Clinical Package Validator 2.3
User Guide

17 July 2015

Approved for external use

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The Clinical Package Validator does not test software against all conformance requirements.

Results from the Clinical Package Validator must not be relied upon to determine software conformity. Vendors must run additional tests on software before declaring software conformance to the PCEHR System Operator.

Refer to the Clinical Package Validator Release Note *for information about the scope of this tool, and the NEHTA Non-Production Disclaimer for appropriate use of the tool.*

For further guidance, contact the NEHTA Help Centre on 1300 901 001 or help@nehta.gov.au.

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2.0	22 August 2014	Major release.
2.1	20 January 2015	Feature and usability enhancements.
2.2	–	Not published.
2.3	17 July 2015	Software enhancements (see release note for details).

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1 Introduction

1.1 Purpose

This document is a guide for developers and testers who use (Users) version 2.3 of NEHTA's 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 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 Release Note*. For further guidance, contact the NEHTA Help Centre on 1300 901 001 or help@nehta.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.

The Validator does not test all conformance specifications and Users should carefully read the *Clinical Package Validator Release Note* to determine what the Validator cannot be used for, and for further guidance contact NEHTA on 1300 901 001 or help@nehta.gov.au.

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 personally controlled electronic health record (PCEHR) 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 Release Note* to determine what the Validator cannot be used for, and for further guidance contact NEHTA on 1300 901 001 or help@nehta.gov.au.

2 Tests performed by the Validator

The Validator performs the following tests:

- package validation;
- template validation; and
- code 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 Section 4 of the *Clinical Package Validator Release Note* 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 PCEHR 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 PCEHR system (referred to as the **PCEHR** 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* [NEHTA2013a].

The **P2P** context imposes fewer constraints on a clinical package than the **PCEHR** 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 PCEHR 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 PCEHR 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 **PCEHR** 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 Release Note* or contact the NEHTA Help Centre on 1300 901 001 or help@nehta.gov.au to confirm that the Validator may be used to carry out the required tests. If the user selects the **PCEHR** context, only the set of tests for the **PCEHR** 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 **PCEHR** 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 **PCEHR** 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 eSignature validated by the Validator.

[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 NEHTA's specifications require the inclusion of the integrity check value in a base64 format rather than in a hexadecimal format.

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. the template which must be applied when the clinical document is being validated for a claimed level of conformance; and
2. an additional template containing additional validation rules.

A 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:

- a template in the PCEHR system does not yet have a complete set of rules for all mandatory requirements; or
- a template is needed to check for the presence of optional data elements. For example, instead of manually inspecting the XML file of a diagnostic imaging report for the presence of a reference to a website, a tester may instead choose to instruct the Validator to test for the presence of a reference by including additional rules in a template.

Templates may be obtained from a number of sources:

- template package libraries published on the NEHTA website[2], which contain a set of PCEHR template packages; and
- PCEHR template packages included in the PCEHR software vendor test environment.

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. Schematron rules are 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 PCEHR 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 http://www.nehta.gov.au/implementation-resources/clinical-documents.

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 childhood 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 PCEHR system, such as:
  - eHealth prescription and dispense views, health check schedule views, Medicare overviews, and observation views.

2.2.1 Limitations of template validation

The template validation function of the Validator has many limitations. These are defined in detail in the *Clinical Package Validator Release Note*.

Broadly speaking, the following high level limitations apply:

1. Templates published by NEHTA have been developed for PCEHR 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 **PCEHR** context.
2. 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.
3. Extensions to a clinical document are only subjected to Australian CDA® schema checks. The PCEHR 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 NEHTA.
4. 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. **Template validation 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.

Table 1 - Code systems supported by the Validator

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

The Validator validates primary codes and translated codes for all conformance levels[3]. Unlike previous versions of the Validator, version 2.3 finds and validates every code in a clinical document that belongs to the code systems listed in Table 1.

[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.

