

Clinical Package Validator User Guide

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1 Introduction

1.1 Purpose

This document is a guide for developers and testers who use ("users") version 2.7 of the Clinical Package Validator ("the Validator") to test whether their healthcare software system is producing clinical packages and documents that conform to the relevant specifications for the document type.

To the extent users wish to use the Validator to test conformance, users should not rely on the Validator alone to determine conformance, and independent testing will be required. The Validator is a tool to assist users only. The Validator does not test all conformance specifications and users should carefully read the *Clinical Package Validator Product Data Sheet*. For further guidance, contact the Agency Help Centre on 1300 901 001 or help@digitalhealth.gov.au.

1.2 Intended audience

This document is intended for:

- testers who use the Validator to assess whether their healthcare software system produces clinical documents and clinical packages that conform to the relevant specifications; and
- developers who use the Validator to provide quick feedback for software development.

1.3 Scope

This document describes the use of the Validator to test:

- whether the syntax and structure of a clinical document are conformant with specifications, and
- whether codes within a clinical document can be found in code systems supported by the Validator.

It also describes how the Validator can be used to validate certain clinical packages and an HL7 Medical Document Management (MDM) wrapped clinical package.

1.4 Overview

The Validator is a tool for testing whether a healthcare software system is producing certain (but not all) clinical documents that conform to the relevant document CDA implementation guide, structured content specification, and the My Health Record conformance profile specification.

In addition, the Validator tests certain (but not all) codes in clinical documents, and tests clinical packages to determine whether they conform to the packaging specifications.

The Validator does not test all conformance specifications and users should carefully read the *Clinical Package Validator Product Data Sheet* to determine what the Validator cannot be used for, and for further guidance contact the Agency on 1300 901 001 or <u>help@digitalhealth.gov.au</u>.

2 Tests performed by the Validator

The Validator performs the following tests:

- package validation;
- template validation;
- code validation; and
- XDS metadata validation

It can be used to assist a vendor testing the following types of files:

- a clinical document;
- a clinical package containing a clinical document, eSignatures, and other documents (e.g. attachments); and
- an HL7 MDM wrapped clinical package containing a clinical document.

Please refer to the *Clinical Package Validator Product Data Sheet* for further details of tests in scope.

2.1 Package validation

2.1.1 Package requirements

The clinical package requirements describe how to construct a conformant ZIP file containing a clinical document, create and include eSignatures, and properly reference attachments from that clinical document.

The requirements for a clinical package are described in the *CDA Package* specification [NEHTA2011a] and the *Clinical Documents - Common Conformance Profile* [NEHTA2015c]. Requirements for referencing attachments are listed in the *CDA Package* specification [NEHTA2011a], *CDA Rendering Specification* [NEHTA2012a], and the *Clinical Documents - Common Conformance Profile* [NEHTA2015c].

Additional requirements for clinical packages apply, depending on whether the My Health Record (MHR) or provider to provider (P2P) context is selected by the user. The *PCEHR Document Exchange Service Logical Service Specification* [NEHTA2014b] and the *PCEHR Document Exchange Service Technical Service Specification* [NEHTA2014c] list requirements that apply to clinical packages sent to the My Health Record system (referred to as the My Health Record context). Requirements for clinical packages sent from one healthcare provider to another healthcare provider (referred to as the P2P context) are listed in the *P2P Document Delivery Technical Service Specification* [NEHTA2012b].

The P2P context imposes fewer constraints on a clinical package than the My Health Record context. For example, a general practitioner may attach a report from a pathology laboratory to an eReferral that is to be sent to a specialist. If, however, the eReferral is to be sent to the My Health Record system, the general practitioner cannot attach the pathology report to the eReferral, because only the author of a document can upload that document to the My Health Record system.

2.1.2 Assessing a clinical package using the Validator

To determine whether a clinical package conforms to some packaging requirements, the Validator applies a non-exhaustive set of tests. The tests that are applied will depend on whether the user has selected the My Health Record or P2P context (Section 3.2.4) and on whether the Validator is able to perform the tests. You should refer to the *Clinical Package Validator Product Data Sheet* or contact the Agency Help Centre on 1300 901 001 or <u>help@digitalhealth.gov.au</u> to confirm that the Validator may be used to carry out the required tests. If the user selects the My Health Record context, only the set of tests for the My Health Record context is applied. Similarly, if the P2P context is selected, only the set of tests for the P2P context is applied.

Some of the clinical package test cases applied by the Validator for both the My Health Record and P2P contexts are described in the *Conformance Test Specification for CDA Packaging* [NEHTA2015b].

2.1.3 Limitations of package validation

The package validation function of the Validator has the following limitations:

- 1 In both the My Health Record and P2P contexts:
 - a The tests that are applied to an attachment to a clinical document do not work if the attachment is compressed.
 - b The Validator checks the dates and times within a Public Key Infrastructure (PKI) certificate to make sure that the certificate was valid when it was used to sign a clinical document. It does not, however, check whether the certificate was on the revocation list when the clinical document was signed.
 - c The Validator does not check whether national healthcare identifiers in the eSignature are registered in the national healthcare identifier service. Nor does it determine whether there is any relationship between the identifier for the approver, the identifier in the certificate, and the identifiers in the clinical document.
 - d Some types of clinical documents may contain a reference to a file (e.g. an image) on a network location such as a website. The Validator does not verify the value of the integrityCheck attribute that may be associated with such a reference.¹
- 2 In the P2P context:
 - a Package validation tests are not applied to an attachment to a clinical document if that attachment is a clinical package. In this case, the tester must extract the attachment from the clinical package and manually apply the Validator to it.
 - b The tests that are applied to an attachment to a clinical document do not work if the attachment and clinical document are in different folders.
 - c A clinical package may contain multiple eSignature files; typically, one for each person who approved the clinical document and the clinical information within it. The primary eSignature file has the filename CDA_SIGN.XML and this is the only

¹ To perform this verification, a tester may access tools or websites that apply the SHA-1 calculation to the referenced file. It is important to note that the Agency's specifications require the inclusion of the integrity check value in a base64 format rather than in a hexadecimal format.

eSignature validated by the Validator. The Validator will report if it finds other eSignatures, but it will not validate them.

d A clinical package may contain a package index, but the Validator does not examine the package index when validating a clinical package.

2.2 Template validation

The Validator can apply two templates to a clinical document:

- 1 a My Health Record template which is applied by the My Health Record system to a clinical document uploaded to it; and
- 2 an additional template containing additional validation rules.

A My Health Record template exists for each type of clinical document at each level of conformance. When a clinical document is being validated, the Validator will apply the template that the user has decided is relevant to that document including user-generated templates.

An additional template containing additional validation rules may also be applied if additional quality criteria apply in a particular context.

My Health Record templates may be obtained from a number of sources:

- template package libraries published on the Agency website², which contain a set of clinical document template packages; and
- template packages included in the My Health Record software vendor test environment.

Additional template packages are available from the Agency.

A template consists of the Australian CDA schema and Schematron rules. The Australian CDA schema constrains the set of data elements that may be used in a clinical document. The Australian CDA schema also contains rules that define the data types that are allowed for a data element, their attributes, and the allowed parent/child relationships. Schema rules are not specific to a type of clinical document or a conformance level, but are derived from the *HL7 Clinical Document Architecture, Release 2.0* specification [HL72004] and the *Australian CDA Schema Extension* [NEHTA2014a].

Schematron is a rule-based validation language that is capable of expressing constraints that cannot be expressed in a CDA schema. My Health Record templates contain Schematron rules developed for each type of clinical document at each level of conformance. These rules describe the required cardinality of data elements in a clinical document and the relationships between these data elements. They also check whether a data element value is an allowed value.

Schematron rules are derived from the My Health Record conformance profile for each type of clinical document, the relevant structured content specification, the relevant CDA implementation guide, and specifications referred to by these documents.

² These can be derived from the relevant clinical document end product at <u>http://www.digitalhealth.gov.au/implementation-</u><u>resources/clinical-documents</u>.

The Validator applies template validation to the following:

- Clinical documents created by clinical information systems and contracted service provider systems, such as:
 - birth details, child parent questionnaires, consumer entered achievements, consumer entered measurements, discharge summaries, eHealth diagnostic imaging reports, eHealth dispense records, eHealth pathology reports, eHealth prescription records, eReferrals, event summaries, health check assessments, shared health summaries, and specialist letters.
- Clinical documents created by consumer portals, such as:
 - advance care directive custodian documents, personal health notes, and personal health summaries.
- Clinical documents created by Medicare repositories, such as:
 - Australian immunisation register reports, Australian organ donor register reports, Medicare Department of Veterans' Affairs (DVA) benefits reports, and pharmaceutical benefits reports.
- Clinical documents created by the My Health Record system, such as:
 - eHealth prescription and dispense views, health check schedule views, Medicare overviews, and observation views.

2.2.1 Limitations of validation by My Health Record templates

The My Health Record template validation function of the Validator has a number of limitations. These are listed in detail in the *Clinical Package Validator Product Data Sheet*.

Broadly speaking, the following high level limitations apply:

- 1 My Health Record templates published by the Agency have been developed for My Health Record requirements rather than P2P requirements. If the P2P context is selected and the Validator reports that the clinical document references attachments of a disallowed type, the template error message may be ignored because the error message only applies to the My Health Record context.
- 2 My Health Record template validation only checks whether the minimum requirements for a conformance level have been met. No checks are applied to those data elements in a clinical document that are not required for that conformance level. For example, because the body of a conformance level 2 document need not contain structured data, the template for a level 2 document does not contain any checks for structured data. The Validator will ignore any structured data that may be present in a document that is being assessed for level 2 conformance. To assess this structured data, a template for level 3A conformance may be applied by the Validator, even though the document is only being assessed for level 2 conformance.
- Extensions to a clinical document are only subjected to Australian CDA schema checks.
 The My Health Record templates contain no Schematron rules for these extensions.
 Extensions may be additional sections or data elements that have not been defined in the

relevant CDA implementation guide. A clinical document may also be extended by incorporating information from any detailed clinical model published by the Agency.

4 My Health Record templates do not include rules for every conformance requirement listed in the specifications. They are only an aid for assessing the conformance of clinical documents. Validation using My Health Record templates must be accompanied by manual inspection of clinical documents and the application of the relevant conformance test specification for the selected type of clinical document.

An additional template with additional rules developed by the user may be applied to assist a user in overcoming these limitations.

2.3 Code validation

Terminology codes from code systems that are static and small in size (e.g. types of telecommunication address) are validated during template validation; whereas codes from code systems that are regularly updated or are large in size may be validated during code validation.

The Validator checks each code system identifier in a clinical document to determine whether it is one of the code system identifiers listed in Table 1. It then determines whether the associated code and display name are present in the relevant code system, and if the code system name has the expected value.

Code system name	Code system identifier
Australian Medicines Terminology (AMT) version 3	2.16.840.1.113883.6.96
Australian Medicines Terminology (AMT) version 2	1.2.36.1.2001.1004.100
Australian and New Zealand Standard Industrial Classification (ANZSIC)	1.2.36.1.2001.1005.47
Australian and New Zealand Standard Classification of Occupations (ANZSCO)	2.16.840.1.113883.13.62
Australian Vaccines codes	1.2.36.1.2001.1005.17
Clinical specialty codes	2.16.840.1.113883.3.879.329673
HL7 identifier types	2.16.840.1.113883.12.203
HL7 service delivery role types	2.16.840.1.113883.1.11.17660
PBS Item codes	1.2.36.1.2001.1005.22
PBS Manufacturer codes	1.2.36.1.2001.1005.23
Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU)	2.16.840.1.113883.6.96

Table 1 - Code systems supported by the Validator

The Validator validates primary codes and translated codes for all conformance levels³, thereby looking up and validating every code in a clinical document that belongs to the code systems listed in Table 1.

2.3.1 Reference set validation

CDA implementation guides for clinical document types specify reference sets for some of the coded fields. Reference sets are subsets of codes applicable to particular usage contexts.

In addition to the generic validation of codes against code sets (see section 2.3), the Validator performs additional validation against reference sets where these are specified in the CDA implementation guide of the particular document type.

Table 2 lists the code systems for which reference sets are currently available.

Code system name	Code system identifier
Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU)	2.16.840.1.113883.6.96
Australian Medicines Terminology (AMT) version 3	2.16.840.1.113883.6.96
Australian Medicines Terminology (AMT) version 2	1.2.36.1.2001.1004.100

Table 2 - Code systems with additional validation against reference sets

Reference sets are specified in the 'Vocab' column of CDA implementation guides. Figure 1 shows the 'Vocab' column of the *eReferral CDA Implementation Guide*.

NEHTA SCS Data Compon- ent	Data Component Definition	Card	CDA Schema Data Element	Vocab	Comments
CDA Body Level 3 Data Elements			Context: ClinicalDocument/component/structuredBody/component[med_hist]/section		
Problem/Diagnosis	The problems and/or diagnoses that form part of the	0*	entry[prob]		
	past and current medical history of the subject of care.		entry[prob]/observation		
			entry[prob]/observation/@classCode="OBS"		
			entry[prob]/observation/@moodCode="EVN"		
			entry[prob]/observation/id	UUID This is a technical identifier that is used for system purposes such as matching. If a suitable internal key is not available, a UUID may be used.	See <id> for avail- able attributes.</id>
			entry[prob]/observation/code		
			entry[prob]/observation/@code="282291009"		
			entry[prob]/observation/@codeSystem="2.16.840.1.113883.6.96"		
			entry[prob]/observation/@codeSystemName="SNOMED CT-AU"		
			entry[prob]/observation/@displayName="Diagnosis interpretation"		
Problem/Diagnosis > Problem/Diagnos- is Identification	Identification of the problem or diagnosis.	11	entry[prob]/observation/value:CD	SNOMED CT-AU Problem/Diagnosis Reference Set	See <code> for available attributes.</code>
Problem/Diagnosis > Date of Onset	Estimated or actual date the Problem/Diagnosis began, in the opinion of the clinician.	01	entry[prob]/observation/effectiveTime		See <time> for available attributes.</time>

Figure 1: Vocab column of eReferral CDA implementation guide

The Validator examines a pre-configured set of locations in clinical documents from a set of clinical document types to make sure that the codes in those locations are from the specified reference sets.

These locations have been configured for the following types of clinical documents:

³ The code system used by a health software system is considered the *primary code system*. If the primary code system is mapped to another code system, a code from the second code system is called a *translation* and may be included in a clinical document.

- Discharge Summary;
- eHealth Diagnostic Imaging Report;
- eHealth Dispense Record;
- eHealth Prescription Record;
- eReferral;
- Event Summary;
- Shared Health Summary;
- Specialist Letter.

In the example in Figure 1, the Validator determines whether codes used for the Problem/Diagnosis data element within an eReferral clinical document are contained within the Problem/Diagnosis reference set of the SNOMED CT-AU code system.

If the Validator finds a code from a code system that is not listed in Table 1, it will report a warning to indicate it cannot validate the code.

2.3.2 Case significance

If a code in a clinical document is from a code system derived from SNOMED CT, including SNOMED CT-AU and AMT version 3, the Validator will use case significance to determine whether the value of the display name of that code is the preferred term. Display names of codes from other code systems supported by the Validator are not considered to be case sensitive.

The *SNOMED CT Technical Implementation Guide* [IHTSDO2014] describes how case significance can be used to determine whether a clinical document display name matches the preferred term from the relevant specification.

If the preferred term is entirely case sensitive, the case and text used in the clinical document display name must exactly match that of the preferred term.

If only the initial character of the preferred term is case insensitive, the initial character of the display name may be either lower or upper case (i.e. the initial character of other words in the term are case sensitive). If the entire preferred term is case sensitive, the text in the display name may be either lower or upper case.

2.3.3 Limitations of code validation

The code validation function of the Validator has many limitations, including the following:

- 1 Validation of ANZSCO codes uses the Australian and New Zealand Standard Classification of Occupations, First Edition Revision 1, issued 25 June 2009. Previous and later versions of ANZSCO are not supported by the Validator.
- 2 Code validation is not yet available for all types of clinical documents supported by version 2.7 of the Validator.
- 3 The Validator searches a clinical document for occurrences of the code system identifiers listed in Table 1 and overlooks occurrences of other code system identifiers. The user must manually inspect a clinical document for occurrences of other code system identifiers to verify the associated code system name, code and display name.

2.4 XDS Metadata validation

Additional rules are applied when uploading a document to the My Health Record system. These rules test data that are not only inside the CDA Package, but accompany the CDA Package as what is known as XDS Metadata.

This validation takes a request SOAP message (XML) for uploading a CDA document to the My Health Record system, and does a number of checks that the My Health Record system also performs, but gives a more helpful response than 'Document metadata failed validation'.

It also displays all the data it did find to that the user can check it was what they expected it to be.

2.5 Other limitations of the Validator

In addition to the limitations of package validation (Section 2.1.3), template validation (Section 2.2.1) and code validation (Section 2.3.3), the following limitations also apply to version 2.7 of the Validator:

- 1 Where the Validator can be used to test a clinical document (please refer to the *Clinical Package Validator Product Data Sheet*), the Validator renders that clinical document into a human-readable form. Its rendering conforms to most, but not all, of the generic requirements for the rendering of clinical documents stated in the *CDA Rendering Specification, Clinical Documentation* [NEHTA2012a].
- 2 The generic requirements for rendering clinical documents do not apply to eHealth prescription and dispense views, even though these views are clinical documents. The Validator does not implement the specific requirements for rendering eHealth prescription and dispense views, but instead applies the generic CDA rendering requirements.
- 3 Some types of conformance tests are inherently manual and cannot be automated in the Validator.

As a result of these and other limitations, the validation of a clinical document cannot be solely performed by the Validator. It must be accompanied by manual inspection of the clinical document's XML file.

3 Using the Validator

This section describes the menus, parameters, commands and other features of the Validator. It also describes the results and reports generated by the Validator.

3.1 Validator menus

This section describes the purpose of each Validator menu option.

Note: Gaps in the file paths within the following screenshots should feature your username or equivalent when following the documented procedures.

3.1.1 File menu

File Config	guration Help	
	Select an input file to validate	
Template:		-
Addn Rules:	Select additional rules template folder for validation	

Figure 2: File menu option

• File \rightarrow Exit

The Validator will close if this menu option is selected.

3.1.2 Configuration menu

File	Configuration Help		
	Manage Templates		
	Manage Terminology		
	Manage Temporary File Location		
Temp	late:	▼	
Addn F	Rules: Select additional rules template folder fo	or validation	

Figure 3: Configuration menu options

• Configuration → Manage Templates

Template Management: This menu option allows the user to import and manage My Health Record templates for validating clinical documents (Figure 4). Template management is described in the *Clinical Package Validator Installation and Configuration Guide*.

