnormality, with a reasonable time 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.</p> <p><b>Unlikely:</b> 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.</p> <p><b>Conditional/Unclassified:</b> 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.</p> <p><b>Unassessible/Unclassifiable:</b> A reported adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.</p>
<b>Conditions of Use Source</b>	Amended from Edwards, IR and C Biriell. 'Harmonisation in Pharmacovigilance'. Drug Safety 10.2 (1994): 93-102; The Uppsala Monitoring Centre; "The use of the WHO-UMC system for standardised and causality assessment". Note: These sources specifically relate to drug adverse events or pharmacovigilance. The modifications here are done to broaden the assessment to all agents which might cause or be suspected of causing an adverse event.
<b>Misuse</b>	

### Relationships

**Parents**

Data Type	Name	Version
<b>T</b> <sub>010</sub>	Agent Description Certainty	1.0

## Agent Type

### Identification

<b>Name</b>	Adverse Reaction Type		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-020	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The category of the agent/substance that classifies the adverse reaction.		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>	Agent class, Substance type.		
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>	The expectation exists that this field will be derived from terminology structure.		
<b>Data Type</b>	CodedText		
<b>Value Domain</b>	Agent Type values		

### Usage


<b>Conditions of Use</b>			
<b>Conditions of Use Source</b>			
<b>Examples</b>	Example 1) Food. Example 2) Animal. Example 3) Chemical.		
<b>Misuse</b>			

### Data Flow

<b>Sender Type</b>	Either system or human.		
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.		
<b>Recipient Type</b>	Either system or human.		
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.		

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Desirable		Single

## VD Agent Type values

### Identification

<b>Name</b>	Agent Type values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-031
<b>Version</b>	1.0

### Definition

<b>Definition</b>	The agent/substance causing an adverse reaction.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Animal; Chemical; Environment; Food; Drug; and None known.

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other. Animal: Includes insects. None known: Use 'None known' for retrospective data collection only.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
T <sub>010</sub>	Agent type	1.0

## REACTION DETAILS

### Identification

<b>Name</b>	REACTION DETAILS	
<b>Metadata Type</b>	Data Group	
<b>Identifier</b>	DG-511	<i>External Identifier</i>
<b>Version</b>	1.0	

### Definition

<b>Definition</b>	The collection of information about specifics of the adverse reaction to an agent/substance.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Scope</b>	Specific information about the agent/substance that has resulted in an adverse reaction.
<b>Scope Source</b>	NEHTA
<b>Assumptions</b>	

### Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Misuse</b>	

### Data Flow




<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Optional		Single

#### Children

Data Type	Name	Version	Obligation	Condition	Occurrence
	Reaction Description	1.0	Desirable		Single
	Severity	1.0	Desirable		Single
	DateTime:Start	1.0	Optional		Single

## Reaction Description

### Identification

<b>Name</b>	Reaction Description		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-063	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The signs and/or symptoms experienced or exhibited by the subject of care as a manifestation of the adverse reaction to a specific agent/substance, as determined by a healthcare provider.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	The signs and/or symptoms of the adverse reaction are relevant as it contributes 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.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	CodedText
<b>Value Domain</b>	<a href="#">Reaction Description values</a>

### Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Examples</b>	Example 1) Itchy eyes. Example 2) Dysphagia. Example 3) Tinnitus.
<b>Misuse</b>	

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	<a href="#">REACTION DETAILS</a>	1.0	Desirable		Single

## VD Reaction Description values

### Identification

<b>Name</b>	Reaction Description values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-032
<b>Version</b>	1.0

### Definition

<b>Definition</b>	The signs and/or symptoms experienced or exhibited as a consequence of the adverse reaction to the agent/substance.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
<b>T/T</b> <sub>010</sub>	Reaction Description	1.0

# Severity

## Identification

<b>Name</b>	Severity		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-031	<i>External Identifier</i>	
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	Clinical judgement of the degree of seriousness of an observed or reported event.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	The severity relates to the level of risk to the subject of care.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	CodedText
<b>Value Domain</b>	Severity values

## Usage


<b>Conditions of Use</b>	To record the severity of an event as determined by clinical judgement following assessment.
<b>Conditions of Use Source</b>	NEHTA
<b>Examples</b>	Example 1) Mild. Example 2) Disabling. Example 3) Life threatening.
<b>Misuse</b>	

## Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

## Relationships

### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	<a href="#">REACTION DETAILS</a>	1.0	Desirable		Single

## VD Severity values

### Identification

<b>Name</b>	Severity values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-005
<b>Version</b>	1.0

### Definition

<b>Definition</b>	Clinical judgement of the degree of seriousness of an issue/event.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Disabling; Life threatening; and Mild.