2.3.1 Additional code validation

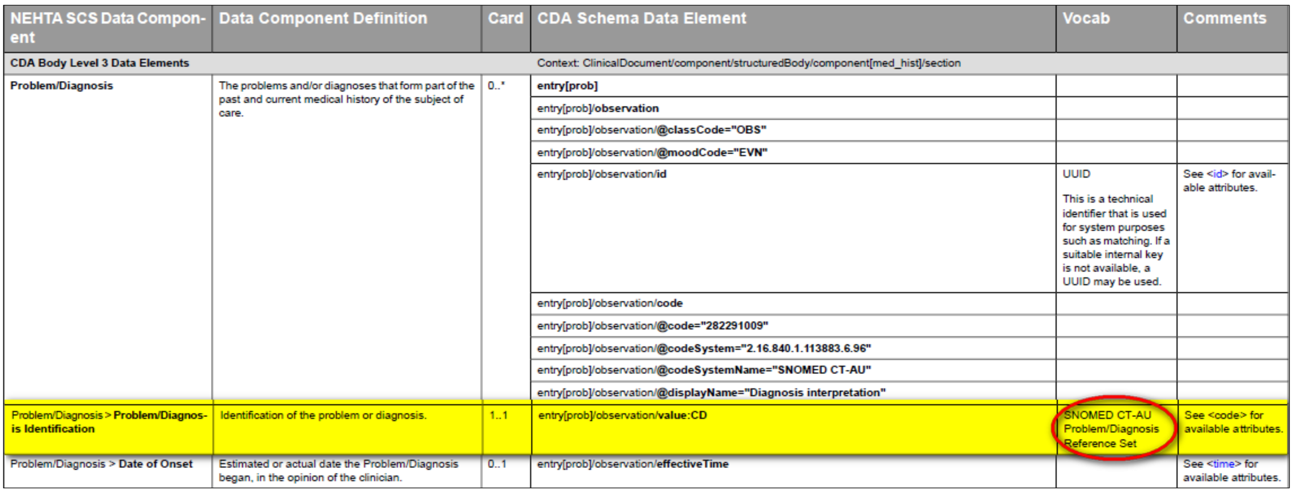
Additional validation is performed on codes from code systems listed in Table 2 as the value of some of these codes must belong to a specified subset of a code system.

Table 2 - Code systems with additional validation

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
Systematized Nomenclature of Medicine - Clinical Terms Australian Release (SNOMED CT-AU)	2.16.840.1.113883.6.96

The subset is specified in the 'Vocab' column of the relevant CDA® implementation guide.

Figure 1 shows the 'Vocab' column of the eReferral CDA implementation guide. The Validator will determine 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.



NEHTA SCS Data Component	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 past and current medical history of the subject of care.	0..*	**entry[prob]**		
			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 available attributes.
			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/Diagnosis Identification**	Identification of the problem or diagnosis.	1..1	entry[prob]/observation/**value:CD**	SNOMED CT-AU Problem/Diagnosis Reference Set	See <code> for available attributes.
Problem/Diagnosis > **Date of Onset**	Estimated or actual date the Problem/Diagnosis began, in the opinion of the clinician.	0..1	entry[prob]/observation/**effectiveTime**		See <time> for available attributes.

Figure 1: Vocab column of eReferral CDA implementation guide

The Validator examines a set of locations in some clinical documents to make sure that the codes in those locations are from the specified subsets of a code system. These locations have been configured for the following types of clinical documents:

- discharge summary;
- eHealth diagnostic imaging report;
- eHealth dispense record;
- eHealth prescription record;
- eReferral;
- event summary;
- shared health summary; and
- specialist letter.

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 not case insensitive. If the entire preferred term is case insensitive, 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. Prior 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 2.3 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 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 2.3 of the Validator:

1 Where the Validator can be used to test a clinical document (please refer to the *Clinical Package Validator Release Note*, 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 The Validator does not test for conformance to the requirements for authoring a clinical document, listed in the *CDA Rendering Specification, Clinical Documentation* [NEHTA2012a].

4 Some types of conformance tests are inherently manual and cannot be automated in the Validator. For example, the Validator cannot test whether clinical information in the structured data of a clinical document is equivalent to clinical information in the narrative of that document.

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

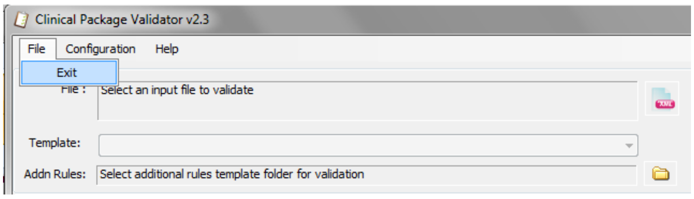
This section describes the menus, parameters, commands and other features of the Validator. It also describes the results and reports generated by the Validator.