		Template Manage	r –	□ ×
Manage Terr Configuration NASH Test Certificate Templates Packages	plates CN=general.8003629900024031.id.electronichealth.net.au,O=DHSITESTORG			✓ /rer 3186: /rer 32721
Refresh from SVT]		Add From Zip File Delete	
				Close

Figure 4: Template management menu

• Configuration \rightarrow Manage Terminology

Terminology Management: This menu option allows the user to see which terminology datasets are installed, load new terminology datasets, and remove terminology datasets (Figure 5). Terminology management is described in the *Clinical Package Validator Installation and Configuration Guide*.

[] Terminology		×
Terminology DB File: Terminology DB.sdf 450MB Refresh Terminology Loaded:	NB: Select the root folder after unzipping the terminology package. The subfolder should be called RF2Release for SNOMED/AMT. From Dec 2015 SNOMED and AMT come in one file. The 'Load SNOMED/AMT v3' now only supports this format. AMT v2 is no longer supported.	
	Load SNOMED/AMT v3; Folder Zip Clear All SNOMED datasets	
	Load PBS: Folder Zip Clear All PBS datasets	
	For SNOMED/AMT data visit this website or use NCTS syndication feed <u>https://www.healthterminologies.cov.au</u> NCTS Syndication Feed	
	For PBS data visit this website, and select PBS XML V3 file (ZIP) http://www.pbs.gov.au/browse/downloads	
Remove old dataset	Compress DB	
	с	llose

Figure 5: Terminology management menu

• Configuration \rightarrow Manage Temporary File Location

Default Temp Directory Path: This menu option allows the user to change the location used for storing temporary files (Figure 6). More information is described in the *Clinical Package Validator Installation and Configuration Guide*. Please note the text in RED. This highlights that the Validator will delete every file and subfolder in this temporary folder, every time it runs. So do not set it to any folder that contains files you need to keep.

	Configuration
Default Ten	np Directory Path :
C:\DigitalHe	ealth\CPV27\Temp
ANYTHING	n to point to where you store your temporary data. PLEASE NOTE, IN THIS DIRECTORY (including sub-directories) WILL BE DELETED E THE VALIDATOR RUNS, so don't set it to a directory where you have In to keep.
	Save Cancel

Figure 6: Default temp directory path menu

3.1.3 Help menu

• Help \rightarrow About

This menu option displays the version number, copyright, and acknowledgements for the Validator.

3.2 Validator parameters

Before the Validator can validate a clinical document or clinical package, some parameters must first be set.

If the Validator has been installed and configured according to the *Clinical Package Validator Installation and Configuration Guide*, the only parameter that may need to be set is the clinical document or package to be validated. The full set of parameters that may be set are listed in Table 3.

Please refer to the *Clinical Package Validator Product Data Sheet* for more details on the scope of template package validation.

Parameter	When to set
Clinical document or package to be validated	Always.
Template to be applied	If there is more than one template to select from.
Additional template to be applied	If an additional template package is to be applied.
Context	If the context is not the default value of 'My Health Record'.

3.2.1 File parameter

The File parameter displays the location of the document that is to be validated (Figure 7).

File Conf	iguration Help				
File :	Select an input file to validate	6	MHR O P2P	Run Conformance	Load and Validate XDS Metadata
Template:	v		0.1	Snow Report	
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only	
Information					



The Validator uses the filename extension to determine the type of the file to be validated:

- a file with the '.xml' or '.XML' filename extension is assumed to be a clinical document;
- a file with the '.zip' filename extension is assumed to be a clinical package; and
- a file with the '.hl7' filename extension is assumed to be an HL7 MDM wrapped clinical package.

Two options are provided for selecting the file that is to be validated. The first option is to select the file by browsing:

1 Click the **File Open** button (Figure 8).

File Configuration Help				
File : Select an input file to validate	<u> </u>	MHR	Run Conformance	Load and Validate XDS Metadata
		○ P2P	Show Report	
Template:	¥			
Addn Rules: Select additional rules template folder for validation			Run Addn Rules Only	
Information				

Figure 8: Selecting the XML button

2 Navigate to the location of the clinical document, clinical package or HL7 MDM wrapped clinical package, select the file and click **Open** (Figure 9).

🔲 Open						x
Solution → test →				✓ Search test		٩
Organize 🔻 New folder				:== ▼ [-	0
🚖 Favorites	Name	Date modified	Туре			
🗼 Downloads	1.3.16.1.38818.2305739 - MBS	22/05/2013 5:42 PM	Compresse			
🧮 Desktop	DDA_in_CDA	9/05/2014 4:42 PM	Compresse			
🕮 Recent Places	DCDA_IN_CDA_2	9/05/2014 4:42 PM	Compresse			
🧮 Desktop (2)	CDA_SIGN	30/04/2014 12:50	XML File			
	Discharge_Summary_Invalid_codeSystem	4/06/2014 11:38 AM	Compresse			
词 Libraries	event summary	16/04/2014 3:16 PM	XML File			
Documents	SharedHealthSummary - Christine Dunca	1/05/2014 4:26 PM	XML File			
👌 Music	TestData_7.hl7	11/04/2014 1:58 PM	HL7 File			
Pictures	1 TestData_7	11/04/2014 1:58 PM	Compresse			
Subversion	TortData 8	13/05/2014 10:05	XML File			
😸 Videos	IntestData_9	30/04/2014 12:50	Compresse			
Ecomputer	<		,	Select a file to preview.		
File name:				✓ CDA Validator Files		
File name					ncel	

Figure 9: Selecting the file to be validated

The second option for selecting the file to be validated is to drag the file and drop it into either the **File** field or the **Information** tab (Figure 10).

File Configuration Help				
File : Select an input file to validate		MHR P2P	Run Conformance	Load and Validate XDS Metadata
Template: v Addn Rules: Select additional rules template folder for validation	6		Run Addn Rules Only	
Information				



The Validator automatically examines the content of the file to determine the type of the clinical document being validated. The types of clinical documents that are known to the Validator are listed in section 2.2. The dinical document type is displayed in the Document Type field in the Information tab (Figure 11).

File Confi	guration Help			
File :	C:\User\Desktop\CDa-DischargeSummary_Test_For_RCH.xml		MHRP2P	Run Conformance
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)			
Addn Rules:	Select additional rules template folder for validation	$\widehat{}$		Run Addn Rules Only
Information				
Configu	ration and Runtime Information			
	Template Package			
	Document Type: Discharge Summary			

Figure 11: Document Type field displaying the type of the clinical document being validated

If the Validator cannot determine the type of the clinical document being validated, an error message is displayed (Figure 12).

ſ	File Error	J
	Error: Could not determine message type from Xml. Processing terminated	
	ОК	

Figure 12: Error message when the type of a clinical document is unknown

The Validator may display other error messages if a severe error prevents it from continuing (Figure 13 and Figure 14).

Error
CDA_ROOT.XML not found.
ОК

Figure 13: Error message when opening a ZIP file that is not a clinical package

File error		X
enough to process. No futher	rse the input file, or the XML is not well formed r processing can commence. ne expected token is '='. Line 7, position 19.	
	OK	

Figure 14: Error message when opening an XML file that does not conform to the HL7 CDA R2 specification

The Validator will display a warning message if it does not have a template to validate the type of clinical document that has been imported (Figure 15).



Figure 15: Warning message when there is no template for the type of clinical document

The user can continue to still run an Additional Rules template even if a document template does not exist.

3.2.2 Template parameter

The **Template** parameter displays the My Health Record template to be used for validating the selected clinical document (Figure 16).

File Confi	guration Help			
File :	Select an input file to validate	6	MHRP2P	Run Conformance
Template:	~			
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
Information				

Figure 16: The My Health Record template to be used for validation

The **Template** field has no information before a clinical document is selected. Once a document is selected, the Validator will determine the type of the selected document.

The Validator needs a My Health Record template for each type of clinical document at each level of conformance. As templates are revised, more than one template may exist for a specific clinical document type and conformance level. Testers should use the most recent version of a template unless there is a reason for choosing an earlier version. A template package directory is published on the Agency website.⁴

If the Validator has more than one template for the type of document to be validated, the **Template** field will contain a drop-down list of all templates that may be applied so that the user can select a template (Figure 17).

⁴ https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-2016/NEHTA-2321-2016

File :	C:\Users\User\Desktop\CDa-DischargeSummary_Test_For_RCH.xml		6	MHR	Run Conformance
				O P2P	Show Report
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)	×			
ddn Rules:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)				Run Addn Rules Onl
duit Ruica.	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.23 ver 32620)				Run Autor Marco On
	e-Discharge Summary 1B (1.2.36.1.2001.1006.1.20000.19 ver 32620) e-Discharge Summary 1B (1.2.36.1.2001.1006.1.20000.24 ver 32620)				
formation	e-Discharge Summary 1B (1.2.36.1.2001.1006.1.20000.9 ver 147)				
0.0	o Disobargo Summany 2 (1 2 26 1 2001 1006 1 20000 10 yor 149)				
Configu	e-Discharge Summary 2 (1.2.36.1.2001.1006.1.20000.20 ver 32620)				
	e-Discharge Summary 2 (1.2.36.1.2001.1006.1.20000.25 ver 32620)				
	e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.11 ver 149)				
	e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.21 ver 32620)				
	e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)				
Templa	e-Discharge Summary 3B (1.2.36.1.2001.1006.1.20000.22 ver 32620)				
Ten	- Discharge Summary 3B (1.2.36.1.2001.1006.1.20000.27 ver 32620)				
C	onformance Level: 1A				
Templ	late Effective Date: Monday, 1 April 2013				
	Template Version: 32620				
	Template Path: C:\DigitalHealth\CPV26\Templates\1.2.36.1.2001.100	A 1 20000 10	22620		
		0.1.20000.18.	32020		
	Temp Work Path: C:\DigitalHealth\CPV26\Temp				
	Zip file size: Not a zip file				

Figure 17: Selecting a template

The **Template** field displays the document type, conformance level and template identifier for each template. Detailed information about the selected template will be displayed in the **Information** tab (Section 3.4).

A warning message is displayed if a template for the type of clinical document being validated is not available (Figure 18).



Figure 18: Warning message if a template is not available

3.2.3 Addn Rules parameter

The **Addn Rules** parameter displays the additional template to be used for validating a clinical document (Figure 19). Information about the role of an additional template is provided in section 2.2.

File Confi	guration Help			
File :	C:\User\User\Desktop\CDa-DischargeSummary_Test_For_RCH.xml		MHR P2P	Run Conformance
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)	_		
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
Information				
Configu	ration and Runtime Information Template Package			
	Document Type: Discharge Summary			

Figure 19: The additional validation template

Two options are provided for selecting the location of an additional template. The first option is to select the additional template by browsing:

1 Click the folder button (Figure 20).

File Confi	guration Help		
File :	C:\User\Desktop\CDa-DischargeSummary_Test_For_RCH.xml	MHR P2P	Run Conformance
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)		
Addn Rules:	Select additional rules template folder for validation		Run Addn Rules Only
Information			
- Configu	ration and Runtime Information		
	Template Package		
	Document Type: Discharge Summary		

Figure 20: Selecting the folder button



2 Navigate to the directory in which the additional template is stored (Figure 21).

Figure 21: Navigating to the directory containing the additional template

Browse For Folder	×
🔺 🚢 SYSTEM (C:)	*
Additional templates	
Narrative block rules	
A 📗 TEMPLATE	=
DEFN	
TRANS	
> 🕒 VALDN	
D 🖟 cca	
Drivers	
GIRDAC	
🔺 🍌 Nehta	
4 🐌 CPV23	-
	OK Cancel

3 Select the additional template (Figure 22).

Figure 22: Locating and selecting the additional template

In Figure 22, 'C:\Additional templates\Narrative block rules' is the subdirectory in which the additional template was stored.

It is important to select the 'Additional templates\Narrative block rules' subdirectory rather than the 'Additional templates\Narrative block rules\TEMPLATE' subdirectory. The 'Additional

templates\Narrative block rules' subdirectory is referred to as a *template package*. It contains the additional template, an index and a README file (Figure 23).

Name	Date modified	Туре	Size
🐌 TEMPLATE	29/06/2015 12:34	File folder	
🔋 index	23/04/2015 12:24	Firefox HTML Doc	1 KB
README	23/04/2015 12:24	Text Document	1 KB

Figure 23: Contents of a template package

An error message is displayed if the combined length of the template location and folder name is more than 80 characters (Figure 24).



Figure 24: Error message when the combined length of the template location and folder name is too long

The second option for selecting the location of an additional template is to drag the template folder and drop it into the **Addn Rules** field (Figure 25).

File Confi	guration Help			
File :	C:\User\Desktop\CDa-DischargeSummary_Test_For_RCH.xml		MHR P2P	Run Conformance
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)	_		
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
Information				
- Configu	ration and Runtime Information Template Package			
	Document Type: Discharge Summary			

Figure 25: Dragging and dropping an additional template folder into the Addn Rules field

3.2.4 Context parameter

The Validator requires a user to select the context for validating a clinical package. The selection of context determines which tests will be applied when a clinical package is validated (Section 2.1).

The Validator supports the My Health Record and P2P contexts:

- The My Health Record context is the set of tests that apply to a clinical package sent to the My Health Record system.
- The P2P context is the set of tests that apply to a clinical package sent from one healthcare provider to another.

The default context for the Validator is My Health Record.

If a file with the '.hl7' filename extension is imported into the Validator, it is assumed to be an HL7 MDM wrapped clinical package and the Validator changes to the P2P context, as the My Health Record system does not support HL7 MDM. For all other types of files the P2P context must be explicitly selected (Figure 26).

File Confi	guration Help		
File :	C:\User\Desktop\CDa-DischargeSummary_Test_For_RCH.xml	MHR	Run Conformance
		O P2P	Show Report
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)		
Addn Rules:	Select additional rules template folder for validation		Run Addn Rules Only
Information			

Figure 26: Selecting the P2P context

3.3 Conformance levels

The conformance level against which a clinical document is to be validated is not explicitly selected. Instead, the user selects the My Health Record template package that applies to the type of clinical document and conformance level against which the clinical document is being assessed (Section 3.2.2).

Detailed descriptions of each conformance level can be found in *Clinical Documents - Common Conformance Profile* [NEHTA2015c]. In general, the conformance levels are 1A, 1B, 2, 3A, and 3B. The conformance levels that actually apply depend on the type of the clinical document. The allowed conformance levels for each type of clinical document are listed in the relevant conformance profile in the end product published on the Agency website⁵ (e.g. the event summary conformance profile is part of the Event Summary end product).

3.3.1 Conformance level 1A

A conformance level 1A clinical document has an XML header, and an XML body containing only a caption and a reference to an attached file. The administrative details form part of the header. In this example, the referral is an Adobe PDF file and the link to the referral is all that is contained in the XML body.

In a conformance level 1A clinical document, the data that would normally appear in the body of the document is instead included in an attached file. The Validator can only validate data that appears in the header of the document.

⁵ <u>http://www.digitalhealth.gov.au/implementation-resources/clinical-documents</u>

The rendered view of a conformance level 1A eReferral is shown in Figure 27. If the referral is an image (e.g. a JPEG file), the image may be displayed in the body of the rendered document, depending on the type of image.

File : C:\Users\User\Des	ktop\EReferral_1A.xml		MHR	Run Conformance	Load and Validate XDS	
			P2P	Show Report	Metadata	
Template: e-Referral 1B (1.2	.36.1.2001.1006.1.21000.14 ver 32624)	~				
Addn Rules: Select additional ru	les template folder for validation	<u> </u>		Run Addn Rules Only		
Information Rendered Documen	t Sign File Sign File Information Template Validation Report	t Package Report Reference	e Sets Other	Terminology Aspects		
Back Forward						
Mr Frank HARDING	22 -	leferral Jul 2015 IHI 8003 6086 6670 1	1594 MF	RN 123456		^
Good Hospita		F DOCUMENT				
Phone 03453 Attached Conten	(General Medical Practitioner) 754566	F DOCUMENT				l
Author Smith Phone 0345	 (General Medical Practitioner) 754566 t					1
Author Smith Phone 0345	 (General Medical Practitioner) 754566 t	F DOCUMENT				
Author Smith Phone 0345	 (General Medical Practitioner) 754566 t		_			
Author Phone Smith 0345 Attached Content Structured Body File	 (General Medical Practitioner) 754566 t	ATIVE DETAILS	Smith a.k.a. 1	Wong Sir (General Medical Practi	itioner)	
Author Smith Phone 0345 Attached Content Structured Body File Patient Name Sex	(General Medical Practitioner) 754566 t Mr Frank Troy HARDING	ATIVE DETAILS Author	a.k.a. I Good H	lospital	itioner)	
Author Smith Phone 03453 Attached Content Structured Body File Patient Name	I (General Medical Practitioner) 754566 t Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Male Neither Aboriginal nor Torres Strait Islander	ATTIVE DETAILS Author Name Organisation Address	a.k.a.) Good F not app	lospital blicable	tioner)	
Author Smith phone 03452 Attached Conten Structured Body File Patient Name Sex Indigenous Status	I (General Medical Practitioner) 754566 t Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Male Neither Aboriginal nor Torres Strait Islander origin	ATTIVE DETAILS Author Name Organisation Address Address	a.k.a.) Good H not app not app	lospital plicable plicable	tioner)	
Author Smith Phone 0345 Attached Content Structured Body File Patient Name Sex	I (General Medical Practitioner) 754566 t Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Male Neither Aboriginal nor Torres Strait Islander	ATTIVE DETAILS Author Name Organisation Address Address Phone	a.k.a.) Good H not app not app 034575	lospital plicable plicable 54566 (Workplace)		
Author Smith phone 03452 Attached Conten Structured Body File Patient Name Sex Indigenous Status	(General Medical Practitioner) 754566 t Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Male Neither Aboriginal nor Torres Strait Islander origin 22 Jul 1958 (57y)	ATTIVE DETAILS Author Name Organisation Address Address	a.k.a.) Good H not app not app 034575	lospital plicable plicable		
Author Smith phone 0345 Attached Content Structured Body File Patient Name Sex Indigenous Status Date of Birth	(General Medical Practitioner) 754566 t Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Male Neither Aboriginal nor Torres Strait Islander origin 22 Jul 1958 (57y) * Age is calculated from date of birth	ATTIVE DETAILS Author Name Organisation Address Address Phone	a.k.a. (Good H not app not app 03457 authen	lospital plicable plicable 54566 (Workplace)		

Figure 27: Rendered view of a level 1A eReferral

3.3.2 Conformance level 1B

A conformance level 1B clinical document has an XML header, and an XML body that includes at least one section that contains a label and a narrative block with clinical information. The data for the body is included in the narrative block(s) and may also appear as structured data.