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	<p>The value domain options are mutually exclusive and cannot be used in conjunction with each other.</p> <ul style="list-style-type: none"> <li>• Mild: A slight reaction which requires little or no treatment and has minimal sequelae.</li> <li>• Disabling: A reaction causing a temporary or permanent loss or restriction of functional ability or activity.</li> <li>• Life Threatening: An extreme reaction which without immediate and/or continuing treatment/intervention will result in serious sequelae or death.</li> </ul>
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
T <sub>010</sub>	Severity	1.0

## DateTime Started

### Identification

<b>Name</b>	DateTime Started		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-15507	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The date or date and time that the specific Reaction was commenced. <i>The date and time could be automatically generated the system, or could be entered or overridden by a user if required.</i>		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>			
<b>Data Type</b>	DateTime		
<b>Value Domain</b>			

### Usage


<b>Conditions of Use</b>	Where possible, exact dates should be used. Incomplete dates should generally only be used for retrospective data collection.		
<b>Conditions of Use Source</b>	NEHTA		
<b>Examples</b>	Example 1) 31/03/2004. Example 2) 03/2004. Example 3) 2004. Example 4) 31/03/2004 13:10.		
<b>Misuse</b>	Entering approximate dates when an exact date is available.		

### Data Flow

<b>Sender Type</b>	Either system or human.		
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.		
<b>Recipient Type</b>	Either system or human.		
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.		

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	<a href="#">REACTION DETAILS</a>	1.0	Optional		Single

## Information Provided By

### Identification

<b>Name</b>	Information Provided By		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-503	<b>External Identifier</b>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	A category of the source of the health information in this record.		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>			
<b>Data Type</b>	CodeableText		
<b>Value Domain</b>	Information Provided By values		

### Usage


<b>Conditions of Use</b>	To specify the source of the subject of care's health information when information is being captured by a healthcare provider.		
<b>Conditions of Use Source</b>	NEHTA		
<b>Examples</b>	Example 1) Subject of care. Example 2) Carer.		
<b>Misuse</b>			

### Data Flow

<b>Sender Type</b>	Either system or human.		
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.		
<b>Recipient Type</b>	Either system or human.		
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.		

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Desirable		Single

## VD Information Provided By values

### Identification

<b>Name</b>	Information Provided By values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-050
<b>Version</b>	1.0

### Definition

<b>Definition</b>	A category which specifies the source of the information.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Carer; Device; Healthcare provider; and Subject of care.

### Usage

<b>Default Value</b>	Healthcare provider.
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other. Carer: An individual who provides regular and sustained care and/or assistance to the subject of care.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
<b>T/T</b> <sub>010</sub>	Information Provided By	1.1

## Adverse Reaction Status

### Identification

<b>Name</b>	Adverse Reaction Status		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-100	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	An indication of whether the stated adverse reaction is considered an active or inactive health issue, as determined by a healthcare provider.		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>			
<b>Data Type</b>	CodedText		
<b>Value Domain</b>	Adverse Reaction Status values		

### Usage


<b>Conditions of Use</b>			
<b>Conditions of Use Source</b>			
<b>Examples</b>	Example 1) Rechallenge outcome - active. Example 2) Active - no rechallenge performed. Example 3) Inactive - no rechallenge performed. Example 4) Rechallenge outcome - inactive.		
<b>Misuse</b>			

### Data Flow

<b>Sender Type</b>	Either system or human.		
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.		
<b>Recipient Type</b>	Either system or human.		
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.		

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Desirable		Single

## VD Adverse Reaction Status values

### Identification

<b>Name</b>	Adverse Reaction Status values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-056
<b>Version</b>	1.0

### Definition

<b>Definition</b>	An indication of whether the stated adverse reaction is considered an active or inactive ongoing health issue.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Active - no rechallenge performed. Inactive - no rechallenge performed. Rechallenge outcome - active. Rechallenge outcome - inactive.

### Usage

<b>Default Value</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
<b>Conditions of Use</b>	Active: The adverse reaction is considered an ongoing health issue, e.g. active allergy to penicillin or bee sting. Inactive: The adverse reaction is not considered an ongoing health issue, e.g. intolerance to lactose was suspected, but this now does not appear to be the case anymore. Rechallenge outcome - active: A rechallenge of the adverse reaction has occurred and it is still considered an ongoing health issue, e.g. an adverse reaction to penicillin was reported. A clinically controlled rechallenge was performed, resulting in symptoms and signs of continuing allergy. Rechallenge outcome - inactive: A rechallenge of the adverse reaction has occurred and it is no longer considered an ongoing health issue, e.g. the subject of care had a reported adverse event to bee sting. After a course of desensitisation, a rechallenge produced no reaction - problem determined now as inactive.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
<b>T</b> <sub>010</sub>	Adverse Reaction Status	1.0

## Adverse Reaction Outcome

### Identification

<b>Name</b>	Adverse Reaction Outcome		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-588	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The state of well-being of the subject of care after experiencing the adverse reaction and being treated for it, if required.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	Information about the clinical status of the subject of care after the adverse reaction occurred and was treated, if treatment was necessary.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	CodeableText
<b>Value Domain</b>	Adverse Reaction Outcome values

### Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Examples</b>	<p>Example 1) Recovered (without sequelae).</p> <p>Example 2) Recovered (with sequelae).</p> <p>Example 3) Death (=death as the primary reaction to the agent).</p> <p>Example 4) Death (=death as an overall outcome of the adverse reaction).</p> <p>Example 5) Death (=unrelated to the adverse event).</p> <p>Example 6) Not yet recovered.</p> <p>Example 7) Unknown.</p>
<b>Misuse</b>	

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Optional		Single

## VD Adverse Reaction Outcome values

### Identification

<b>Name</b>	Adverse Reaction Status values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-126
<b>Version</b>	1.0

### Definition

<b>Definition</b>	The state of well-being of the subject of care after experiencing the adverse event and being treated for it, if required.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	Australia Adverse Drug Reaction Reporting System, TGA
<b>Version Number</b>	
<b>Permissible Values</b>	Death (=death as an overall outcome of the adverse reaction); Death (=death as the primary reaction to the agent); Death (=unrelated to the adverse event); Not yet recovered; Recovered (with sequelae); Recovered (without sequelae); and Unknown.

### Usage

<b>Default Value</b>	
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
<b>T/T</b> <sub>010</sub>	Adverse Reaction Outcome	1.0

## Adverse Reaction Note

### Identification

<b>Name</b>	Adverse Reaction Note		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-590	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	Free text comments relevant to the adverse reaction in question.		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>	Used to provide additional narrative information in relation to the adverse reaction.		
<b>Context Source</b>	NEHTA		
<b>Assumptions</b>			
<b>Data Type</b>	Text		
<b>Value Domain</b>			

### Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Examples</b>	
<b>Misuse</b>	

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Optional		Single

# REPORTER IDENTIFICATION

## Identification

<b>Name</b>	REPORTER IDENTIFICATION		
<b>Metadata Type</b>	Data group		
<b>Identifier</b>	DG-15520	<b>External Identifier</b>	AS4846-2006
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	Details pertinent to the identification of a healthcare provider individual who is reporting the alert information.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	
<b>Context Source</b>	NEHTA
<b>Scope</b>	
<b>Scope Source</b>	NEHTA
<b>Assumptions</b>	

## Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Misuse</b>	

## Data Flow



<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.





## Relationships

### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Essential		Single

### Children

Data Type	Name	Version	Obligation	Condition	Occurrence
	HEALTHCARE PROVIDER IDENTIFIER-INDIVIDUAL (see external reference for full specification: AS4846 - 2006)	1.0	Desirable		Single
	PERSON NAME (see external reference for full specification: AS4846 - 2006)	1.0	Essential		Single

	<p><b>ORGANISATION NAME</b> (see external reference for full specification: AS4846 - 2006)</p>	1.0	Conditional	(required if requesting healthcare provider facility is external to the Diagnostic Imaging Service provider facility)	Single
	<p><b>ADDRESS</b> (see external reference for full specification: AS4846 - 2006)</p>	1.0	Conditional	(required if requesting healthcare provider facility is external to the Diagnostic Imaging Service provider facility)	Single
	<p><b>ELECTRONIC COMMUNICATION DETAILS</b> (see external reference for full specification: AS4846 - 2006)</p>	1.0	Essential		Single
	<p><b>Provider Occupation Category</b></p>	1.0	Optional	(may be required for certain test requests, e.g. MRI)	Single

# DE DateTime Reported

## Identification

<b>Name</b>	DateTime Reported		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-15508	<i>External Identifier</i>	
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	The date or date and time that the specific Adverse Reaction was reported. <i>The date and time could be automatically generated the system, or could be entered or overridden by a user if required.</i>		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>			
<b>Data Type</b>	DateTime		
<b>Value Domain</b>			

## Usage


<b>Conditions of Use</b>	Where possible, exact dates should be used. Incomplete dates should generally only be used for retrospective data collection.		
<b>Conditions of Use Source</b>	NEHTA		
<b>Examples</b>	Example 1) 31/03/2004. Example 2) 03/2004. Example 3) 2004. Example 4) 31/03/2004 13:10.		
<b>Misuse</b>	Entering approximate dates when an exact date is available.		

## Data Flow

<b>Sender Type</b>	Either system or human.		
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.		
<b>Recipient Type</b>	Either system or human.		
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.		

## Relationships

### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	ADVERSE REACTION	1.0	Optional		Single

# Acronyms

<b>AIHW</b>	Australian Institute of Health & Welfare
<b>EHR</b>	Electronic Health Record
<b>HL7</b>	Health Level Seven
<b>MBS</b>	Medical Benefits Scheme
<b>METeOR</b>	MEtadata On-line Registry ( <a href="http://meteor.aihw.gov.au">http://meteor.aihw.gov.au</a> )
<b>NEHTA</b>	National E-Health Transition Authority
<b>SEHR</b>	Shared Electronic Health Record

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