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 : Select an input file to validate

Template:

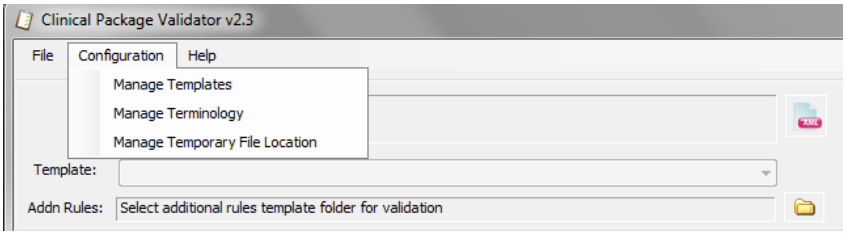
Addn Rules: Select additional rules template folder for validation

Figure 2: File menu option

- File → Exit

The Validator will close if this menu option is selected.

3.1.2 Configuration menu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File
Configuration
Help
Manage Templates
Manage Terminology
Manage Temporary File Location

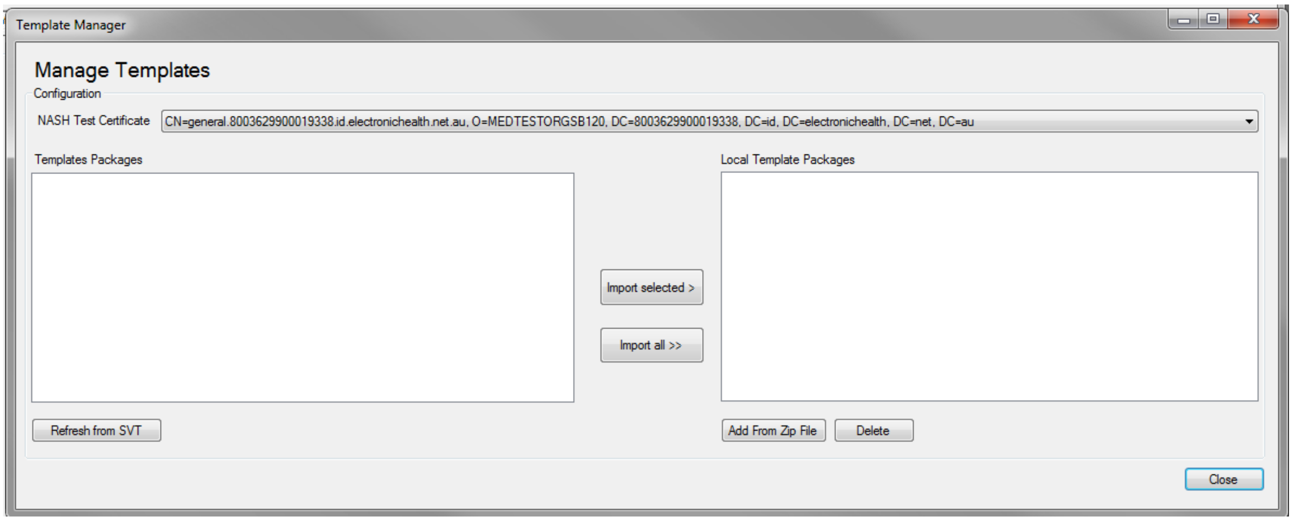
Template:

Addn Rules: Select additional rules template folder for validation

Figure 3: Configuration menu options

- Configuration → Manage Templates

  Template Management: This menu option allows the user to import and manage templates for validating clinical documents (Figure 4). Template management is described in the *Clinical Package Validator 2.3 Installation and Configuration Guide* [NEHTA2015a].