As structured data is not required in the body of a level 1B clinical document, any structured data in the body will not be validated by the Validator using a conformance level 1B template. Any terminology codes from supported code systems will however be validated.

The rendered view of a conformance level 1B eReferral is shown in Figure 28. There is only one section in the body of this rendered eReferral, although level 1B clinical documents may have more than one section. The label of the section is **Title** and the text below the label is the rendered text from the narrative block.

In Rules: Select additional rules template folder for validation Immation Rendered Document Sign File Sign Sign	Metadata
In Rules: Select additional rules template folder for validation report Package Report Reference Sets Other Terminology Aspects	
mation Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects	
ack Forward	
cc i olward	
	_
e-Referral	
22 Jul 2015	
r Frank HARDING DoB 22 Jul 1958 (57y*) SEX Male IHI 8003 6086 6670 1594 MRN 123456	
START OF DOCUMENT	
uthor Smith (General Medical Practitioner)	
Ithor Smith (General Medical Practitioner)	
Ithor Smith (General Medical Practitioner) None 0345754566	
Ithor Smith (General Medical Practitioner) 0000 0345754566	
Ithor Smith (General Medical Practitioner) 0000 0345754566	
Smith (General Medical Practitioner) 0345754566 itle mrative ADMINISTRATIVE DETAILS	-
Smith (General Medical Practitioner) 0345754566 itle ADMINISTRATIVE DETAILS Patient Author	-
Smith (General Medical Practitioner) 0345754566 itle Intrative ADMINISTRATIVE DETAILS Patient Author Name Mr Frank Troy HARDING Name Smith	
Smith (General Medical Practitioner) 0345754566 itle ADMINISTRATIVE DETAILS Patient Author Name Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Smith a.k.a. Wong Sir (General Medical Practition a.k.a. Wong Sir (General Medical Practition)	er)
Smith (General Medical Practitioner) 0345754566 International Medical Practitioner) Internationer ADMINISTRATIVE DETAILS Patient Author Name a.k.a. Mr Frank Troy HARDING Name a.k.a. Wr Frank Tobie HARDING a.k.a. Wong Sir (General Medical Practitioner) a.k.a. Wong Sir (General Medical Practitioner) Sex Male Organisation Good Hospital	er)
Atthor one Smith (General Medical Practitioner) 0345754566 itle Atthor Antional Constraints Author Patient Author Name Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Name Smith a.k.a. Wor Sir (General Medical Practition a.k.a. Mr Frank Tobie HARDING Sex Male Organisation Good Hospital Indigenous Status Neither Aboriginal nor Torres Strait Islander Address not applicable	ier)
Author one Smith (General Medical Practitioner) 0345754566 itle Author Application Author Patient Author Name Mr Frank Troy HARDING a.k.a. Mr Frank Tobie HARDING Name Smith a.k.a. Wong Sir (General Medical Practition a.k.a. Wong Sir (General Medical Practicion a.k.a. Wong Sir (General Medical Practition a.k.a. Wong Sir (General	ier)
hone 0345754566 itle arrative Patient Author Name Mr Frank Toy HARDING Name Smith a.k.a. Mr Frank Tobie HARDING a.k.a. Mr Frank Tobie HARDING Sex Male Organisation Good Hospital Indigenous Status Neither Aboriginal nor Torres Strait Islander Address not applicable origin Address not applicable	ier)

Figure 28: Rendered view of a level 1B eReferral

3.3.3 Conformance level 2

A conformance level 2 clinical document has an XML header and an XML body that contains all the mandatory sections specified in the relevant CDA implementation guide. Each mandatory section has a label and a narrative block with clinical information. The data for the body is included in the narrative blocks and may also appear as structured data.

As structured data is not required in the body of a level 2 clinical document, any structured data in the body will not be validated by the Validator using a conformance level 2 template. Any terminology codes from supported code systems will however be validated.

The rendered view of a conformance level 2 eReferral is shown in Figure 29. Each section has a label and a narrative block.

File Configuration Help		
File : C:\Users\User\Desktop\EReferral_2.xml		and Validate XDS Metadata
Template: e-Referral 2 (1.2.36.1.2001.1006.1.21000.15 ver 32624)	V Show Report	
Addn Rules: Select additional rules template folder for validation	Run Addn Rules Only	
Information Rendered Document Sign File Sign File Information Template Validation Report Package Re	port Reference Sets Other Terminology Aspects	
Back Forward		
e-Referral 22 Jul 2015 Mr Frank HARDING DoB 22 Jul 1958 (DECEASED) SEX Male IHI 8	003 6086 6670 1594 MRN 123456	^
START OF DOCUMEN	T I	
Good Hospital Author Phone Doctor Good Smith (General Medical Practitioner) 0345754566 Referral Detail		
Reason for Referral		_
Referral reason		
Date and Duration		
Date Duration		
22 Jul 2015 15:32:20+1000 22 Jul 201	15 15:32:20+1000 -> 22 Jul 2015 15:32:20+1000	
Adverse Reactions		
Adverse Reactions		_
Substance/Agent Manifestations	Reaction Type	
Plant diterpene • Fetal viability • Sterility	Allergic reaction	
kana Manadala Pakata da Mila.	AU	~

Figure 29: Rendered view of a level 2 eReferral

3.3.4 Conformance level 3A

A conformance level 3A clinical document has an XML header, and an XML body that contains all the mandatory sections specified in the relevant CDA implementation guide. Each mandatory section has a label and a narrative block with clinical information. In addition, each section has structured clinical information for mandatory data elements.

Any terminology codes from supported code systems will be validated by the Validator (Section 2.3).

A rendered conformance level 3A clinical document is identical to a rendered conformance level 2 clinical document. Similarly, the XML files are identical except the XML file of the level 3A document contains additional structured data.

3.3.5 Conformance level 3B

A conformance level 3B clinical document has an XML header, and an XML body that contains all mandatory sections specified in the relevant CDA implementation guide. Each mandatory section has a label and a narrative block with clinical information. In addition, each section has structured clinical information for mandatory data elements.

A conformance level 3B clinical document must contain codes from specified code systems, which is optional for lower levels of conformance. Terminology codes such as AMT, SNOMED CT-AU, or

PBS must be present wherever they are allowed in the level 3B clinical document. The Validator will check whether the codes used in the clinical document can be found in the specified code systems (Section 2.3).

Any terminology codes from supported code systems will be validated by the Validator (Section 2.3).

A rendered conformance level 3B clinical document is identical to a rendered conformance level 2 and 3A clinical document. The XML file of a level 3B clinical document is identical to the XML file of a level 3A clinical document, except the XML file of the level 3B document must also contain codes from the specified code systems.

3.4 Configuration and runtime information

The **Information** tab displays information about the type of the clinical document being validated and information about the template (Figure 30) as well as the content of the zip file (if one chosen).

File Config	guration Help			
File :	C:\Users\User\Desktop\DS-Max-Dodgy.zip	6	• MHR	Run Conformance
			O P2P	Show Report
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)			
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
Information				
Configu	ration and Runtime Information	1		
	Template Package		Files found i	n zip file:
	Document Type: Discharge Summary			SET01/CDA_ROOT.XML

Figure 30: Configuration and runtime information

The information displayed is described in Table 4.

Label	Description
Document Type	The type of the clinical document to be validated.
Template Package Name	The name of the template package as recorded in the template package metadata.
Template Package ID	The identifier of the template package as recorded in the template package metadata.
Conformance Level	The conformance level as recorded in the template package metadata.
Template Effective Date	The date the template package was approved as recorded in the template package metadata.
Template Version	The version number of the template package as recorded in the template package metadata.
Template Path	The location of the template package.

Label	Description
Temp Work Path	The location used by the Validator to store temporary files.
Zip file size	The size of the zip file (if the file is a zip file).

If both the Document Type and the Template Package Name fields display names of differing types of documents, an incorrect template package has been selected.

Note: Some document names have changed over time, so it is possible that the Document Type and Template Package Name fields may display different names for the same type of document. This is not a problem, and validation can proceed normally.

If an additional template is selected, the Information tab displays information about the additional template (Figure 31).

e Configuration Help					
File : C:\Users\User\Deskto	p\DS-Max-Dodgy.zip	6	MHR	Run Conformance	Load and Validate XDS Metadata
			P2P	Show Report	rietauata
	1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)				
ddn Rules: C:\DigitalHealth\TP-IQ	Rules_v1.4.9			Run Addn Rules Only	
ormation					
Configuration and Runt	ime Information				
Templa	te Package		Files found i	n zip file:	
Template Package Name: Template Package ID: Conformance Level: Template Effective Date: Template Version: Template Path:	1.2.36.1.2001.1006.1.20000.18 1A Monday, 1 April 2013 32620 C:\DigitalHealth\CPV26\Templates\1.2.36.1.2001.1006.1.20000.18.3 C:\DigitalHealth\CPV26\Temp	32620	IHE_XDM/SUB IHE_XDM/SUB IHE_XDM/SUB	SET01/CDA_ROOT.XML SET01/CDA_SIGN.XML SET01/path1234.pdf SET01/x-ray.jpg SET01/logo.png	
Additio	nal Rules				
Template Package ID: Conformance Level: Template Effective Date: Template Version:	Friday, 1 May 2015				

Figure 31: Information about an additional template

The information displayed about the additional template is described in Table 5.

Table 5 –Information about	it the additional template
----------------------------	----------------------------

Label	Description
Template Package Name	The name of the additional template package as recorded in the template package metadata.

Label	Description
Template Package ID	The identifier of the additional template package as recorded in the template package metadata.
Conformance Level	The conformance level as recorded in the additional template package metadata.
Template Effective Date	The date the additional template package was approved as recorded in the template package metadata.
Template Version	The version number of the additional template package as recorded in the template package metadata.
Template Path	The location of the additional template package.

The "Files found in zip file" box only appear if a cda package has been selected. It lists the files found in the zip file.

3.5 Run Conformance command

The **Run Conformance** command allows a user to request the Validator to test whether a clinical document or clinical package (for which the Validator may be used) conforms to the relevant specifications (Figure 32), subject to the limitations set out in the *Clinical Package Validator Product Data Sheet*.

File Confi	guration Help			
File :	C:\User\User\Desktop\DS-Max-Dodgy.zip	6	MHR	Run Conformance
			○ P2P	Show Report
Template:	e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620) V			
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
Information				
	Select additional rules template folder for validation			Run Addn Rules Only

Configuration and Runtime Information

Figure 32: Requesting the Validator to test the conformance of a clinical document or clinical package

The tests that are performed vary with the type of object being validated:

- 4 If the object is a clinical package (i.e. a .zip file), the package will be validated as well as the clinical document within the clinical package.
- 5 If the object is an HL7 MDM wrapped clinical package (i.e. an .hl7 file), the clinical package is extracted and both the clinical package and the clinical document within it are validated.
- 6 If the object is a clinical document (i.e. an .xml or .XML file), the clinical document is validated but package validation is not performed.

Template validation is applied to every type of supported clinical document. Validation results are displayed on the graphical user interface (Section 3.7).

3.6 Run Addn Rules Only command

The **Run Addn rules Only** command allows a user to request the Validator to just run the additional rules against the clinical document.

Validation results are displayed on the graphical user interface (Section 3.7).

3.7 Validation results

The following tabs are used to display the results of a clinical document or clinical package validation (for which the Validator may be used).

3.7.1 Information tab

In addition to displaying the information listed in section 3.4, the **Information** tab also contains a summary of the validation results.

Label	Description
Label	Description
Template Validation Results	The total number of errors reported by template validation.
Package Results	The total number of errors reported by package validation. This information is only included if a clinical package was validated.
Reference Set Results	The total number of errors and warnings reported by validation of codes against reference sets, where specified in CDA implementation guide.
Other Terminology Results	The total number of errors and warnings reported by validation of codes against supported code systems.
Additional Rules	The total number of errors reported by validation using the additional template. This information is only included if additional rules have been applied.

3.7.2 Rendered Document tab

The **Rendered Document** tab displays the rendered clinical document (for which the Validator may be used) that is being validated (Figure 33).

File :	C:\Users\User\Desktop\EReferral_3A_Max.hl7		O MHR	Run Conformance
			P2P	Show Report
Template:	e-Referral 1A (1.2.36.1.2001.10 Sign File Information Template Validation Report Package Report Reference Sets	Other Terminology	Aspects	
ddn Rules:	Select additional rules template folder for validation			Run Addn Rules Only



Figure 34 is an example of a rendered clinical document displayed on the **Rendered Document** tab. The **Back** and **Forward** buttons allow the user to go back to the rendered view of the clinical document, or forward from the rendered view of the clinical document to the attachment.

File Configuration Help	
File: C:\Users\User\Desktop\DS-Max-Dodgy.zip MHR Run Conformance Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects	
Addn Rules: Select additional rules template folder for validation	
Information Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects	
Back Forward	
Discharge Summary 11 May 2016	^
Mr Frank HARDING DoB 11 May 1959 (DECEASED) SEX Male IHI 8003 6086 6670 1594 MRN 123456	
START OF DOCUMENT	
Good Hospital Author Phone Discharge To Discharge From Discharge F	
Health Profile	
This section may contain the following subsections Adverse Reactions and Alerts.	
Adverse Reactions	
• Disc	
• Circle	
Square	
i. LittleRoman	
I. BigRoman	~

Figure 34: Rendered clinical document displayed on the Rendered Document tab

3.7.3 Sign File tab

The **Sign File** tab displays the contents of the CDA_SIGN.XML file in a clinical package (Figure 35). The **Sign File** tab is only displayed when the file being validated is either a clinical package or an HL7 Medical Document Management (MDM) wrapped clinical package.

File Confi	juration Help	
File :	Template Validation Report Package Report Reference Sets Other Terminology Aspects C:\Users\User\Desktop\EReferral_3A_Max.hl7 Image: Complex Co	Run Conformance
	P2P	Show Report
Template:	e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ver 32624)	
Addn Rules:	Select additional rules template folder for validation	Run Addn Rules Only
Information	Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Terminology	Aspects

Figure 35: Sign File tab

Figure 36 is an example of a CDA_SIGN.XML file that is displayed on the Sign File tab.



Figure 36: Display of a CDA_SIGN.XML file

3.7.4 Sign File Information tab

The **Sign File Information** tab displays selected information from the CDA_SIGN.XML file in a clinical package (Figure 37). This complements information in the **Sign File** tab as this information is more readable. Information from the Public Key Infrastructure (PKI) certificate is also displayed.

The **Sign File Information** tab is only displayed when the file being validated is either a clinical package or an HL7 Medical Document Management (MDM) wrapped clinical package.

File Config	uration Help			
File :	C:\Users\User\Desktop\EReferral_3A_Max.hl7	6	O MHR	Run Conformance
			P2P	Show Report
Template:	e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ve Template Validation Report Package Report Reference Sets Other Template Validation Report Package Report Ref	erminology Aspects		
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
nformation	tendered Document Sign File Sign File Information Template Validation Report Package Report Refe	erence Sets	Other Terminology	/ Aspects

Figure 37: Sign File Information tab
Figure 38 is an example of the information displayed on the Sign File Information tab.

File Configuration Help					
File : C:\Users\User\Desktop\DS-	Max-Dodgy.zip	6	MHR	Run Conformance	Load and Validate XDS Metadata
			O P2P	Show Report	Freddata
Template: e-Discharge Summary 1A (1	1.2.36.1.2001.1006.1.20000.18 ver Template Validation Report Package Report	Reference S	Sets Other Term	inology Aspects	
Addn Rules: Select additional rules temple			1	Run Addn Rules Only	
Information Rendered Document Sign File	e Sign File Information Template Validation Report Package Report Ref	erence Sets	Other Terminology	Aspects	
CDA Sign File Information					
	2016-11-07T23:48:00.6249184Z http://ns.electronichealth.net.au/id/hi/hpii/1.0/8003615833334 Doctor Good Smith	118			
Organisation Certificate	This is a NASH Certificate				
Valid From : Valid To :	CN=general.8003628233352432.id.electronichealth.net.au, O= 24/01/2015 2:24:53 AM 24/01/2017 2:24:52 AM Policy for NASH PKI certificate for healthcare provider organisa		RGSB115, DC=	:8003628233352432, DC=ic	d, DC=electronichealth, DC=net, DC
Other signature files in package :					

Figure 38: Display of eSignature file information

The information displayed is listed in Table 7.

Label	Description				
Signing Time	The date and time that the clinical document was signed using the PKI certificate.				
Approver Person Id	The identifier of the approver, in the form of a Uniform Resource Identifier (URI). The approver is the person that reviewed and approved the content of the clinical document [NEHTA2015c]. Possible values are:				
	 'http://ns.electronichealth.net.au/id/null/person/1.0' if there was no approver. 				
	 'http://ns.electronichealth.net.au/id/hi/hpii/1.0/' followed by the approver's HPI-I. 				
	 'http://ns.electronichealth.net.au/id/hi/ihi/1.0/' followed by the approver's IHI. 				
	• The domain namespace of an organisation followed by a local identifier. In this case the organisation is the one that allocated the identifier to the approver.				
Approver Person Name	The title and name of the person that reviewed and approved the content of the clinical document. If the name is 'NA', there was no approver.				
Organisation Certificate	States whether the certificate is a National Authentication Service for Health (NASH) Public Key Infrastructure (PKI) certificate.				

Table 7 – Summary of information	n displayed in the Sign File Information tab
----------------------------------	---

Label	Description
Subject	A set of domain components ('DC'), an organisation name ('O') and a common name ('CN').
	The attributes most relevant to conformance testing are the organisation name, and the national healthcare identifier which is one of the domain components and is also found within the common name. The organisation name and identifier are the name of the healthcare provider organisation or supporting organisation that the certificate was assigned to, and the identifier of that organisation.
Valid From	The start of the validity period for the PKI certificate. The date is displayed in green if the current date (not the signing date) is at or after the start of the validity period, otherwise it is red.
Valid To	The end of the validity period for the PKI certificate. The date is displayed in green if the current date (not the signing date) is at or before the end of the validity period, otherwise it is red.
Certificate Policies	States whether the certificate is for a healthcare provider individual, a healthcare provider organisation or a supporting organisation.
Other eSignature files in package	The name(s) of any other eSignature files found within the clinical package. These names are found by opening the clinical package whereas all of the information above this row in this table is obtained from the CDA_SIGN.XML eSignature file.

Figure 39 is another example of the information displayed on the **Sign File Information** tab when a certificate is not a NASH certificate, the certificate policy is unrecognised and a second eSignature file was found in the clinical package.