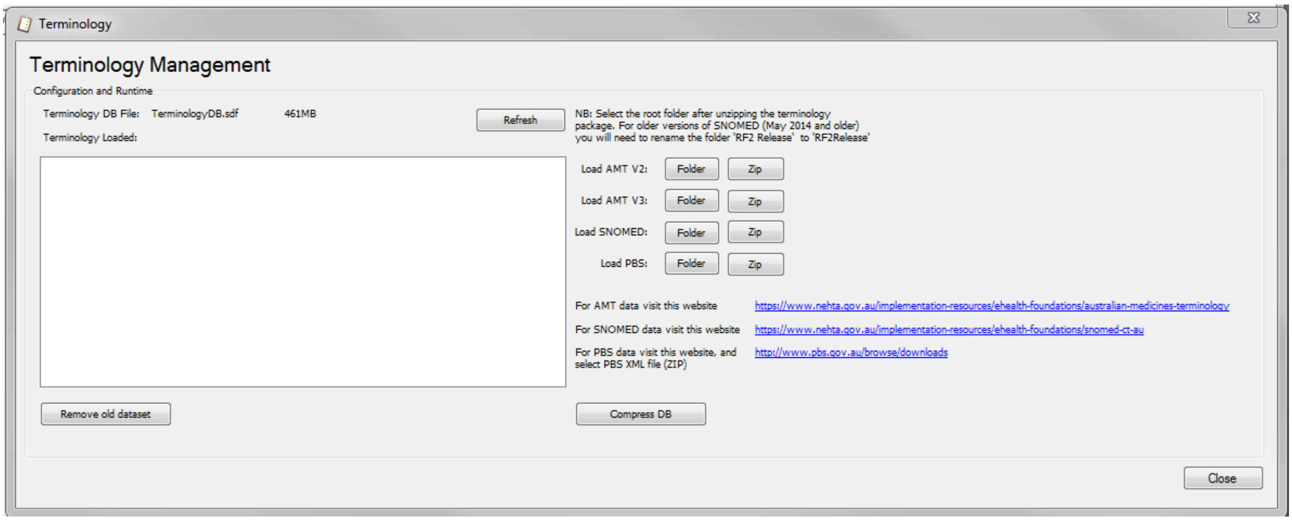


NASH Test Certificate: CN=general.8003629900019338.id.electronichealth.net.au, O=MEDTESTORGSB120, DC=8003629900019338, DC=id, DC=electronichealth, DC=net, DC=au

Figure 4: Template management menu

- Configuration → 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 2.3 Installation and Configuration Guide* [NEHTA2015a].



Terminology DB File: TerminologyDB.sdf 461MB

NB: Select the root folder after unzipping the terminology package. For older versions of SNOMED (May 2014 and older) you will need to rename the folder 'RF2 Release' to 'RF2Release'

For AMT data visit this website https://www.nehta.gov.au/implementation-resources/ehealth-foundations/australian-medicines-terminology

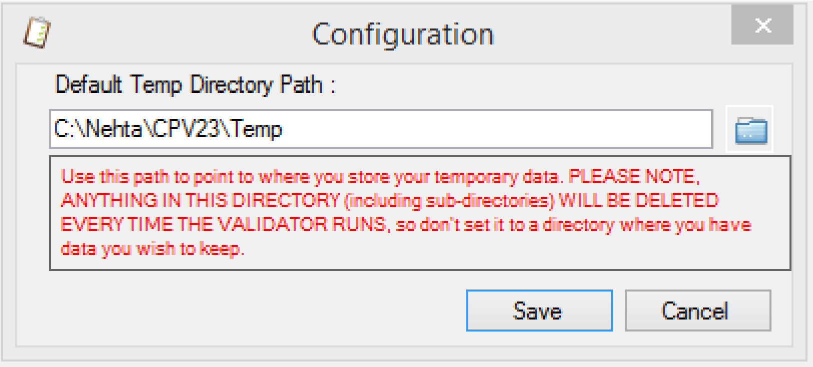
For SNOMED data visit this website https://www.nehta.gov.au/implementation-resources/ehealth-foundations/snomed-ct-au

For PBS data visit this website, and select PBS XML file (ZIP) http://www.pbs.gov.au/browse/downloads

Figure 5: Terminology management menu

- Configuration → 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 2.3 Installation and Configuration Guide* [NEHTA2015a]. 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.



Default Temp Directory Path :

C:\Nehta\CPV23\Temp

Use this path to point to where you store your temporary data. PLEASE NOTE, ANYTHING IN THIS DIRECTORY (including sub-directories) WILL BE DELETED EVERY TIME THE VALIDATOR RUNS, so don't set it to a directory where you have data you wish to keep.

Figure 6: Default temp directory path menu

3.1.3 Help menu

- Help → 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 2.3 Installation and Configuration Guide* [NEHTA2015a], 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.

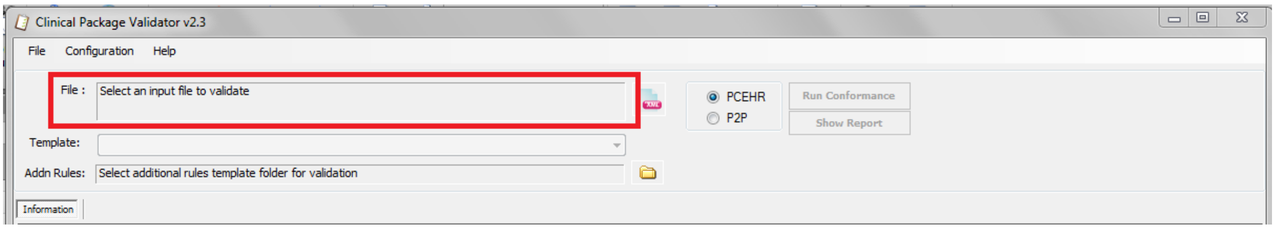
Please refer to Section 4.3 of the *Clinical Package Validator Release Note* for more details on the scope of template package validation.

Table 3 – Validator parameters

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 ’PCEHR‵

3.2.1 File parameter

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



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File :
Select an input file to validate
XML
● PCEHR
○ P2P
Run Conformance
Show Report
Template:
Addn Rules:
Select additional rules template folder for validation
Information

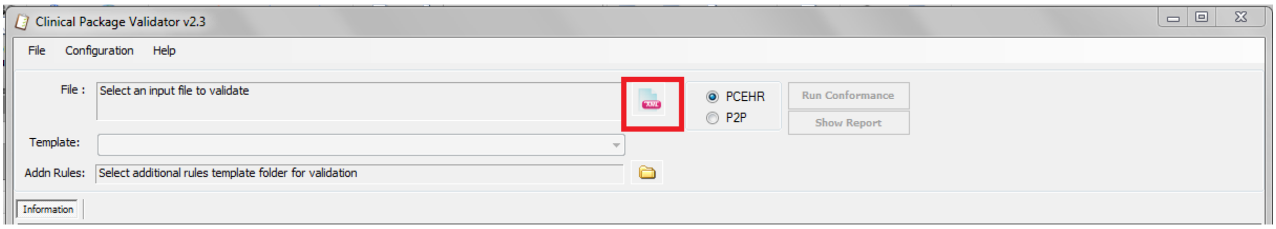
Figure 7: File parameter

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:

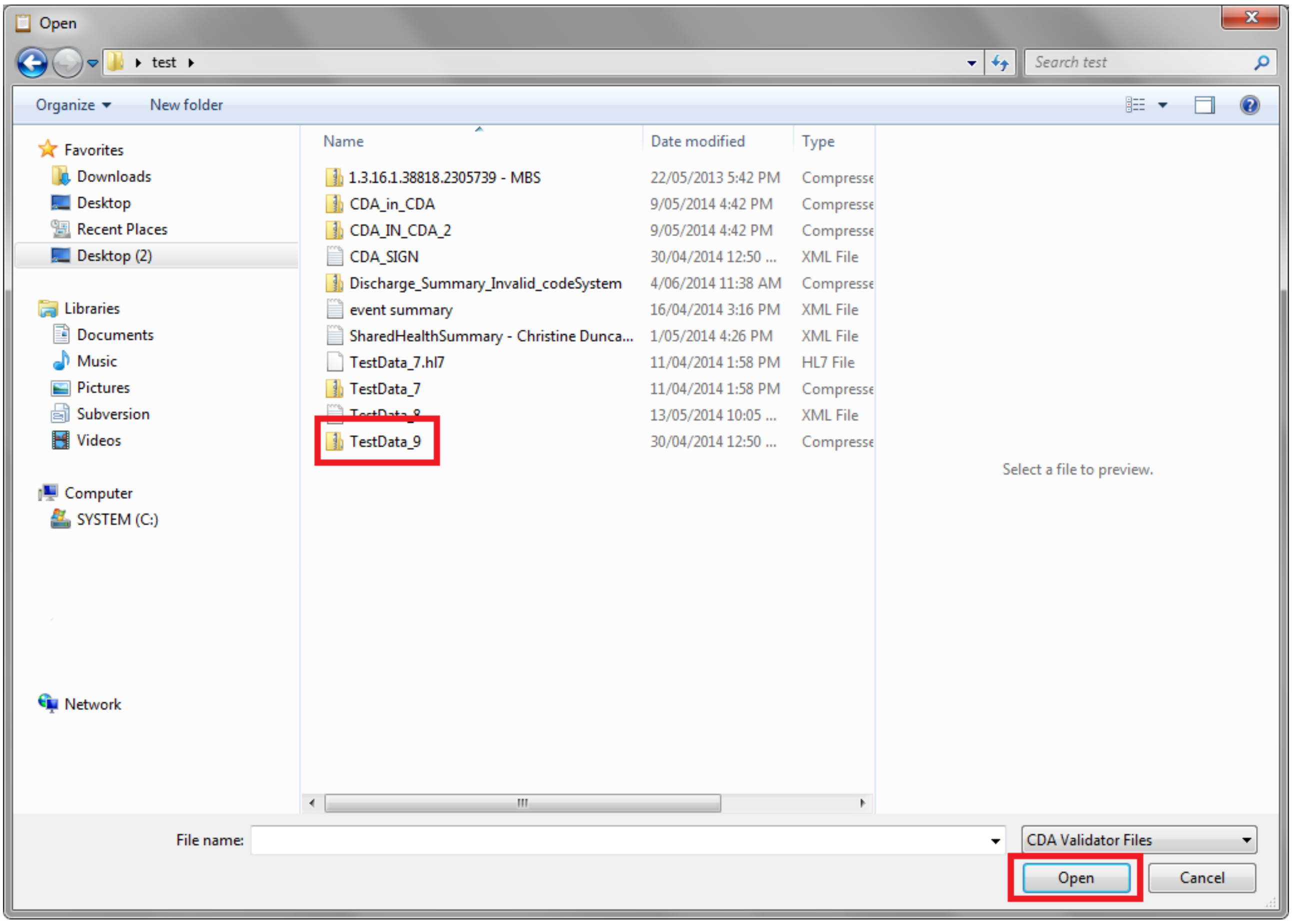
1 Click the **XML** button (Figure 8).