File : C:\Users\User\Desktop\ERe	ferral_3A_Max.zip	6	MHR	Run Conformance
			O P2P	Show Report
Template: e-Referral 1A (1.2.36.1.200	1.1006.1.21000.13 ver Template Validation Report Package Report	Reference Sets Other Terminology	Aspects	
Addn Rules: Select additional rules templa	ate folder for validation	<u> </u>		Run Addn Rules Only
nformation Rendered Document Sign File	Sign File Information Template Validation Report Pack	age Report Reference Sets	Other Terminolog	v Aspects
1			1	.,
-CDA Sign File Information -				
Signing Time :	2017-10-06T06:25:27.16337717			
5 5	2017-10-06T06:25:27.1633771Z http://ns.electronichealth.net.au/id/hi/hpii/1.0/8	003610000021101		
5 5	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8	003610000021101		
Approver Person Id :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8	003610000021101		
Approver Person Id : Approver Person Name :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith	003610000021101		
Approver Person Id :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith	003610000021101		
Approver Person Id : Approver Person Name : Organisation Certificate	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate			
Approver Person Id : Approver Person Name : Organisation Certificate Subject :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate CN=Test Site A094 :9981466254, OU=Test Site		4, L=TUGGERAN	IONG, S=ACT, C=AU
Approver Person Id : Approver Person Name : Organisation Certificate Subject : Valid From :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate CN=Test Site A094 :9981466254, OU=Test Site 11/05/2015 10:30:15 PM		4, L=TUGGERAN	IONG, S=ACT, C=AU
Approver Person Id : Approver Person Name : Organisation Certificate Subject : Valid From : Valid To :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate CN=Test Site A094 :9981466254, OU=Test Site 11/05/2015 10:30:15 PM 11/05/2020 10:30:12 PM		4, L=TUGGERAN	IONG, S=ACT, C=AU
Approver Person Id : Approver Person Name : Organisation Certificate Subject : Valid From : Valid To :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate CN=Test Site A094 :9981466254, OU=Test Site 11/05/2015 10:30:15 PM		4, L=TUGGERAN	IONG, S=ACT, C=AU
Approver Person Id : Approver Person Name : Organisation Certificate Subject : Valid From : Valid To :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate CN=Test Site A094 :9981466254, OU=Test Site 11/05/2015 10:30:15 PM 11/05/2020 10:30:12 PM		4, L=TUGGERAN	IONG, S=ACT, C=AU
Approver Person Id : Approver Person Name : Organisation Certificate Subject : Valid From : Valid To :	http://ns.electronichealth.net.au/id/hi/hpii/1.0/8 Doctor Good Smith This is not a NASH Certificate CN=Test Site A094 :9981466254, OU=Test Site 11/05/2015 10:30:15 PM 11/05/2020 10:30:12 PM		4, L=TUGGERAN	IONG, S=ACT, C=AU



3.7.5 Template Validation Report tab

The **Template Validation Report** tab displays the results of the My Health Record template validation (for which the Validator may be used) and the clinical document XML file (Figure 40).

File :	C:\Users\User\Desktop\EReferral_3A_Max.hl7	Package Report Reference Sets	Other Terminology Aspects	R	Run Conformance
				PZP	Show Report
emplate:	e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ver 32624)		~		
dn Rules:	Select additional rules template folder for validation				Run Addn Rules Only

Figure 40: Template Validation Report tab

Any template validation issue is displayed in this report along with information about the issue, and the context of the issue. A template validation report is generated each time the Validator is run.

Schema issues are displayed before Schematron issues, followed by a display of the clinical document XML file. Figure 41 shows a report with a schema issue highlighted.

File: C:\Users\User\Desktop\EReferral_3A_Max2.zip Run Conformance Show Report Template: e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ver 32624) Image Report Run Addn Rules Only Addn Rules: Select additional rules template folder for validation Run Addn Rules Only Run Addn Rules Only Information Rendered Document Sign File Sign File Sign File Sign File Information Template Validation Report VALIDATION STATUS Complete SERVICE NAME e-Referral - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-0ct-2017 TIME OF TEST 17:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1 ISSUE COUNT 1 SIGNATURE VALIDATION See Package Report Tab	
Template: e-Referral 1A (12.36.1.2001.1006.121000.13 ver 32624) Addn Rules: Select additional rules template folder for validation Information Rendered Document Sign File Sign File Sign File Sign File VALIDATION STATUS Complete SERVICE NAME e Referral - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 7:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1)S
Information Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects Template Validation Report VALIDATION STATUS Complete SERVICE NAME e - Referral - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 1:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1	
Information Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects Template Validation Report VALIDATION STATUS Complete SERVICE NAME e - Referral - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 1:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1	
Template Validation Report VALIDATION STATUS Complete SERVICE NAME e-Referral - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 17:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1	
VALIDATION STATUSCompleteSERVICE NAMEe-Referral - 1ASERVICE PROVIDERAustralian Digital Health AgencySTANDARD TYPECDA R2DATE OF TEST06-Oct-2017TIME OF TEST1:27:28 +11:00RESULT OF TESTFalseISSUE COUNT1	
VALIDATION STATUSCompleteSERVICE NAMEe-Referral - 1ASERVICE PROVIDERAustralian Digital Health AgencySTANDARD TYPECDA R2DATE OF TEST06-Oct-2017TIME OF TEST1:27:28 +11:00RESULT OF TESTFalseISSUE COUNT1	
SERVICE NAMEe-Referral - 1ASERVICE PROVIDERAustralian Digital Health AgencySTANDARD TYPECDA R2DATE OF TEST06-Oct-2017TIME OF TEST17:27:28 +11:00RESULT OF TESTFalseISSUE COUNT1	
SERVICE PROVIDERAustralian Digital Health AgencySTANDARD TYPECDA R2DATE OF TEST06-Oct-2017TIME OF TEST17:27:28 +11:00RESULT OF TESTFalseISSUE COUNT1	
STANDARD TYPECDA R2DATE OF TEST06-Oct-2017TIME OF TEST17:27:28 +11:00RESULT OF TESTFalseISSUE COUNT1	
DATE OF TEST 06-oct-2017 TIME OF TEST 17:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1	
TIME OF TEST 17:27:28 +11:00 RESULT OF TEST False ISSUE COUNT 1	
RESULT OF TEST False ISSUE COUNT 1	
ISSUE COUNT 1	
SIGNATURE VALIDATION See Package Report Tab	
	—
<	>
Schema Violations	а. Г
	h .
# Message 1 (Line:5 Pos:4) The element 'ClinicalDocument' in namespace 'urn:hl7-org:v3' has invalid child element 'typeI' in namespace 'urn:hl7-org:v3'. L	-
typeId' in namespace 'urn:hi7-org:v3'. L typeId' in namespace 'urn:hi7-org:v3'.	د
Test Object	
<clinicaldocument 2.16.840.1.113883.1.3"="" extension="POCD_HD000040" xmlns:ext="http://ns.electronichealth.net.au/Ci/Cda/Extensions/3.0" xmlns:xsi="http://www.w3.org/2001/XMLSche</td><td>38</td></tr><tr><td><typeI root="></clinicaldocument>	
<pre><templateid extension="2.2" root="1.2.36.1.2001.1001.101.100.1002.2"></templateid> <templateid extension="1.0" root="1.2.36.1.2001.1001.100.149"></templateid></pre>	
<pre>cid root="2.25.2029740843639219315855974423396617341"/></pre>	~
	\sim

Figure 41: Template Validation Report tab with schema issue highlighted

Figure 42 shows the report with Schematron issues highlighted.

File Configuration Help				
File : E: \DigitalHealth \CDA \Exam	npleSHSwithDVA.xml Package Report Reference Sets Other Terminology Aspects	P2P	Run Conformance	Load and Validate XDS Metadata
Template: e-Discharge Summary 1A	(1.2.36.1.2001.1006.1.20000.13 ver 31147)	0.11	Show Report	
Addn Rules: Select additional rules tem			Run Addn Rules Only	
Information Rendered Document Tempi	ate Validation Report Reference Sets Other Terminology Aspects			
	Temp	late Valio	dation Report	^
VALIDATION STATUS	Complete			
SERVICE NAME	Shared Health Summary - 1A			
SERVICE PROVIDER	Australian Digital Health Agency			
STANDARD TYPE	CDA R2			
DATE OF TEST	06-Oct-2017			
TIME OF TEST	16:40:57 +10:00			
RESULT OF TEST	False			
ISSUE COUNT	3			
SIGNATURE VALIDATION	N/A			
<				>
		Erro	ors	
# Message		Context		Test
 Error: e-Discharge Su Clinical Document - "ClinicalDocument / te The 'templateId' tag 'r attribute shall contain '1.2.36.1.2001.1001.1 If the 'root' value is 	mplateId" - 'oot' the value 101.100.1002.4'.	/ClinicalDoc	ument[1]	count(cda:template '1.2.36.1.2001.100 and @extension='3 <u>Issue</u>
'1.2.36.1.2001.1001.1 then the 'extension' a contain the value '3 4'	ttribute shall			~

Figure 42: Template Validation Report tab with Schematron errors highlighted

Figure 43 shows a report where no schema or Schematron issues were found during template validation.

File Cont	figuration Help								
			Package Report Refi	rence Sets Other 1	Terminology Aspects				
File ;	C: \Users \User \Deskt	op\EReferral_3A_Max1.zip			`	MHR	Run Conformance	Load and Validate XDS Metadata	
						P2P	Show Report		
Template:	e-Referral 3A (1.2.36	.1.2001.1006.1.21000.11 ver 144)			~				
Addn Rules:	Select additional rules	template folder for validation					Run Addn Rules Only		
Information	Rendered Document	Sign File Sign File Information Ten	plate Validation Report Pa	ckage Report	Reference Sets	Other Terminolog	y Aspects		
	1	1		1					
					Templ	ate Valid	ation Report		^
VALIDA	TION STATUS	Complete					•		
SERVICE	E NAME	e-Referral - 3A							
SERVICE	E PROVIDER	Australian Digital Heal	th Agency						
	ARD TYPE	CDA R2							
DATE O		06-Oct-2017							
TIME OF		17:41:52 +11:00							
	OF TEST	True							
ISSUE C									
		0							
SIGNAT	URE VALIDATION	See Package Report	i ab						_
<									>
						Test O	bject		
<clini< td=""><td>calDocument xm</td><td>lns:ext="http://ns.elec</td><th>tronichealth.net</th><th>.au/Ci/Cd</th><th>a/Extensi</th><td>ons/3.0" xm</td><td>lns:xsi="http://www.</td><td>w3.org/2001/XMLSchema-instance"</td><td>x</td></clini<>	calDocument xm	lns:ext="http://ns.elec	tronichealth.net	.au/Ci/Cd	a/Extensi	ons/3.0" xm	lns:xsi="http://www.	w3.org/2001/XMLSchema-instance"	x
		40.1.113883.1.3" extens							
		2.36.1.2001.1001.101.10			/>				
-		2.36.1.2001.1001.100.14		0"/>					
		40854336392193158859744 codeSystem="2.16.840.1		SugtonNo	mo-ULOTNC	" dignlar/Na	mo-"Doformal noto"/>		
	>e-Referral <td></td> <th>.113883.0.1 000</th> <th>сауасенича</th> <th>me- Toluc</th> <td>dispiaywa</td> <td>me- Kelellal Hote //</td> <td></td> <td></td>		.113883.0.1 000	сауасенича	me- Toluc	dispiaywa	me- Kelellal Hote //		
		="20170621085945+1000"/	>						
<confi< td=""><td>dentialityCode</td><td>nullFlavor="NA"/></td><th></th><th></th><th></th><td></td><td></td><td></td><td></td></confi<>	dentialityCode	nullFlavor="NA"/>							
	ageCode code="								~
<setid< td=""><td>root="06c870a</td><td>4-ba69-4cf2-98c9-f57e78</td><th>4088b1"/></th><th></th><th></th><td></td><td></td><td></td><td>\sim</td></setid<>	root="06c870a	4-ba69-4cf2-98c9-f57e78	4088b1"/>						\sim
<								>	

Figure 43: Template Validation Report tab reporting no errors

The upper portion of the report includes a summary of the schema and Schematron errors, and contains the following information.

Table	8 -	Report	labels
-------	-----	--------	--------

Label	Description	
Validation status	Complete indicates the Validator has completed the validation process. If the Validator does not complete the validation process, the text An Error occurred while trying to run the Validator. No Output was produced. will be displayed.	
Service name	The type of the clinical document and the target conformance level.	
Service provider	Australian Digital Health Agency	
Standard type	HL7 CDA R2 indicates the clinical document specifications are based on release 2 of the HL7 Clinical Document Architecture [HL72004].	
Date of test	The date in the dd-mmm-yyyy format.	
Time of test	The time when the test was run.	

Label	Description
Result of test	The overall result of the validation. The result is True if template validation found no issues, and False if issues were found during template validation.
Issue count	The total number of schema and Schematron issues.
Signature validation	Indicates whether any errors were found in the eSignature. N/A is displayed if there was no eSignature. See Package Report Tab is displayed if there was an eSignature to validate.

If schema issues are found, the middle portion of the report contains the XML line number where the issue is located, the position of the issue within the line, and a description of the issue (Figure 41).

If Schematron issues are found (Figure 42), the middle portion of the report contains the information in Table 9.

Label	Description
#	The issue number.
Message	The issue message.
Context	The location in the XML where the issue was found (XPath).
Test	The Go To Issue link at the end of the test information can be used to go to the location of the issue in the clinical document XML file.

Table 9 - Schematron issue information

Figure 44 is an example of information that is displayed in the **Template Validation Report** tab when a **Go To Issue** link is selected. The issue message highlighted in red indicates the XML element that was in issue.

File Configuration Help						
File : E:\DigitalHealth\CDA\Exar	npleSHSwithDVA.xml	6	MHRP2P	Run Conformance	Load and Validate XDS Metadata	
Template: e-Discharge Summary 1A	(1.2.36.1.2001.1006.1.20000.13 ver 31147)	~		· ·		
Addn Rules: Select additional rules tem	plate folder for validation Package Report Reference Sets Other Ter	rminology Aspects		Run Addn Rules Only		
Information Rendered Document Temp	Nate Validation Report Reference Sets Other Terminology Aspects					
Information Rendered Document Temp	late Validation Report Relevence Sets Other Terminology Aspects					
		Templa	ate Valid	lation Report		^
VALIDATION STATUS	Complete	rempi				
SERVICE NAME	, Shared Health Summary - 1A					
SERVICE PROVIDER	Australian Digital Health Agency					
STANDARD TYPE	CDA R2					
DATE OF TEST	06-Oct-2017					
TIME OF TEST	16:40:57 +10:00					
RESULT OF TEST	False					
ISSUE COUNT	3					
SIGNATURE VALIDATION	N/A					
<						>
C C						
	eId[@root = '1.2.36.1.2001.1001.101.100.1002.4' and @e	extension='3	3.4'])>0			
	0.1.113883.1.3" extension="POCD HD000040" />					\sim
<pre><typeid 1.2.<="" pre="" root="2.16.640 <templateId root="></typeid></pre>	.36.1.2001.1001.101.100.1002.120" extension="1	.4" />				
	.36.1.2001.1001.100.149" extension="1.0" />					
<id root="2.25.9321946</td><td>59058693736806932555453532442281"></id>						
Issue #2 - @code = '18842-5	r -					- 11
Top						
	yName, 'abcdefghijklmnopqrstuvwxyz', 'ABCDEFGHIJKLMNC	OPQRSTUVW	XYZ') = 'DISC	HARGE SUMMARIZATION NO	DTE'	
Top	codeSystem="2.16.840.1.113883.6.1" codeSystemN	ame="LOING	" dimlar"	lama="Datient gummarr"	/>	~
and a second second second second		ame- LOING	. цізріаул	ame- ratient summary	12	~
<						>

Figure 44: Template Validation Report tab when a Go to Issue link is selected

Figure 45 shows the display of a clinical document XML file. The clinical document XML file is presented immediately after the display of any Schematron issues.