Clinical Package Validator v2.3
File
Configuration
Help
File :
Select an input file to validate
XML
● PCEHR
○ P2P
Run Conformance
Show Report
Template:
Addn Rules:
Select additional rules template folder for validation
Information

Figure 8: Selecting the XML button

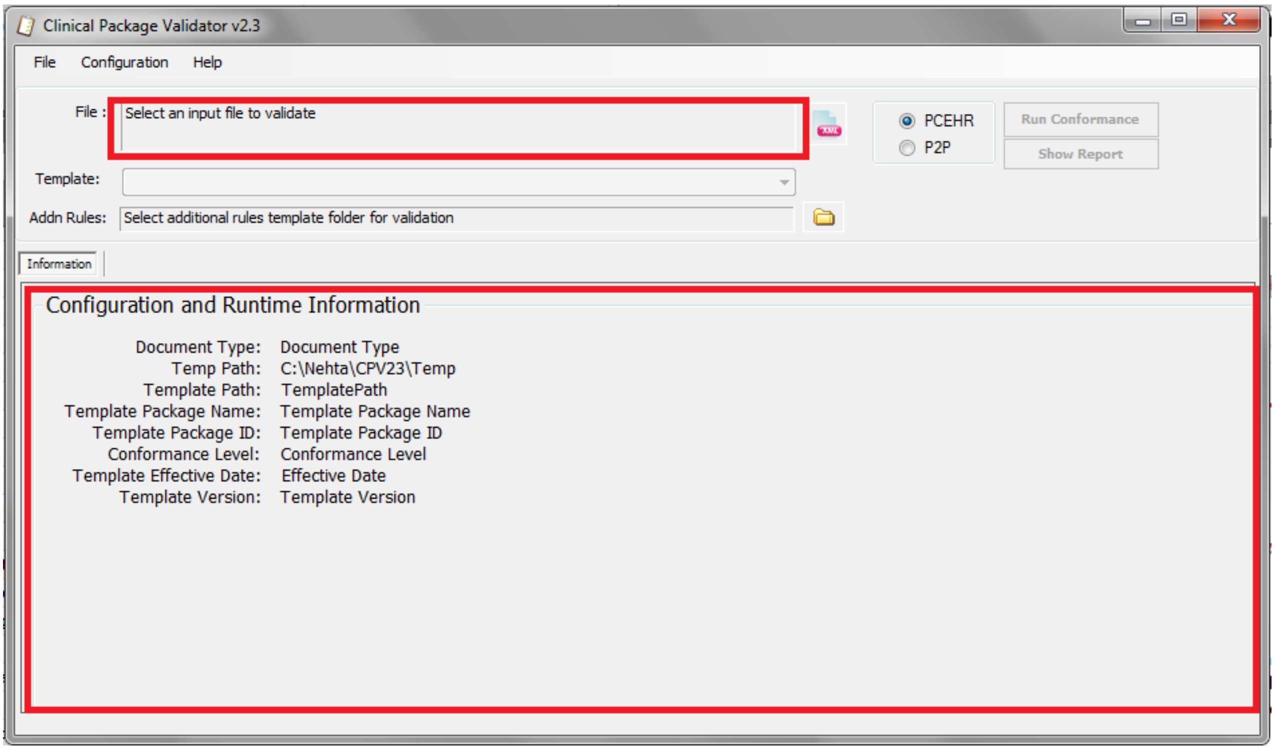
2 Navigate to the location of the clinical document, clinical package or HL7® MDM wrapped clinical package, select the file and click **Open** (Figure 9).