File Configuration Help File: El-Diptatheadth/CoA/ExampleSHSwithOVA.xml File: El-Diptatheadth/SWITHAWA.Xml File: El-Dip	Clinical	I Package Validator	v2.6						-	- 🗆 🗙
Template: Provide and the set of the state of the stat	File Con	figuration Help								
Add Rules: Belet additional rules template folder for validation Information Recleved Document Reclev							0			
Information Rendered Document Template Validation Report VALIDATION STATUS Complete SERVICE NAME Shared Health Summary - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-00t-2017 TIME OF TEST 16:40:57 + 10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A	Template:	e-Discharge Sum	mary 1A (1.2.36.1.2001.1006.	1.20000.13 ver 3 Pac	kage Report Reference Sets	Other Terminology Aspects				
Template Validation Report VALIDATION STATUS Complete SERVICE NAME Shared Health Summary - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 16:40:57 + 10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A Cultification cumment xmins:text="nucp://ins.electroniconesitin.net.au/cl/cum/factensions/s.or" xmins:txs1="nucp://www.ws.org/2001/AmLSONema=instance" x a name="yyy1" xmins="">	Addn Rules:	Select additional r	ules template folder for valida	ition				Run Addn Rules Only		
VALIDATION STATUS Complete SERVICE NAME Shared Health Summary - 1A SERVICE NAME Shared Health Summary - 1A SERVICE RAME Shared Health Summary - 1A SERVICE RAME Shared Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 16:40:57 +10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A CLINICALDOUMENT Xmin5:ext-"nttp://ns.tectronicneaith.net.au/cl/tda/Extensions/5.0" Xmin5:XS1-"nttp://www.ws.org/2001/AmlSonema-instance" x <cupre>cup = 100 couple = 10</cupre>	Information	Rendered Document	Template Validation Report	Reference Sets 0	Other Terminology Aspects					
SERVICE NAME Shared Health Summary - 1A SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 16:40:57 +10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A						Temp	ate Vali	dation Report		^
SERVICE PROVIDER Australian Digital Health Agency STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 16:40:57 +10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A	VALIDA	TION STATUS	Complete							
STANDARD TYPE CDA R2 DATE OF TEST 06-Oct-2017 TIME OF TEST 16:40:57 +10:00 RESULT OF TEST 16:40:57 +0:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A	SERVIC	E NAME	Shared Healt	h Summary - 1	LA					
DATE OF TEST 06-Oct-2017 TIME OF TEST 16:40:57 +10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A C C CLINICALDOCUMENT XMINS:EXT-"NCUP://NS.ElectronicHearth.Net.au/Cl/Cda/Extensions/3.0" XMINS:XMI-"NCUP://WWW.WS.Org/2001/AMLSCHEMa-INStance" X (a name="yyy1" xmlns=""> (cupited cout="1.2.36.1.2001.1001.100.100.120" extension="1.4"/> (cupited cout="1.2.36.1.2001.1001.100.100.120" extension="1.4"/> (cupited cout="1.2.36.1.2001.1001.100.100.120" extension="1.4"/> (cupited cout="1.2.36.1.2001.1001.100.101.100/> (cupited cout="1.2.36.1.2001.1001.100.1109" xmlns=""> (cupited cout="1.2.36.1.2001.1001.100.1002.120" extension="1.4"/> (cupited cout="1.2.36.1.2001.1001.100.101.100/> (cupited cout="1.2.36.1.2001.1001.100.1109" xmlns=""> (cupited cout="1.2.36.1.2001.1001.100.1002.120" extension="1.4"/> (cupited cout="1.2.36.1.2001.1001.100.101.100/> (code code="60591-5" codeSystem="yy3" xmlns=""> (code code="60591-5" codeSystem="yy3" xmlns=""> (code code="60591-5" codeSystem="yy3" xmlns=""> (code code="60591-5" codeSystem="2.16.800.1.11383.6.1" codeSystemName="LOINC" displayName="Patient summary"/> (cupited mout="2016051152330+1000"/> (confidentialityCode nullFlavor="N#N/> (languageCode code==n-AUT/> (setId root="db291ca3-cd5-fedd-a3e9-1a8601783db4"/>	SERVIC	E PROVIDER	Australian Di	gital Health Ag	ency					
TIME OF TEST 16:40:57 +10:00 RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A	STAND	ARD TYPE	CDA R2							
RESULT OF TEST False ISSUE COUNT 3 SIGNATURE VALIDATION N/A Image: "yyy1" xmlns=""> Image: "yyy1" xmlns=""> Image: "yyy1" xmlns="> Image: "yyy1" xmlns="> Image: "yyy1" xmlns="> Image: "yyy1" xmlns="> Image: "yyy2" xmlns="> Image: "yy2" xmlns=" <	DATE C	OF TEST	06-Oct-2017	,						
ISSUE COUNT 3 SIGNATURE VALIDATION N/A	TIME O	F TEST	16:40:57 +1	0:00						
SIGNATURE VALIDATION N/A	RESULT	OF TEST	False							
<pre></pre>	ISSUE	COUNT	3							
<pre></pre> <pre><</pre>	SIGNAT	URE VALIDATIO	DN N/A							
<pre></pre> <pre><</pre>										
<pre></pre> <pre><</pre>										
<pre> <typeid extension="FOCD_HD000040" soot="2.16.840.1.113883.1.3"></typeid> <templateid extension="1.4" root="1.2.36.1.2001.1001.101.00.102.120"></templateid> <templateid extension="1.4" root="1.2.36.1.2001.1001.100.149"></templateid> <ca name="yyy2" xmln=""> <ca name="yyy2" xmln=""> </ca></ca></ca></ca></ca></ca></ca></ca></ca></ca></ca></pre>	<									>
<pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre><pre></pre></pre>				ns.erectroni	cnearch.net.au	/ CI/ COA/ EXCENSI	uns/3.0" x	mins:xsiuccb://ww	w.wo.org/2001/Ambochema-10	iscance: x
<pre><cemplateid extension="1.4" root="1.2.36.1.2001.1001.100.102.120"></cemplateid> <cemplateid extension="1.4" root="1.2.36.1.2001.1001.100.149"></cemplateid> <id root="2.25.9321946905869373680693255545352442281"></id> </pre> <code code="60591-5" code3ystem"<="" p=""> >:0.6.3401.113893.6.1" code3ystemName="Patient summary"/> Shared Health Summary <confidentialitycode nullflavor="NAW"></confidentialitycode> <td></td><td></td><td></td><th></th><td></td><td></td><td></td><td></td><td></td><td>~</td></code>										~
<pre><cemplateid extension="1.0" root="1.2.36.1.2001.1001.100.149"></cemplateid> <id root="2.25.9321940905809373680693255545332442281"></id> <td><type]< td=""><td>Id root="2.16</td><td>.840.1.113883.1.3</td><th>'extension="</th><td>'POCD_HD000040"</td><td>/></td><td></td><td></td><td></td><td></td></type]<></td></pre>	<type]< td=""><td>Id root="2.16</td><td>.840.1.113883.1.3</td><th>'extension="</th><td>'POCD_HD000040"</td><td>/></td><td></td><td></td><td></td><td></td></type]<>	Id root="2.16	.840.1.113883.1.3	'extension="	'POCD_HD000040"	/>				
<pre><di root="2.25.931946005869375860673255545353242291"></di> <code code="60591-5" codesystem="2.16.840.1.113893.6.1" codesystemname="LOINC" displayname="Patient summary"></code> <title>Shared Health Summary</title> <codercode="2016051152930+1000"></codercode="2016051152930+1000"> <confidentialitycode a='nAU"/' nullflavor="NAW'/> <languageCode code="> <setid root="db291ca3-cad5-9edd-a3e9-1a8601783db4"></setid> </confidentialitycode></pre>										
<pre><code code="60591-5" codesystem="2.16.840.1.113883.6.1" codesystemname="LOINC" displayname="Patient summary"></code> <title>Shared Health Summary//title> <ffectiveFime value="2016051152930+1000"/> <confidentialityCode nullFlavor="NAM"/> <languageCode code="en-AUM"/> <setId root="db291ca3-cd85-fedd-a3e9-la8601783db4"/> </pre></td><td></td><td></td><td></td><th></th><td></td><td>·</td><td></td><td></td><td></td><td></td></tr><tr><td><title>Shared Health Summary</title> <effectivetime value="20160511152930+1000"></effectivetime> <confidentialitycode nullflavor="NA"></confidentialitycode> <languagecode code="en-AU"></languagecode> <setid root="db291ca3-cd65-4edd-a3e9-1a8601783db4"></setid></pre>										
<pre><effectivetime value="20160511152930+1000"></effectivetime> <confidentialitycode men-au"="" nullflavor="%#/> <languageCode code="></confidentialitycode> <setid root="db291ca3-cd65-4edd-a3e9-1a8601783db4"></setid> </pre>					883.6.1" codeSy	stemName="LOINC	" displayN	Name="Patient summar	¥./>	
<pre><confidentialitycode nullflavor="NA"></confidentialitycode> <languagecode code="en-NA"></languagecode> <setid root="db291ca3_cd65-4edd-a3e9-la8601783db4"></setid></pre>										
<languagecode code="en-AU"></languagecode> <setid root="db291ca3-cd55-4edd-a3e9-1a8601783db4"></setid> """""""""""""""""""""""""""""""""""										
	<setio< td=""><td>d root="db291</td><td>ca3-cd65-4edd-a3e9</td><th>9-1a8601783db</th><td>04"/></td><td></td><td></td><td></td><td></td><td>×.,</td></setio<>	d root="db291	ca3-cd65-4edd-a3e9	9-1a8601783db	04"/>					×.,
	<									>

Figure 45: Template Validation Report tab displaying a clinical document XML file

3.7.6 Additional Rules Report tab

The **Additional Rules Report** tab displays the outcome of applying additional rules to the clinical document (Figure 46). This tab is only displayed if an additional template package was imported into the Validator (Section 3.2.3).

File Confi	guration Help						
File :	C:\Users\User\Pesktop\EReferral_3A_Max1.zip	ackage Repo	rt Refe	<u> </u>	Other Terr MHR P2P	Run Conformance	
Template:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.11 ver 144)	~				Show Report	
	C:\DigitalHealth\TP-IQRules_v1.4.9		`			Run Addn Rules Only	_
Information	Rendered Document Sign File Sign File Information Template Validation Report Additional Rules	Report	Package	Report	Reference	ce Sets Other Terminology	/ Aspects

Figure 46: Additional Rules Package Report Reference Sets Other Terminology Aspects

Information is displayed in the **Additional Rules Report** tab in the same way as information is displayed in the **Template Validation Report** tab (Section 3.7.5).

3.7.7 Package Report tab

The **Package Report** tab displays the results of package validation (for which the Validator may be used) (Figure 47). This tab is only displayed after a clinical package or an HL7 MDM wrapped clinical package has been validated (Section 3.2.1).

File :	C:\Users\User\Desktop\EReferral_3A_Max1.zip	6	MHR	Run Conformance
	Reference Sets Other Terminology Aspects		O P2P	Show Report
Femplate:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.11 ver 144)			
ddn Rules:	C:\DigitalHealth\TP-IQRules_v1.4.9			Run Addn Rules Only

Figure 47: Package Report tab

The **Package Report** tab displays the validation result for each test case that was applied for the selected context, and a symbol that summarises each validation result (Figure 48). Section 2.1 provides information about these test cases.

File Conf	guration Help											
File :	C:\Users\User\Des	sktop\EReferra	al_3A_Max1.zip			6	MHR	Ru	n Conformance	Load and Validate XDS		
						-	O P2P		Show Report	Metadata		
Template:	e-Referral 3A (1.2	.36.1.2001.10	06.1.21000.11 ver 14	4)	¥							
Addn Rules:	C:\DigitalHealth\TP	P-IQRules_v1.	.4.9			eference Sets	other Terminology		Addn Rules Only			
Information	Rendered Document	Sign File	Sign File Information	Template Validation Report	Additional Rules Report				Other Terminology Aspects			
											Override Re	sults
_												
CDA Pac	kaging Validat	tion										
Test Dat	e: 6/10/2017	, 5:45:57	PM									
												_
CDA XM	L Document											
PKG_CDA	_014 - Verify the	CDA Docum	nent is valid for its	document type							1	
Pass) 🖌 🖌	
											r T	
	_015 - Verify any	packaged a	attachments are re	presented using an ED-	type element						-	
Pass											`	
	_016 - Verify the	ED-type ele	ement integrityChe	ckAlgortihm = 'SHA-1'							_	
Pass										· · · · · · · · · · · · · · · · · · ·		
PKG_CDA	_017 - Verify the	ED-type ele	ement contains a si	ngle cda:reference elen	ient							\sim

Figure 48: Package Report tab showing results of clinical package validation

Package validation symbols and their meanings are listed in Table 10.

Symbol	Explanation	Usage
V	Pass	The Validator determined a definite 'Pass' for the test case.
×	Fail	The Validator determined a definite 'Fail' for the test case.
P	Warning	The outcome of the test case can only be determined through manual inspection and then a decision of 'Pass' or 'Fail'.
-	Not Run	The test case is conditional (e.g. upon an attachment being present) and the validation was not run as the condition was not met.

3.7.8 Reference Sets tab

The **Reference Sets** tab (Figure 49) displays the results of validations of codes against reference sets where these are specified in the CDA implementation guide for the particular document type (see section 2.3.1 for details).

File Config	uration Help			
File :	C:\Users\User\Desktop\EReferral_3A_Max1.zip		MHR	Run Conformance
			O P2P	Show Report
Template:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.11 ver 144)			
Addn Rules:	C:\DigitalHealth\TP-IQRules_v1.4.9			Run Addn Rules Only
Information	Rendered Document Sign File Sign File Information Template Validation Report Additional Rules Report	Package	Report Reference S	Sets Other Terminology Aspects

Figure 49: Reference Sets tab

Reference set validation results are displayed for every data element for which the CDA implementation guide specifies a reference set in its 'Vocab' column. They include information that describes the validation result and a symbol representing this result (Figure 50).

File : C:\Users\User\Desktop\EReferral_3A_Max1.zip Image: C:\Users\User\Desktop\EReferral_3A_Max1.zip Image: C:\Users\User\Desktop\EReferral_3A_Max1.zip Image: C:\Users\User\Desktop\EReferral_3A_Max1.zip Load and Validate XDS Image: Display the second sec	
emplate Information Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Tempinology Aspects	
dn Rules: C:\DigitalHealth\TP-IQRules_v1.4.9	
mation Rendered Document Sign File Sign File Information Template Validation Report Additional Rules Report Package Report Other Terminology Aspects	
Ον	erride Results
erminology Validation	_
n minology validadon	
dverse Reaction > Substance/Agent	
ass ode Value = 86461001 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Plant diterpene Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:act[1]/cda:participant[1]/cda:component[2]/cda:code[1]	\checkmark
dverse Reaction > Substance/Agent	
ass ode Value = 117491007 CodeSystem = 2.16.840.1.113883.6.96 Display Name= trans-Nonachlor Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody]/cda:component[2]/cda:section[1]/cda:entry[2]/cda:act[1]/cda:participant[1]/cda:code[1]/cda:code[1]	\checkmark
dverse Reaction > Reaction Event > Manifestation	
ass ode Value = 21909001 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Fetal viability Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody	
ass ode Value = 21909001 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Fetal viability Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:entryRelationship[1]/cda:observation[1]/cda:cbservation[~
ass ode Value = 21909001 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Fetal viability Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody	~
ass ode Value = 21909001 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Fetal viability Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:entryRelationship[1]/cda:observation[1]/cda:cbservation[×
ass ode Value = 21909001 CodeSystem = 2.16.840.1.113883.6.95 Display Name= Fetal viability Calculated Name:/cda:ClinicslDocument[1]/cda:component[1]/cda:structuredBody]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:entryRelationship[1]/cda:observation[1]/cda:entryRelationship[1]/cda:cobservation[1]/cda:code[1] dverse Reaction > Reaction Event > Manifestation ass ode Value = 15296000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Sterility Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component	 ✓
ass de Value = 21909001 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Fetal viability Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:code[1] //cda:component[2]/cda:section[1]/cda:entry[1]/cda:entryRelationship[1]/cda:observation[1]/cda:entryRelationship[1]/cda:cobservation[1]/cda:code[1] dverse Reaction > Reaction Event > Manifestation ass ode Value = 15296000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Sterility Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component]/cda:section[1]/cda:entry[1]/cda:entryRelationship[1]/cda:component]/cda:section[1]/cda:entry[1]/cda:entryRelationship[1]/cda:component]✔]✔

Figure 50: Reference Sets tab showing results of reference set validation

Validation result symbols and their meanings are listed in Table 11.

Symbol	Explanation	Usage
V	Pass	All attributes of the data element have the expected value.
×	Fail	A code of the required type was found but did not have the expected value, or the display name was not correct.
-	Warning	An attribute of the data element does not have the expected value and the test result can only be determined through manual inspection and then a decision of 'Pass' or 'Fail'.
	Not Run	The data element is either not present or does not contain terminology codes.

Table 11 – Reference set v	validation symbols
----------------------------	--------------------

If the conformance level is 3B, the Validator reports a Fail (🗱) if a clinical document does not use the code set specified in the 'Vocab' column of the relevant CDA implementation guide.

For all conformance levels, the Validator reports a Fail (lpha) if:

- the value of a code does not exist in the terminology reference set specified in the relevant CDA implementation guide; or
- the display name of a code in a clinical document does not match that code's display name in the terminology reference set.

For all conformance levels, the Validator reports a Warning (📂) if:

- the code system name in a clinical document is not the name specified for that code system; or
- the clinical document contains a code from a code system that is not supported by the Validator.

3.7.9 Other Terminology Aspects tab

The **Other Terminology Aspects** tab (Figure 51) displays the results of validating any codes within the clinical document (for which the Validator may be used) that are members of the code systems listed in Table 1.

File :	C:\Users\User\Desktop\EReferral_3A_Max1.zip	6	MHR	Run Conformance
			P2P	Show Report
mplate:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.11 ver 144)			
n Rules:	C:\DigitalHealth\TP-IQRules_v1.4.9	\square		Run Addn Rules Only

Figure 51: Other Terminology Aspects tab

Information is displayed in the **Other Terminology Aspects** tab in the same way as information is displayed in the **Reference Sets** tab (Section 3.7.8).

3.8 Override Results command

After the validation has been performed (for a purpose for which the Validator may be used), the **Override Results** command is displayed in the Terminology Report tab (Figure 52).

File Configuration Help			
File : C:\Users\User\Desktop\EReferral_3A_Max1.zip	 MHR P2P 	Run Conformance Show Report	Load and Validate XDS Metadata
Template: Information Rendered Document Sign File Sign File Information Template Validation Report Package Report	Reference Sets Other Terminology	/ Aspects	
Addn Rules: C:\DigitalHealth\TP-IQRules_v1.4.9		Run Addn Rules Only	
Information Rendered Document Sign File Sign File Information Template Validation Report Additional Rules Report	Package Report Reference	Sets Other Terminology Aspects	
			Override Results

Figure 52: Override results command displayed in Other Terminology Aspects tab

The Validator allows the user to override package and code validation results. This is useful for tests that may result in a 'Warning' rather than a 'Pass' or a 'Fail'. A 'Warning' is displayed when the outcome of a test can only be determined by manual inspection.

The Validator allows a user to manually change a test result when a 'Warning' message is displayed. Although the purpose of this command is to allow a user to override a 'Warning' test result, the command also allows the user to override a 'Pass' or 'Fail' result. Overriding a 'Fail' result may result in an overall 'Pass' being reported in the test report although the My Health Record system may reject the clinical document when it is uploaded.

By selecting **Override Results,** a new window that allows the user to select the code validation result to be overridden is displayed (Figure 53).

Failed	Passed	a Warning	
	XPath	AssessmentComments ActualResult	OverrideResult
Þ	Code Va	falue = 430698003 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Replacement of total knee joint. Calculated Name / coda Clinica Warning	•
	Code Va	falue = 399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Name = chest x-ray Calculated Name /cda.ClinicalDocument(1)/cda.c Warning	
	Code Va	alue = 426496006 CodeSystem = 2.16.840.1.113883.6.96 Display Name- Hydrogen cyanide gas Calculated Name:/cda:ClinicalDocum	_
	Code Va	/alue = 80313002 CodeSystem = 2.16.840.1.113883.6.96 Display Name = Palpitations Calculated Name /cda.ClinicalDocument[1]/cda.c Warning	· ·

Figure 53: Overriding a code validation result

The XPath column contains the value of the code, the code system object identifier, the value of the display name, and the location of the data element that contains the code.

The user can manually record a new result and the reason for the change (Figure 54).

Note: To avoid processing errors, double quotation marks ("") should be used rather than single quotes (") to record the reason for the change. For example, "SNOMED CT-AU" should be used rather than 'SNOMED CT-AU'.

Failed	Passed Warning				
	XPath	AssessmentComments	ActualResult	OverrideResult	
1	Code Value = 430698003 Code System = 2.16.840.1.113883.6.96 Display Na	The actual name of SNOMED is close enough to the expected value of SNOMED CT-AU	Warning	Warning	•
	Code Value = 399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Na		Warning		-
	Code Value = 426496006 CodeSystem = 2.16.840.1.113883.6.96 Display N		Warning		-
	Code Value = 80313002 CodeSystem = 2.16.840.1.113883.6.96 Display Na		Warning		-

Figure 54: Recording a new code validation result and the reason for the change

The override changes the overall test result displayed on the Validator's Information tab (Section 3.7.1).