Name	Date modified	Type
1.3.16.1.38818.2305739 - MBS	22/05/2013 5:42 PM	Compresse
CDA_in_CDA	9/05/2014 4:42 PM	Compresse
CDA_IN_CDA_2	9/05/2014 4:42 PM	Compresse
CDA_SIGN	30/04/2014 12:50 ...	XML File
Discharge_Summary_Invalid_codeSystem	4/06/2014 11:38 AM	Compresse
event summary	16/04/2014 3:16 PM	XML File
SharedHealthSummary - Christine Dunca...	1/05/2014 4:26 PM	XML File
TestData_7.hl7	11/04/2014 1:58 PM	HL7 File
TestData_7	11/04/2014 1:58 PM	Compresse
TestData_8	13/05/2014 10:05 ...	XML File
TestData_9	30/04/2014 12:50 ...	Compresse

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).



● PCEHR
○ P2P

File : Select an input file to validate

Template:

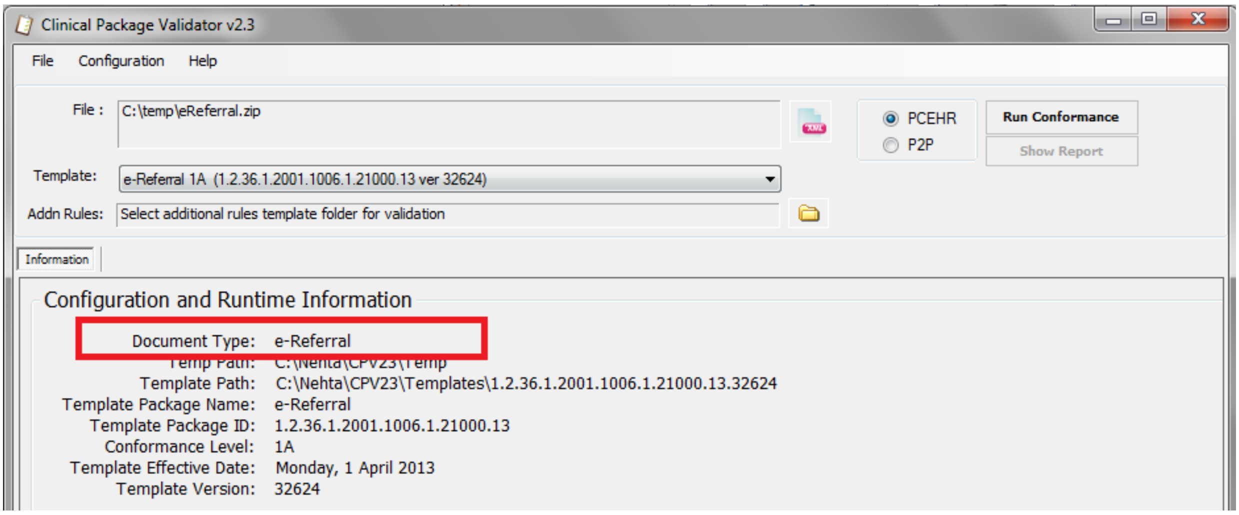
Addn Rules: Select additional rules template folder for validation

Configuration and Runtime Information

Document Type: Document Type
Temp Path: C:\Nehta\CPV23\Temp
Template Path: TemplatePath
Template Package Name: Template Package Name
Template Package ID: Template Package ID
Conformance Level: Conformance Level
Template Effective Date: Effective Date
Template Version: Template Version

Figure 10: Selecting the file to be validated by dragging and dropping

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 clinical document type is displayed in the **Document Type** field in the **Information** tab (Figure 11).