3.9 Show Report command

The **Show Report** command (Figure 55) allows a user to request the Validator to create a test report (for which the Validator may be used). It also creates an HTML file that is a rendered view of the clinical document that has been validated.

File :	C:\Users\User\Desktop\EReferral_3A_Max1.zip	6	MHR	Run Conformance
			O P2P	Show Report
Template:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.11 ver 144)			
ddn Rules:	C:\DigitalHealth\TP-IQRules_v1.4.9			Run Addn Rules Only

Figure 55: Requesting the Validator to create a test report

The Validator also provides the user with the option of entering information about the tests performed including the name of the author and tester; the names of the software development and tester organisations; and information about the software being tested and the test environment (Figure 56). This information is remembered and does not need to be re-entered every time the Validator is used.

[] Conformance Report Information		x
Report Details		
Author Name:		
Software Development Organisation:		
Report Identifier:		
Developer Name:		
Name of implementation under test:		
Version of implementation under test:		
Test environment:		
Location of assessment (address):		
Tester name:		
Tester organisation:		
Other information:		
	Continue	xel

Figure 56: Recording information about the tests performed

The test report is in Adobe PDF format and contains:

- assessment details, such as the conformance level, context and template ID;
- a list of terminology codes used;

- a summary of the validation test results;
- a detailed error report for each type of validation;
- a reference to the HTML file containing the rendered view of the clinical document that has been validated; and

The PDF file is saved and is located in the same directory as where the target file has been selected from.

The summary of the validation test results shows the overall result and the total number of issues and warnings reported by the Validator (Figure 57).

Note: If there are warnings but no issues, the overall test result recorded is a 'Pass', as shown in the 'Overall result' for the 'Other Terminology Validation' in Figure 57.

	Overall result	Error count	Warning count	Comments
Template Validation	×	2	0	
Package Validation	×	12	0	
Terminology Validation	×	1	10	
Other Terminology Validation	~	0	4	
Additional Rules Validation	-	0	0	



If a validation result is overridden before the test report is generated, the report records the original result, the new result, and the reason why the original result was overridden (Figure 58). The Validator uses the new result when it produces the summary of validation results in the test report.

#	CodeSet/Code/Name	Comment	Resul t	Overr ide
1	Code Value = 73817000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Enteritis due to radiation	The actuial codeSystemName value "SNOMED" is close enough to the expected value "SNOMED CT-AU"	Warni ng	Pass
	Calculated XPath;/cda:ClinicalDocument[1]/cda:component[1]/cda:struct uredBody[1]/cda:component[1]/cda:section[1]/cda:component [1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:value[1]			



3.10 Cumulative report of test results

The Validator creates a cumulative report of test results in the file report.csv which is located in the same directory as where the target file has been selected from. A new row is added to this file each time a clinical document or clinical package (for which the Validator may be used) is validated. The information recorded in this file is listed in Table 12.

Label	Description
Input File Name	The filename of the clinical document or clinical package that was validated.
Test Date	The date and time the file was assessed by the Validator.
Template Name	The name of the My Health Record template package as recorded in the template package metadata.
Template ID	The identifier of the My Health Record template package as recorded in the template package metadata.
Template Version	The version number of the My Health Record template package as recorded in the template package metadata.
Template Effective Date	The date the My Health Record template package was approved as recorded in the template package metadata.
Conformance Level	The conformance level as recorded in the template package metadata.
Test Context	The value is either 'MHR' or 'P2P'.
Package Errors	The number of clinical package errors.
Package Warnings	The number of clinical package warnings.
Template Errors	The number of errors reported by applying the My Health Record template package.
Template Warnings	The number of warnings reported by applying the My Health Record template package. Note: template packages in the My Health Record system do not report warnings.
Additional Rules Issues	The number of issues reported by applying the additional template package.
Additional Rules Warnings	The number of warnings reported by applying the additional template package.
Reference Set Errors	The number of errors reported by applying reference set validation (Section 2.3.1).
Reference Set Warnings	The number of warnings reported by applying reference set validation (Section 2.3.1).
Other Terminology Errors	The number of errors reported when validating codes from supported code systems.
Other Terminology Warnings	The number of warnings reported when validating codes from supported code systems.
Summary	An overall Pass or Fail.

Table 12 – Information in the report.csv file

The Validator also creates an analysis report of test results in the file analysis.csv which is located in the same directory as where the target file has been selected from. A new row is added to this file for each result reported for a clinical document being validated so there may be 0 or more rows returned depending on the issues found. The information recorded in this file is listed in Table 13.

Label	Description
Document Creation Date	The date the document was created (effectiveTime)
Document Creation Time	The time the document was created (effectiveTime)
Error ID	<empty></empty>
Priority	The priority level of issue raised
Error Type	Whether the issue is from a template package or conformance set of rules (Conformance or Template)
Error Classification	Classification type of issue raised (ERROR, HINT, RECOMMENDATION, FINDING, WARNING)
Document Type	CDA document type
Conformance Level	The level of conformance the document is being tested at
Template Package ID	Template package ID being used to test the document.
Document Id	The id of the document (id root)
Site Impacted in Sample	The Organisation that authored the document
Error	The error reported
Conformance Specification	<empty></empty>
Guidance	<empty></empty>
XML Evidence	<empty></empty>
Proposed Vendor Action	<empty></empty>
Timeframe for Completion	<empty></empty>
Expected Version Containing Fix	< <empty></empty>

Table 13 –	Information	in the r	report.csv file
	mjormation	in the i	

Many of the fields may be empty as this analysis report is used by the conformance team to record and analyse issues.

3.11 Load and Validate XDS Metadata

The **Load and Validate XDS Metadata** command allows a user to request the Validator to test a SOAP upload document xml file and run a series of tests that the my Health Record system also performs when uploading a document (Figure 59).

File Configura	ation Help			
File : E:	\DigitalHealth\CDA\ExampleSHSwithDVA.xml	MHR P2P	Run Conformance	Load and Validate XDS Metadata
Template: e-	Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.13 ver 31147) ver 31147)			
Addn Rules: Se	lect additional rules template folder for validation		Run Addn Rules Only	

Figure 59: Requesting the Validator to load and validate a soap upload document request

This function would generally be used when a user is experiencing problems uploading a document to the My Health Record system and getting the generic error message "PCEHR_ERROR_3002 - Document metadata failed validation".

In order to use this command, the user must have captured the SOAP request message that is sent to the My Health Record system and saved as an xml file.

The SOAP message can come in two formats:

• where the document is contained within the xml file as a base64 string



• or as a reference to the document when the sent as in MTOM format. For this format, the Validator will also prompt the user to select the cda package (zip) that was sent in order to complete the tests it runs.



The Screen shot below (Figure 60) shows the result of having selected a SOAP message to validate. The example shows the IHI's have not matched.

The screen details show:

- The certificate that signed the SOAP message
- The XDS Metadata that was included with the CDA document
- The custom SOAP Header data
- A Report summary of the tests carried out

File : E: \DigitalHealth\CDA\ExampleSHSwithDVA.xml		MHR P2P	Run Conformance	Load and Validate XDS Metadata
plate: e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.13 ver 31147)			Show Report	
Rules: Select additional rules template folder for validation			Run Addn Rules Only	
sport DS Metadata Report Signing Cert Details				
Sign Cert CM : CN-general.8003628233352432.id.electronichealth.net.au, G=ME Sign Cert Hpic: 8003628233352432 Xds Metadata creationTime : 20170620230015 languageCode : en-AU serviceStopTime : 20170620230015 serviceStopTime : 20170620230015 sourcePartientId : 800360833429777~1.2.36.1.2001.1003.0.ISO authorInstitution : Good Hospital^concord.2.36.1.2001.1003.0.80036282333 authorPerson : Smith~Good~~Doctor~1.2.36.1.2001.1003.0.8003616566 authorSpecialty : General Medical Practitioner classCode : 60591-5 (Shared Health Summary) docAccessLevel : GENERAL formatCode : 1.2.36.1.2001.1006.1.16615.15 (Specialist Letter 2 R htcareFacilityType : 8401 (Hospitals)	52432 667096I	·	SOAP Header Id Type : HPII Id : 80036 Username : Jacly Ihi Numb : 800384 Vendor : NEHT Prod name : NEHT Prod ver : 6.1 Flatform : Wind Sys Type : CIS	516566667096 m Marschke 508666701594 4 k HIPS WS
Initialization State State	52432		HPII's Match in XDS HPIO's Match in Hea HPIO's Match XDS a	er, XDS and CDA document: False and CDA document: True ider and Signing Cert: True nd CDA document: True top time are valid: True

Figure 60: Requesting the Validator to load and validate a soap upload document request

The tests that are performed are:

- 1 Check that the file provided is a validate XML document
- 2 The Soap message was signed
- 3 The XDS Metadata was included
- 4 The CDA package was valid (zip file format)
- 5 Report the following test results:
 - a The IHI's Match in SOAP Header, XDS metadata and CDA document
 - b The HPII's Match in the XDS metadata and CDA document
 - c The HPIO's Match in Header and Signing Cert
 - d The HPIO's Match XDS metadata and CDA document
 - e The Service Start and Stop time are valid

4 Examples of validation

This section provides examples to demonstrate how the Validator can be used to validate clinical documents and clinical packages (for which the Validator may be used). The Validator is a tool to assist users only and while it assists in testing conformance, it does not, and should not be relied upon to test all conformance specifications. Please refer further to the *Clinical Package Validator Product Data Sheet* and confirm your intended use with the Agency Help Desk on 1300 901 001.

4.1 Validate a 3A eReferral clinical package, My Health Record context

The following example shows how the Validator may be used to assess an eReferral clinical document within a clinical package for level 3A conformance in the My Health Record context.

1 If the Validator has been installed and configured but is not already launched, launch the Validator as follows.

If using Windows 7, navigate to Start > All Programs > Agency > Clinical Package Validator.

If using Windows 8 or above, click the Windows icon to open the Metro view and either search for "Clinical Package Validator" or visually locate the application menu.

			Clinical Packa	ge Valio	dator v2.6		- - ×
File Conf	iguration Help						
File :	Select an input file to v	alidate		6	MHR P2P	Run Conformance	Load and Validate XDS Metadata
Template:			Y		0 121	Show Report	
Addn Rules:	Select additional rules	template folder for validation				Run Addn Rules Only	
Information							
Templ Te	Document Type: late Package Name: mplate Package ID: Conformance Level: olate Effective Date: Template Version: Template Path:	te Package Document Type Template Package Name Template Package ID Conformance Level Effective Date Template Version TemplatePath C:\DigitalHealth\CPV26\Temp					

The default screen will appear (Figure 61).

Figure 61: Default Validator screen

- 2 Click the Open File button () next to the **File** parameter and locate the clinical package to be validated, or drag the clinical package onto the **Information** tab or the **File** location field (Section 3.2.1).
- 3 If more than one eReferral template is imported in the Validator, select the relevant template for a level 3A eReferral (Figure 62).

The default context for validating a clinical package is My Health Record (Section 3.2.4).

File Config	guration Help		
File :	E:\Sample documents\Section 4.1\eReferral.zip	MHR O P2P	Run Conformance
Template:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)		Silow Report
Addn Rules:	Select additional rules template folder for validation		Run Addn Rules Only
Information			

Figure 62: Template selection

Figure 63 shows the Validator Information tab, after the parameters for testing an eReferral for level 3A conformance in the My Health Record context have been selected.

File Confi	guration Help	
File :	E:\Sample documents\Section 4.1\eReferral.zip	MHRP2P
Template:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)	
Addn Rules:	Select additional rules template folder for validation	
Information		
- Configu	ration and Runtime Information	

Figure 63: Information tab showing information about the clinical document and template package

4 Click the **Run Conformance** button to perform the validation (Figure 64).

File Confi	guration Help			
File :	E:\Sample documents\Section 4.1\eReferral.zip	6	MHR P2P	Run Conformance
Template:	e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)		0	Show Report
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only
Information				
Configu	ration and Runtime Information			

Figure 64: Selecting the Run Conformance button

The **Information** tab shows a summary of the validation results (Figure 65). In this example there are 0 template errors, 7 CDA Package errors, 1 reference set errors and 3 warnings for other terminology aspects.

File Configuration Help				
File : G:\Program and Project Documents\26 CCA\CDA Validator development\CP Validator 2.3\Manuals\L guide figures and sample documents\Sample documents\Section 4.1\eReferral.zip	lser	MHR P2P	Run Conformance	Load and Validate XDS Metadata
Template: e-Referral 3B (1.2.36.1.2001.1006.1.21000.22 ver 32624)	\sim			
Addn Rules: Select additional rules template folder for validation			Run Addn Rules Only	
Information Rendered Document Sign File Sign File Information Template Validation Report Package Report	Reference Sets	Other Terminology	y Aspects	
Configuration and Runtime Information				
Template Package		Files found in	n zip <mark>f</mark> ile:	
Document Type: e-Referral Template Package Name: e-Referral Template Package ID: 1.2.36.1.2001.1006.1.21000.22 Conformance Level: 38 Template Effective Date: Monday, 1 April 2013 Template Version: 32624 Template Path: D:/DigitalHealth/CPV26/Templates\1.2.36.1.2001.1006.1.21000 Temp Work Path: C:/DigitalHealth/CPV26/Temp Zip file size: 42.34 KB	0.22.32624	IHE_XDM/SUBS	SET01/CDA_SIGN.XML SET01/x-ray.jpg SET01/CDA_ROOT.XML	
		Template Valida Pack Reference	ation Results: 0 Errors age Results: 7 Errors Set Results: 1 Errors logy Results: 0 Errors 3	Warnings

Figure 65: Information tab showing a summary of the validation results

The **Rendered Document** tab displays a rendered view of the eReferral that was validated (Figure 66).

File: G:\Program and Project Documents\26 CCA\CDA Validator development\CP Validator 2.3\Manuals\User Image: Conformance Run Conformance guide figures and sample documents\Sample documents\Section 4.1\eReferral.zip Image: Conformance Show Report Template: e-Rt Information Rendered Document Sign File Image: Conformation Template Validation Report Package Report Reference Sets Other Terminology Aspects Image: Conformation Template Validation Report Package Report Reference Sets Other Terminology Aspects Image: Conformation Template Validation Report Package Report Reference Sets Other Terminology Aspects Image: Conformation Conformation Conformation Conformation Reference Sets Other Terminology Aspects Image: Conformation Conformation <td< th=""></td<>
Information Redered Document Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects Information Rendered Document Sign File Template Validation Report Package Report Reference Sets Other Terminology Aspects Back Forward Forward Forward Forward Forward Forward
Back Forward
e-Referral
6 Aug 2012 Beau O'KEEFE DoB 6 Jun 2005 (7y) SEX Male IHI 8003 6067 9000 0495 START OF DOCUMENT
Good Hospital Author Phone Doctor Henry Button (General Medical Practitioner) 0345754566
Referral Detail
Date and Duration
Date Duration
12 Dec 2011 16:10+1000 6 month
Reason for Referral
Thank you for seeing this 7 year old Qantas baggage handler with pain in his Left knee. He injured the knee whilst disembarking from an aircraft at work. WorkCover have requested that he seek an opinion from a specialist to ascertain the extent of his injury.
Medications
Medications
Medication Directions
naproxen 250 mg tablet, 50 6 to 8 hours as needed. Do not exceed 4 within 24 hours. Do not crush, chew, or break an extended-release or enteric-coated tablet. Swallow the pill whole.
tramadol hydrochloride 50 mg capsule, 20 Every 4 to 6 hours not to exceed 400 mg per day
Medical History

Figure 66: Rendered Document tab showing a rendered view of the validated clinical document

4.1.1 View information about the eSignature file

The **Sign File Information** tab displays information about the primary eSignature file of the clinical package (Figure 67).

File	Config	guration Help						
	File :	G:\Program and Project Docu guide figures and sample doc				6	MHR	Run Conformance
							O P2P	Show Report
Ten	nplate:	e-Referral 3B (1.2.36.1.2001	.1006.1.21000.22 ver 326	624)	~			
Addr	n Rules:	Select additional rules templa	te folder for validation					Run Addn Rules Only
Inform	Information Rendered Document Sign File Sign File Information Template Validation Report Package Report Reference Sets Other Terminology Aspects							
C	DA Sig	n File Information –						
	Signing Time : 2012-08-07T06:29:48.7091593Z Approver Person Id : http://ns.electronichealth.net.au/id/hi/hpii/1.0/8003615833334118 Approver Person Name : Doctor Henry Button							
	Orga	anisation Certificate	This is not a NASH Ce	ertificate				
			13/07/2012 9:08:13 7/07/2013 10:00:00	AM	ITA, DC=ELECTRONIC	CHEALTH,	DC=NET, DC=A	'n
0	ther sigr	nature files in package :						

Figure 67: Sign File Information tab showing a summary of information about the primary eSignature file

This includes information about an approver's name and HPI-I, whether the PKI certificate had expired at the time of running the validation, and whether the PKI certificate is a NASH certificate.

The approver's name and HPI-I reported by the Validator in this tab can be used to check whether the healthcare software system is recording the same person as the approver of the clinical document.

In the above example, the Validator reported that the PKI certificate had expired when the validation was performed. This is not a problem if the certificate had not expired when the clinical document was signed.

In the above example, the Validator reported that the organisation certificate was not a NASH certificate. It is a requirement that all certificates used for signing clinical packages be NASH PKI certificates for healthcare provider organisations or NASH PKI certificates for supporting organisations. This error is also reported against the relevant test case in the **Package Report** tab.

The information displayed in the **Sign File Information** tab is usually the only information about the eSignature that is needed for validating a clinical document.

Additional information about the eSignature may be obtained by examining the CDA_SIGN.XML file displayed in the **Sign File** tab. In the following example, the PKI certificate is displayed to the right of the <X509Certificate> XML tag (Figure 68).

			lidator development\CP Valid ents\Section 4.1\eReferral.zi			MHR	Run Conformance	Load and Validate X Metadata
emplate:	e-Referral 3B (1.2.36.1.20	01.1006.1.21000.22 ver 3	2624)	```	1			
In Rules:	Select additional rules temp				ort Reference		Run Addn Rules Only	
mation	Rendered Document Sign F	()	ile Information Template Validation Report		ort Reference Sets	Other Terminolog	nology Aspects	
						1	1	
		://ns.electronic	health.net.au/xsp	/xsd/SignedPa	yload/20	010">		
	atures>			4.U				
	gnature xmins=" nttp SignedInfo>	://www.w3.org/	2000/09/xmldsig#	">				
- <		thod Algorithm="	ttp://www.w3.org	/2001/10/ym	-exc-c1/	1n#" />		
			/www.w3.org/2000					
_			4848-bcfc-f54756a			15		
	 <transforms></transforms> 							
	<transform algo<="" td=""><td>orithm="http://ww</td><td>ww.w3.org/2001/1</td><td>0/xml-exc-c14</td><td>4n#" /></td><td></td><td></td><td></td></transform>	orithm="http://ww	ww.w3.org/2001/1	0/xml-exc-c14	4n#" />			
			/2000/www.w3.org		ha1" />			
	Digost\/pluo>dD	1Qy4XYnp6AyPU	RpK/dVJQBNoo= </td <td>DigestValue></td> <td></td> <td></td> <td></td> <td></td>	DigestValue>				
<								
<	 /SignedInfo>	COI Yefhai2v/V	MiAkf93DnCuTI n/H	dKmEav0YBOY	unh1+w(w5eKrygwP	FAWtaP+niAhKA120Y	cr7YCaCvwAllIYvIIPa3
	 /SignedInfo> <signaturevalue>P4</signaturevalue>	eGOLXefhqj3y/Y	MiAkf83DnGuTLrvH	dKmFax0XBOY	unhJ+w(Gv5eKrxqwR	FAWtaR+piAhKAJ2QY	sr7YCgGywAUlXvURg3
- <	 /SignedInfo>	eGOLXefhqj3y/Y	MiAkf83DnGuTLrvH	dKmFax0XBOY	unhJ+w(Gv5eKrxqwR	TAWtaR+piAhKAJ2QY	sr7YCgGywAUlXvURg3
- <	 /SignedInfo> <signaturevalue>Po KeyInfo> <x509data></x509data></signaturevalue>							
- <	 /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509certificat< td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td></x509certificat<></x509data></signaturevalue>							
- < -	 /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509certificat </x509certificat </x509data></signaturevalue>							
- < -	 /SignedInfo> <signaturevalue>P4 KeyInfo> <x509data> <x509data> /X509Data> /KeyInfo></x509data></x509data></signaturevalue>							
- < - <td> /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509data> /KeyInfo> ignature></x509data></x509data></signaturevalue></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>	 /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509data> /KeyInfo> ignature></x509data></x509data></signaturevalue>							
- < - <td> /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509data> /KeyInfo> ignature> natures></x509data></x509data></signaturevalue></td> <td>e><mark>MIII4TCCB8m</mark>g</td> <td>JAWIBAJIETXQYKT<i>i</i></td> <td>NBgkqhkiG9w(</td> <td></td> <td></td> <td></td> <td></td>	 /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509data> /KeyInfo> ignature> natures></x509data></x509data></signaturevalue>	e> <mark>MIII4TCCB8m</mark> g	JAWIBAJIETXQYKT <i>i</i>	NBgkqhkiG9w(
- < - <td> /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509data> </x509data> /KeyInfo> ignature> atures> edPayloadData id="1</x509data></signaturevalue></td> <td>e>MIII4TCCB8mg b37d9c2-7b7b-4</td> <td>gAwIBAgIETXqyKTA 1848-bcfc-f54756a2</td> <td>NBgkqhkiG9w(34fd2"></td> <td>BAQUFA</td> <td>DAxMQswCC</td> <td>QYDVQQGEwJBVTESM</td> <td></td>	 /SignedInfo> <signaturevalue>Po KeyInfo> <x509data> <x509data> </x509data> /KeyInfo> ignature> atures> edPayloadData id="1</x509data></signaturevalue>	e>MIII4TCCB8mg b37d9c2-7b7b-4	gAwIBAgIETXqyKTA 1848-bcfc-f54756a2	NBgkqhkiG9w(34fd2">	BAQUFA	DAxMQswCC	QYDVQQGEwJBVTESM	
- < - - <sign - <q1< td=""><td> /SignedInfo> <signaturevalue>P4 KeyInfo> <x509data> <x509data> /KeyInfo> ignature> natures> edPayloadData id="1 :eSignature xmlns:q</x509data></x509data></signaturevalue></td><td>e>MIII4TCCB8mg b37d9c2-7b7b-4 1="http://ns.ele</td><td>JAWIBAJIETXQYKT<i>i</i></td><td>NBgkqhkiG9w(34fd2"> u/cdaPackage</td><td>BAQUFA</td><td>DAxMQswCC</td><td>QYDVQQGEwJBVTESM</td><td>SF7YCgGywAUlXvURg3 BAGA1UEChMJTkVIVEF</td></q1<></sign 	 /SignedInfo> <signaturevalue>P4 KeyInfo> <x509data> <x509data> /KeyInfo> ignature> natures> edPayloadData id="1 :eSignature xmlns:q</x509data></x509data></signaturevalue>	e>MIII4TCCB8mg b37d9c2-7b7b-4 1="http://ns.ele	JAWIBAJIETXQYKT <i>i</i>	NBgkqhkiG9w(34fd2"> u/cdaPackage	BAQUFA	DAxMQswCC	QYDVQQGEwJBVTESM	SF7YCgGywAUlXvURg3 BAGA1UEChMJTkVIVEF

Figure 68: Sign File tab displaying the PKI certificate in the CDA_SIGN.XML file

To examine the PKI certificate, use a text editor to copy and save it to a document with the '.cer' filename extension. Double-click to open the saved document and view the certificate (Figure 69 and Figure 70).

Certificate							
General Details Certification Path							
Certificate Information							
Windows does not have enough information to verify this certificate.							
Issued to: bay-hill-hospital.nehta.net.au							
Issued by: SubCA							
Valid from 13/ 07/ 2012 to 7/ 07/ 2013							
Install Certificate							
Learn more about <u>certificates</u>							
ОК							

Figure 69: A view of the PKI certificate

Certificate	×						
General Details Certification Path							
Show: <all></all>	•						
Field	Value						
Valid from Valid from Valid to Subject Public key Authority Information Access Enhanced Key Usage Certificate Policies Subject Alternative Name	Friday, 13 July 2012 11:08:13 Sunday, 7 July 2013 12:00:00 bay-hill-hospital.nehta.net.au, RSA (2048 Bits) [1]Authority Info Access: Acc Server Authentication (1.3.6 I]Certificate Policy:Policy Ide DNS Name=hav-hill-honenital n						
[1, 1]Policy Qualifier Info: Policy Qualifier Id=CPS Qualifier: http://policy.testsubmod1.pki.electronichealth.net.au/testsubmod1/po							
licy/NASH_HPIO_CP.pdf [1,2]Policy Qualifier Info:	-						
Ec	lit Properties Copy to File						
	ОК						

Figure 70: PKI certificate details

4.1.2 Display template validation results

To view the detailed template validation results, click the **Template Validation Report** tab (Figure 71). In this example, the error count was zero as no errors were found during template validation. The clinical document still needs to be manually inspected for conformance to requirements because not all conformance tests can be specified in a template (Section 2.2.1).

File Configuration Help					
File : E:\Sample documents\Sec		6	MHR P2P	Run Conformance Show Report	Load and Validate XDS Metadata
e-Referral 3B (1.2.36.1.2)	001.1006.1.21000.22 ver 32624)	\checkmark			
Addn Rules: Select additional rules tem	plate folder for validation	`		Run Addn Rules Only	
Information Rendered Document Sign	File Sign File Information Template Validation Report	Package Report Reference Sets	Other Terminology	Aspects	
		Temp	late Valida	tion Report	^
VALIDATION STATUS SERVICE NAME SERVICE PROVIDER STANDARD TYPE DATE OF TEST TIME OF TEST RESULT OF TEST ISSUE COUNT SIGNATURE VALIDATION	Complete e-Referral - 3B Australian Digital Health Agency CDA R2 09-Oct-2017 11:30:15 +10:00 True 0 See Package Report Tab				>
			Test Ob	iect	
<typeid 1.2.3<br="" root="2.16.840.
<templateId root="><templateid 76af7a71-f40a<="" root="1.2.3
<id root=" td=""><td>0120806161622+1000"/> 11Flavor="NA"/></td><td>000040"/> tension="2.2"/> ="1.0"/></td><td>ons/3.0" xmlr</td><td>ns:xsi="http://www.</td><td></td></templateid></typeid>	0120806161622+1000"/> 11Flavor="NA"/>	000040"/> tension="2.2"/> ="1.0"/>	ons/3.0" xmlr	ns:xsi="http://www.	

Figure 71: Template Validation Report tab showing template validation results

4.1.3 Display package validation results

To view the detailed package validation results, click the **Package Report** tab (Figure 72). The Validator reports some errors with the clinical package in this example, including the absence of a valid NASH certificate.

File Con	nfigura	ation He	lp																										
File :	E:	\Sample do	cument	Section	4.1\eRe	ferral.zip								6		MHR P2P			n Conf Show I	ormance			L	oad and \ Met	/alidate adata	≥ XDS			
Template:	e-	Referral 3E	(1.2.36	.1.2001.	1006.1.2	1000.22	ver 3262	24)						\sim		0			Shown	leport									
Addn Rules:	Se	ect additio	nal rule:	; templat	e folder i	for valida	tion							6				Run	Addn I	Rules On	ly								
nformation	Ren	dered Docun	ient	Sign File	Sign F	ile Informa	ation	Template '	Validatio	ion Report	ort [Package R	Report	Reference S	5ets	Other Term	inology	y Aspec	5							0	verride	e Results	~
CPCD_02	4630) - Verify	all pac	caged a	ttachm	ents ha	ve filen	ame ex	tensio	ons whi	hich m	natches	i their M	IME type													_		
Pass																										0		V	
CPCD_02	3743	3 - Verify	that CI)A paci	age is r	not large	er than	10MB																		_		~	l
contain a	n eSi	ignature	with a v	ralid NA	SHPKI	certific	ate for	support	ting or	rganisa	sation	15				vith a valid upporting						hcare p	provid	ler orgai	nisatio	ns, or		*	
PKG_024	732 -	- Verify a	diagno	stic rep	oort, inc	luding t	he atta	iched PC	DF file	e, MAY	refei	erence a	ın objec	t outside	of th	e CDA pac	kage	e.										_	~
1																										~		- 5	



4.1.4 Display code validation results

To view the detailed code validation results, click the **Reference Sets** tab (Figure 73) and the click the **Other Terminology Aspects** tab (Figure 74). If any warning is reported, the clinical document must be manually inspected to determine whether a 'Pass' or 'Fail' should be recorded for the relevant code. The override facility may be used to record the outcome of this inspection (Section 3.8).

File Cor	nfiguration Help						
File :	E:\Sample documents\Section 4. 1\eReferral.zip		 MHR P2P 	Run Conformance	Load and Validate XDS Metadata	5	
Template:	e-Referral 3B (1.2.36.1.2001.1006.1.21000.22 ver 32624)			•			
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only			
Information	Rendered Document Sign File Sign File Information Template Validation Report Package Report R	eference Sets	Other Terminology	y Aspects			
Imagir	ng Examination Result/Imaging Examination Result Group > Anato	omical S	ite > Specifi	c Location > Side		Override Results	^
Name:/co '102.161	ing elements found da:ClinicalDocument/cda:scmponent/cda:structuredBody/cda:component/cda:section[cda:co d5']/cda:entryRelationship/cda:organizer[@ a:targetSiteCode/cda:qualifier/cda:value						
Imagir	g Examination Result/Imaging Examination Result > Anatomical S	Site > S	pecific Locat	ion > Anatomical Lo	ocation Name		
Name:/co	ing elements found Ja:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:co 45]/cda:entry/cda:observation[@classCode = '0BS']/cda:targetSiteCode	de/@code	= '101.20117']/d	:da:component/cda:section([cda:code/@code =		
Imagir	ng Examination Result/Imaging Examination Result > Anatomical S	Site > S	pecific Locat	ion > Side			
Name:/co	ing elements found da:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:co d5]/cda:entry/cda:observation[@classCode = '0BS']/cda:targetSiteCode/cda:qualifier/cda:v		= '101.20117']/c	da:component/cda:section[[cda:code/@code =	-	
Medica	tion Instruction > Medicine						Į,
Unit of U Code Val	ing code found for '275550110000361' in code system '1.2.36.1.2001.1004.100' for the ref se (MPUU), Trade Product (TP), Trade Product Pack (TPP), Trade Product Unit of Use (TPUU use 27555010000361 codeSystem = 1.2.36.1.2001.1004.100 Display Name naproxen ; tructuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:substanceAdministrati ode[1]), Containe 250 mg tai	ered Trade Produ plet, 50 Calculate	ct Pack (CTPP)' ed Name:/cda:ClinicalDocum	nent[1]/cda:component	×	
Medica	tion Instruction > Medicine						
	ue = 28222011000036107 CodeSystem = 1.2.36.1.2001.1004.100 Display Name= tramado opposent[1]//da:structuredBodu[1]//da:composent[2]//da:sertion[1]//da:structuredBodu[2]//da:sertion[2]//da					~	~

Figure 73: Reference Sets tab showing reference set validation results

File Con	figuration Help						
File :	E:\Sample documents\Section 4.1\eReferral.zip	6	MHR P2P	Run Conformance	Load and Validate XDS Metadata	5	
Template:			U P2P	Show Report			
remplate.	e-Referral 3B (1.2.36.1.2001.1006.1.21000.22 ver 32624)						
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only			
Information	Rendered Document Sign File Sign File Information Template Validation Report Package Report R	eference Sets	Other Terminolog	y Aspects			
						Override Results	
							~
	ue = 308552006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= report status Calc omponent[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observatio					~	
SNOME	ED CT						
	ue = 88101002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Pathology diagnosi omponent[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observatio					\checkmark	
SNOME	D CT						
Code Val	nd but the display name did not match. Expected: 'Laboratory data interpretation' ue = 386344002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Laboratory finding tructuredBody(1)/cda:component[5]/cda:section[1]/cda:					1	
SNOME	D CT						
	ing elements found xtt*[@codeSystem='2.16.840.1.113883.6.96']						
Austral	lian Medicines Terminology (AMT)						1
Code Val	ing code found for '275550110000361' in code system '1.2.36.1.2001.1004.100' ue = 275550110000361 CodeSystem = 1.2.36.1.2001.1004.100 Display Name= naproxen tructuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:substanceAdministrat ode[1]					P	
Austral	lian Medicines Terminology (AMT)						~



4.1.5 Generate a test report

To generate a test report in Adobe PDF format, click the **Show Report** button (Figure 75). Enter details of information to be included in the report and then click the **Continue** button (Figure 76).

File Confi	guration Help						
File :	E: \Sample documents \Section 4.1\eReferral.zip	6	MHR P2P	Run Conformance Show Report	Load and Validate XD Metadata	5	
Template:	e-Referral 3B (1.2.36.1.2001.1006.1.21000.22 ver 32624)						
Addn Rules:	Select additional rules template folder for validation			Run Addn Rules Only			
Information	Rendered Document Sign File Sign File Information Template Validation Report Package Report R	eference Sets	Other Terminolog	gy Aspects			
						Override Results	
Pass Code Valu	e = 308552006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= report status Calcu	ulated Nam	ne:/cda:ClinicalD	ocument[1]/cda:component	[1]/cda:structuredBody		
	mponent[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observatio	on[1]/cda:	entryRelationship	[4]/cda:observation[1]/cda	:code[1]		
SNOME	D CT						
Pass							
	e = 88101002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Pathology diagnosi: mponent[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observatic					×	
SNOME	р ст						
0.1.6	d but the display name did not match. Expected: 'Laboratory data interpretation'						
Code Valu	d but the display name did not match. Expected: Laboratory data interpretation = 386344002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Laboratory finding ucturedBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:					, 🍋	
SNOME		=110 y[1]/00	a.observation[1	j/cda.endykeiadonsnip[0]/k	coalobservation[1]/coalcobe[1	.1	
SNOPL							
	ng elements found t:*[@codeSystem='2.16.840.1.113883.6.96']						
	an Medicines Terminology (AMT)						1
Mustrun							
Code Valu	ng code found for '275550110000361' in code system '1.2.36.1.2001.1004.100' = 275550110000361 CodeSystem = 1.2.36.1.2001.1004.100 Display Name= naproxen : ucturedBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:substanceAdministrati de[1]					P	
Australi	an Medicines Terminology (AMT)						~



[] Conformance Report Information	X
Report Details	
Author Name:	John Goodson
Software Development Organisation:	Good software coporation
Report Identifier:	2015-06-15-01
Developer Name:	
Name of implementation under test:	Good clinical information system
Version of implementation under test:	4.0
Test environment:	Windows 7
Location of assessment (address):	400 George Street, Brisbane, QLD, 4000
Tester name:	John Goodson
Tester organisation:	Good software coporation
Other information:	
	Continue Cancel

Figure 76: Adding test report information

The test report is now complete (Figure 77).

Clinical Document Conformance Benert
Clinical Document Conformance Report
(for producers of clinical documents)
Prepared by
John Goodson
for
Good software coporation
Report identifier: 2015-06-15-01
Test date: Monday, 15 June 2015

Figure 77: Completed test report

4.2 Examples of code validation

The Validator examines codes and their associated display names in some clinical documents and compares these against codes and display names in supported code systems. It then reports whether a code in a clinical document and its associated display name are valid i.e. the Validator will report a 'Pass', 'Fail' or 'Warning' for that code and display name.

A 'Warning' is reported if the Validator is unable to find a matching code and display name in a supported code system. As a warning may be reported due to an underlying error in the clinical document, warnings are investigated to determine why a code or display name in the clinical document could not be found in the supported code system. This helps the tester to determine whether to override the 'Warning' and record a 'Pass' or 'Fail' for that code and display name.

This section contains examples of code validation performed on some clinical documents created by actual health software systems, including examples where the result of code validation was overridden.

Please refer to the *Clinical Package Validator Product Data Sheet* for further details on the scope of tests for clinical terminology validation.

4.2.1 Australian Vaccine code error

Figure 78 shows a 'Warning' reported in the **Other Terminology Aspects** tab because the value of the displayName attribute for an Australian Vaccine code in a clinical document was not the expected name.

P

An examination of the list of Australian Vaccine codes (in the Australian Vaccine codes <u>website⁶</u>) showed that the expected displayName for the vaccine code 'ADT' is 'ADT' (the vaccine brand name). The override facility was used to report a 'Fail' because the displayName in the clinical document was 'BOOSTRIX'.

The display name is the name associated with a code, and both the code and display name should be imported into a clinical document from a code system. The originalText element is used to record text that is typed in or selected by a healthcare provider. In this example, the originalText element was not present in the clinical document. Instead of storing this text in the originalText element, the healthcare software system may have mistakenly recorded the text in the displayName attribute instead.

Australian Vaccine Code

Code found but the display name did not match. Expected: 'ADT' Code Value = ADT CodeSystem = 1.2.36.1.2001.1005.17 Display Name= BOOSTRIX Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody [1]/cda:component[5]/cda:section[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]

Figure 78: Other Terminology Aspects tab showing a warning for an Australian Vaccine code

4.2.2 ANZSCO code error

Figure 79 shows a 'Warning' reported in the **Other Terminology Aspects** tab because an Australian and New Zealand Standard Classification of Occupations (ANZSCO) code in the clinical document was not a valid code.

An examination of the set of ANZSCO codes showed that '2515' was not a valid code as it did not have the required six characters. '2515' indicates a group of classifications so trailing zeroes should have been added to this code i.e. '251500'. The letters 'nfd' (not further defined) should also have been added to the display name of the code i.e. 'Pharmacists nfd' [ABS1220.0]. The override facility was used to report a 'Fail'.

ANZSCO Type Code

No matching code found for '2515' in code system '2.16.840.1.113883.13.62' Code Value = 2515 CodeSystem = 2.16.840.1.113883.13.62 Display Name= Pharmacists Calculated Name:/cda:ClinicalDocument[1]/cda:author[1]/cda:assignedAuthor [1]/cda:code[1]

Figure 79: Other Terminology Aspects tab showing a warning for an ANZSCO code

4.2.3 Australian PBS item code error

Figure 80 shows a 'Warning' reported in the **Other Terminology Aspects** tab because a PBS item code was not valid.

When a PBS item code is used to identify a therapeutic good in an eHealth prescription record or eHealth dispense record, the code must be at least six characters in length [NEHTA2015d]. The override facility was used to report a 'Fail' because the PBS item code only had five characters i.e. '1081X'. If the PBS item code had been prepended with one or more zeroes (e.g. '01081X'), the Validator would not have a reported a 'Warning'.

⁶ <u>http://www.humanservices.gov.au/health-professionals/services/australian-childhood-immunisation-register/acir-vaccine-code-formats</u>

Australian PBS Code

No matching code found for '1081X' in code system '1.2.36.1.2001.1005.22' Code Value = 1081X CodeSystem = 1.2.36.1.2001.1005.22 Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[1]/cda:section [1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]

Figure 80: Other Terminology Aspects tab showing a warning for an Australian PBS item code

4.2.4 Health Care Facility Type code error

Figure 81 shows a 'Warning' reported in the Other Terminology Report tab because the ANZSCO code that was used to describe the role of the document author i.e. '253111' did not have the matching ANZSCO code system identifier. Instead, the Validator found the ANZSIC code system identifier i.e. '1.2.36.1.2001.1005.47 and ANZSIC is used to describe the role of an organisation or facility, not the role or occupation of a person. The override facility was used to change the 'Warning' into a 'Fail' because the ANZSCO code system identifier should have been used.

Health Care Facility Type Code

No matching code found for '253111' in code system '1.2.36.1.2001.1005.47' Code Value = 253111 CodeSystem = 1.2.36.1.2001.1005.47 Display Name= General Medical Practitioner Calculated Name:/cda:ClinicalDocument[1]/cda:author [1]/cda:assignedAuthor[1]/cda:code[1]

Figure 81: Other Terminology Aspects tab showing a warning for a healthcare facility type code

4.2.5 Valid Australian Vaccine code

Figure 82 shows a 'Warning' and Figure 83 shows a 'Pass' for an Australian Vaccine code in an event summary. The 'Warning' was displayed in the **Reference Sets** tab and the 'Pass' was displayed in the **Other Terminology Aspects** tab.

The Validator examines the locations in a clinical document where an AMT, SNOMED CT-AU or PBS item code is expected, and reports a 'Warning' in the **Reference Sets** tab if one of the locations contains a code from an unexpected code system. In this example, the Validator expected a code from the AMT code system but instead found a code from the 'Australian vaccines codes' code system.

In the **Other Terminology Aspects** tab, however, the Validator reported a 'Pass' because the Validator found a code and display name from a code system supported by the Validator i.e. the 'Australian vaccines codes' code system.

The override facility was used to change the 'Warning' in the **Reference sets** tab into a 'Pass' because the Validator found a valid code from a supported code system and an AMT code is not mandatory when a clinical document is being tested for level 3A conformance.

Immunisation > Therapeutic Good Identification

No matching code system found; Found: Australian Vaccine Code[1:2:36.1:2001.1005.17] Expected: 1.2:36.1:2001.1004.100 or 2.16.840.1.113883.6.96 Code Value = PRPT CodeSystem = 1.2:36.1:2001.1005.17 Display Name= ACTHIB Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:settroi(1)/

Figure 82: Reference Sets tab showing a warning for an Australian Vaccine code

Australian Vaccine Code

Code Value = PRPT CodeSystem = 1.2.36.1.2001.1005.17 Display Name= ACTHIB Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody [1]/cda:component[5]/cda:section[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1]

Figure 83: Other Terminology Aspects tab showing a pass for an Australian Vaccine code

4.2.6 SNOMED CT-AU display name error

Figure 84 shows a 'Fail' reported in the **Reference Sets** tab for the display name of a SNOMED CT-AU code. The Validator reported that the display name 'Myocardial infarction' was expected but 'Myocardial Infarction' was found.

An examination of the SNOMED CT-AU database shows that the value of the case significance indicator for SNOMED CT-AU code '22298006' is '900000000000000020002', meaning that only the first character of the first word is case insensitive and all other characters are case sensitive i.e. the allowed spellings are either 'myocardial infarction' or 'Myocardial infarction'. The Validator correctly reported a 'Fail' for the display name in the clinical document.

```
Problem/Diagnosis > Problem/Diagnosis Identification
```

Code found but the display name did not match. Expected: 'Myocardial infarction' Code Value = 22298006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Myocardial Infarction Calculated Name:/cda:ClinicalDocument[1]/cda:component [1]/cda:structuredBody[1]/cda:component[3]/cda:section[1]/cda:entry[2]/cda:observation[1]/cda:value[1]

Figure 84: Reference Sets tab showing a SNOMED CT-AU display name error

4.2.7 Valid omission of a code

Adverse Reaction > Substance/Agent

No matching code system found; Found: none Code Value = CodeSystem - Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:act [1]/cda:participant[1]/cda:participantRole[1]/cda:playingEntity[1]/cda:code[1]

Figure 85 shows a 'Warning' reported by the Validator in the **Reference Sets** tab. No code was found in any of the locations where the Validator searches for codes. In this example, the clinical document was an event summary, which was being tested for level 3A conformance so inclusion of the code was optional. The 'Warning' was overridden with a 'Pass'.

Adverse Reaction > Substance/Agent

No matching code system found; Found; none Code Value = CodeSystem = Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:act [1]/cda:structiopant[1]/cda:participantRole[1]/cda:playingEntity[1]/cda:code[1]

Figure 85: Reference Sets tab showing a warning for an omitted code

4.2.8 SNOMED CT-AU code error

Figure 86 shows a warning reported by the Validator in the **Other Terminology Aspects** tab for the code '152305019'. An examination of the SNOMED CT-AU code set showed that '152305019' is a description identifier, rather than a concept identifier. The 'Warning' was overridden with a 'Fail' because a concept identifier should have been used.

SNOMED CT

No matching code found for '152305019' in code system '2.16.840.1.113883.6.96' Code Value = 152305019 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Allergy to nuts Calculated Name:/cda:ClinicalDocument[1]/cda:component [1]/cda:suturedBody[1]/cda:component[1]/cda:section[1]/cda:section[1]/cda:section[1]/cda:entry[1]/cda:bservation[1]/cda:participant[0]/cda:participantRole [1]/cda:playingEntity[1]/cda:code[1]

Figure 86: Other Terminology Aspects tab showing a warning for a SNOMED CT-AU code

5 Batch validation

As an alternative to using the graphical user interface of Validator 2.7, the command line interface can be used to perform template, package, and code validation (for which the Validator may be used), and to produce test reports in XML format. The command line interface is used to validate batches of clinical documents and clinical packages. To confirm when the Validator can be used please refer to the *Clinical Package Validator Product Data Sheet* and confirm the intended use with the Agency Help Desk on 1300 901 001.

The Validator's command line interface is intended for use by software developers and testers using scripts or a batch file. For example, a software developer can create a script to command the Validator to validate a file, or to analyse test reports to determine whether any errors were found or if an expected error was reported. The script is invoked through the Validator command line interface.

5.1 Using the command line interface

To validate a file using the Validator command line interface:

1 Open the Windows Command Prompt (Figure 87) by selecting **Start -> All programs ->** Accessories, and then clicking **Command Prompt**.



031	Command Prompt	-	×
Microsoft Windows [(c) 2013 Microsoft	Uersion 6.3.9600] Corporation. All rights reserved.		^
C:\Users\User Name>	>		
			\sim

Figure 87: Command prompt

2 Navigate to the root directory by typing the command cd\ and then press Enter (Figure 88).

C3.	Command Prompt	-	×	
Microsoft Windows [Version 6.3 (c) 2013 Microsoft Corporation	.9600] . All rights reserved.		^	
C:\Users\User Name>cd\				
C:\>				

Figure 88: Root directory

3 Navigate to the Validator directory (i.e. 'CPV27') by typing the command cd "DigitalHealth\CPV27" and then press Enter (Figure 89).

C .	Command Prompt	-	×
C:\>cd DigitalHealth\CPU25			^
C:\DigitalHealth\CPV25>			

Figure 89: Navigating to the Validator directory

4 Launch the Validator through the command line interface by typing the command

CPvalidator.exe "FileDirectory" "FileName/Pattern" "TemplateDirectory" "Target" "IncludePDFReport" "AdditionalRulesTemplateFolder"

where:

- a FileDirectory is the absolute path to the directory that contains file to be validated;
- b FileToValidate is the file/pattern of files to be validated;
- c TemplateDirectory is the OID of the template package which must have been downloaded already through the GUI;
- d Target is the context for package validation, i.e. My Health Record or P2P;
- e IncludePDFReport is either True or False depending on if you require the PDF summary report (which is saved and located in the same directory as where the target file has been selected from);; and
- f AdditionalRulesTemplateFolder is the absolute path to the root directory that contains the template package with additional validation rules.

Then press Enter.

If no additional rules are to be applied during package validation, the "AdditionalRulesTemplatePath" can be excluded from the above command (Figure 90).

81.	Command Prompt	-		×
Microsoft Windows [Ve <c> 2013 Microsoft Co</c>	ersion 6.3.9600] rrporation. All rights reserved.			Ŷ
C:\>cd DigitalHealth				
C:\DigitalHealth>cd (2PU25			
C:\DigitalHealth\CPV2 006.1.20000.21 MHR tr	25>CPUalidator.exe c:\digitalhealth\ cda.zip 1.2.3 we	6.1	.200	1.1

Figure 90: Launching the Validator through the command line interface

5 If, however, additional rules are also to be applied during package validation, the "AdditionalRulesTemplatePath" should be included in the above command (Figure 91).



Figure 91: Launching the Validator through the command line interface

- 6 To use the command line interface, there are a number useful tips.
 - a Make sure you execute the command from the C:\DigitalHealth\CPV27 directory as the executable needs a number of files in order to run.
 - b Put quotation marks around each parameter, as for example some directory names have spaces in their names.
 - c For directory paths, use a double backslash as the application interprets single backslashes as escape characters
 - d For processing multiple files at the same time, you can only process files of the same document type, given that you have to specify the template type.

Below are some examples of how to use the command line interface.

Drop into a command prompt and type:

CD C:\DigitalHealth\CPV27

Example 1: single file with no PDF report

cpvalidator "c:\\temp\\" "cda.xml" "1.2.36.1.2001.1006.1.170.5" "MHR" "false"

Example 2: multiple files with a PDF report

cpvalidator "c:\\temp\\" "pres*.xml" "1.2.36.1.2001.1006.1.170.5" "MHR" "true"

Example 3: single file using an additional rules template

cpvalidator "c:\\temp\\" "cda.xml" "1.2.36.1.2001.1006.1.170.5" "MHR" "false" "c:\\temp\\AdnRulesTemplate"

Example 4: single zip file testing for Point to Point (P2P) rules and a report

cpvalidator "c:\\temp\\" "cda.zip" "1.2.36.1.2001.1006.1.170.5" "P2P" "true"

Example 5: single file using an additional rules template and no template package

cpvalidator "c:\\temp\\" "cda.xml" "" "MHR" "false" "c:\\temp\\AdnRulesTemplate"

5.2 Analysing validation results

Validation results are stored in XML files in the "C:\DigitalHealth\CPV27\Temp" directory (Figure 92). If a script is written to validate a batch of clinical packages or clinical documents, it could

contain instructions to copy these files to another directory after each validation because these files will be removed when another validation is performed. This is not mandatory as if you request the report PDF, it should contain all the details you need about each file, in addition to the report.csv and analysis.csv file.

🛃 🚺 =	Temp		- 🗆 🗙
File Home S	nare View		~ (
€ ∋ - ↑ 퉫	This PC → Windows (C:) → Nehta → CPV24 → Temp	✓ C Search Ten	np 🔎
🔆 Favorites	^ Name		Date modified
Desktop	EventSummaryTestSet01_1A.zip.xml_Error_output	15/04/2016 9:55 AM	XML_ERROR_OUT
bownloads	EventSummaryTestSet01_1A.zip_Additional_output	15/04/2016 9:55 AM	ZIP_ADDITIONAL
🖳 Recent places	EventSummaryTestSet01_1A.zip_Error_output_Term	15/04/2016 9:55 AM	ZIP_ERROR_OUTP
	EventSummaryTestSet01_1A.zip_Other_Terminology_Valid	15/04/2016 9:55 AM	ZIP_OTHER_TERM
輚 Homegroup	EventSummaryTestSet01_1A.zip_PkgValResult	15/04/2016 9:55 AM	ZIP_PKGVALRESU
🌉 This PC			
隆 Desktop			
Documents			
🚺 Downloads	v <		>
18 items			100 E

Figure 92: Storage of validation results including additional template validation results

The XML files created by the Validator to store validation results are listed in Table 14, where <FileName> is the name of the file (i.e. clinical package or clinical document) that was validated.

File name	Description
<filename>.xml_Error_output.xml</filename>	An XML report of template validation errors.
<filename>.xml_PkgValResult.xml</filename>	An XML report of package validation errors. This report is only produced if the file that was validated was either a clinical package or an HL7 MDM wrapped clinical package.
<filename>_Error_output_Term.xml</filename>	An XML report of reference set validation errors.
<filename>_Other_Terminology_Validations.xml</filename>	An XML report of other terminology aspects validation errors.
<filename>_Additional_output.xml</filename>	An XML report of additional template validation errors.
	Note: This xml file only appears if the AdditionalRulesTemplatePath is used.

Table 14 - Files created by the Validator to store validation results

The file "report.csv" (Section 3.10) contains a cumulative summary of test results, file "analysis.csv" (Section 3.10) contains a list of the issues, and the XML files listed in Table 14 contain detailed test results. The cumulative summary of test results may be used to complement analysis of the detailed test results.

A user of the Validator may write a script to interrogate the test report XML files. Unlike the graphical user interface where an image is displayed for a test result (Figure 93), the test results in the XML files are stored as references to an image (Figure 94) i.e. the graphical user interface reports a 'Fail' as K whereas the test result XML files report a 'Fail' as .

ntain an eSignature with a valid NASH PKI certificate for supporting organisations	
il: CDA Package has NOT been signed with a NASH PKI certificate for a healthcare provider organisation, or a supporting organisation (a CSP or GSO).	÷

Figure 93: Graphical user interface with image reporting a 'Fail' for clinical packaging test case CPCD_023744

<testdataitem> <reference>CPCD 0237445/Reference></reference></testdataitem>
<message>Fail: CDA Package has NOT been signed with a</message>
NASH PKI certificate for a healthcare provider organisation,
or a supporting organisation (a CSP or GSO).
<description>Verify that a signed CDA package sent to</description>
the PCEHR system SHALL either contain an eSignature with a
valid NASH PKI certificate for healthcare provider
organisations, or contain an eSignature with a valid NASH PKI
certificate for supporting organisations
<result></result>
<text>Fail: CDA Package has NOT been signed with a</text>
NASH PKI certificate for a healthcare provider organisation,
or a supporting organisation (a CSP or GSO).
Circu get

Figure 94: XML file with image reference reporting a 'Fail' for clinical packaging test case CPCD_023744

Scripts that interrogate the test result XML files should search for XML tags with references to an image. They should not search the error message for 'Pass', 'Fail' or 'Warning' text (Figure 94).

Table 15 describes the image reference associated with each test result.

Table 15 – Test result	s and image	references
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Test result	Image reference
Pass	
Fail	
Warning	
Not Run	

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture
DVA	Department of Veterans' Affairs
HL7	Health Level Seven
HTML	HyperText Markup Language
JPEG	Joint Photographic Experts Group (image format)
MDM	Medical Document Management
МТОМ	Message Transmission Optimization Mechanism
NASH	National Authentication Service for Health
P2P	provider to provider
PBS	Pharmaceutical Benefits Scheme
РКІ	Public Key Infrastructure
SNOMED CT-AU	Systematized Nomenclature of Medicine Clinical Terms - Australia
SOAP	Simple Object Access Protocol
URI	Uniform Resource Identifier
XML	Extensible Markup Language
ZIP	archive file format

Glossary

Term	Meaning
body	The body of a clinical document contains the clinical information.
header	The header of a clinical document contains information about the patient, healthcare provider and administrative details.
narrative block	A narrative block is an XML fragment enclosed within <text> elements. A narrative block contains unstructured narrative text that is to be rendered into human-readable form. The narrative block may contain XML tags that rendering systems use to format the narrative.</text>
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms is the internationally pre- eminent clinical terminology that has been identified as the preferred national terminology for Australia and has been endorsed by all Australian governments.
SNOMED CT-AU	SNOMED CT Australian Release (SNOMED CT-AU) is the Australian extension to SNOMED CT, providing local variations and customisations of terms relevant to the Australian healthcare community. It includes the international resources along with all Australian developed terminology.
structured data	Structured data is an XML fragment intended for computer processing. Structured data is not rendered for human readers. Some structured data is referred to as 'coded data' as it is associated with a code system.

References

Reference	Description
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[IHTSDO2014]	SNOMED CT Technical Implementation Guide; International Health Terminology Standards Development Organization, 2014; <u>http://www.snomed.org/</u>
[NEHTA2011a]	CDA Package, version 1.0; NEHTA, 2011; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-</u> 2016/NEHTA-1229-2011
[NEHTA2012a]	CDA Rendering Specification, version 1.0; NEHTA, 2012; <u>https://www.digitalhealth.gov.au/implementation-resources/clinical-documents/EP-2320-</u> 2016/NEHTA-1199-2012
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