● PCEHR
○ P2P

File : C:\temp\eReferral.zip

Template: e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ver 32624)

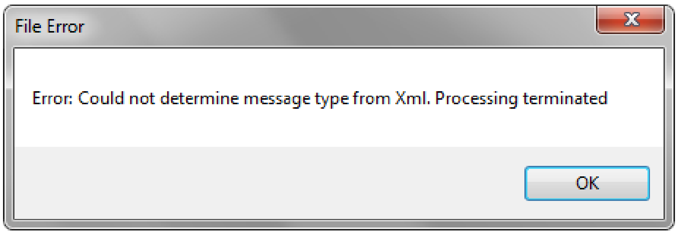
Addn Rules: Select additional rules template folder for validation

Configuration and Runtime Information

Document Type: e-Referral
Temp Path: C:\Nehta\CPV23\Temp
Template Path: C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.21000.13.32624
Template Package Name: e-Referral
Template Package ID: 1.2.36.1.2001.1006.1.21000.13
Conformance Level: 1A
Template Effective Date: Monday, 1 April 2013
Template Version: 32624

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

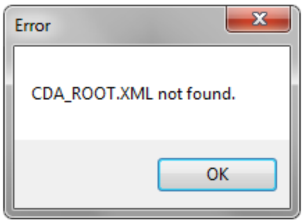
If the Validator cannot determine the type of the clinical document being validated, an error message is displayed (Figure 12).



Error: Could not determine message type from Xml. Processing terminated

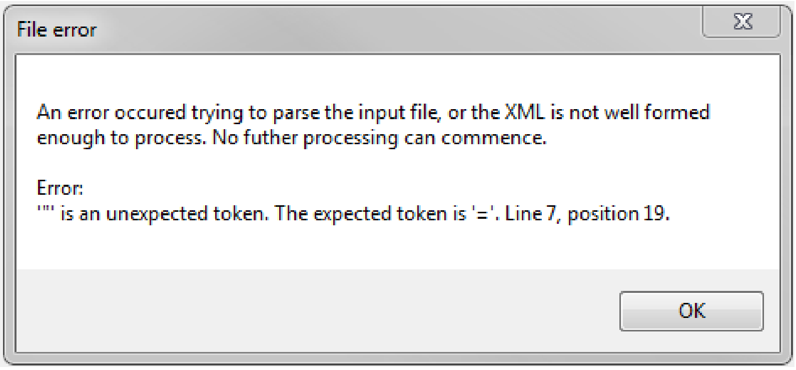
Figure 12: Error message when the type of a clinical document is unknown

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



CDA_ROOT.XML not found.

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

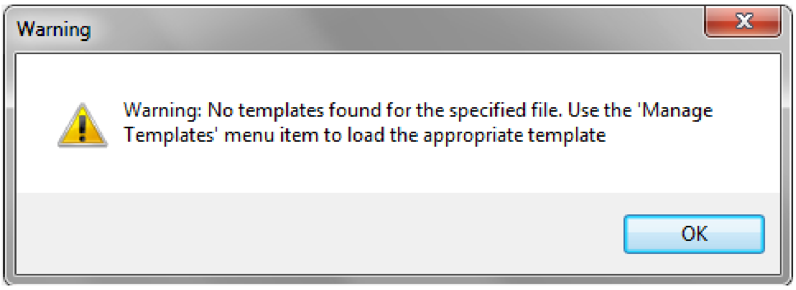


An error occured trying to parse the input file, or the XML is not well formed enough to process. No futher processing can commence.

Error:
'"' is an unexpected token. The expected token is '='. Line 7, position 19.

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

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

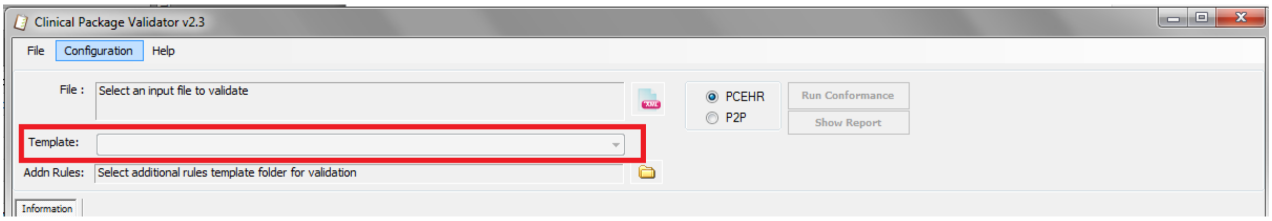


Warning: No templates found for the specified file. Use the 'Manage Templates' menu item to load the appropriate template

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

3.2.2 Template parameter

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



File : Select an input file to validate

Template:

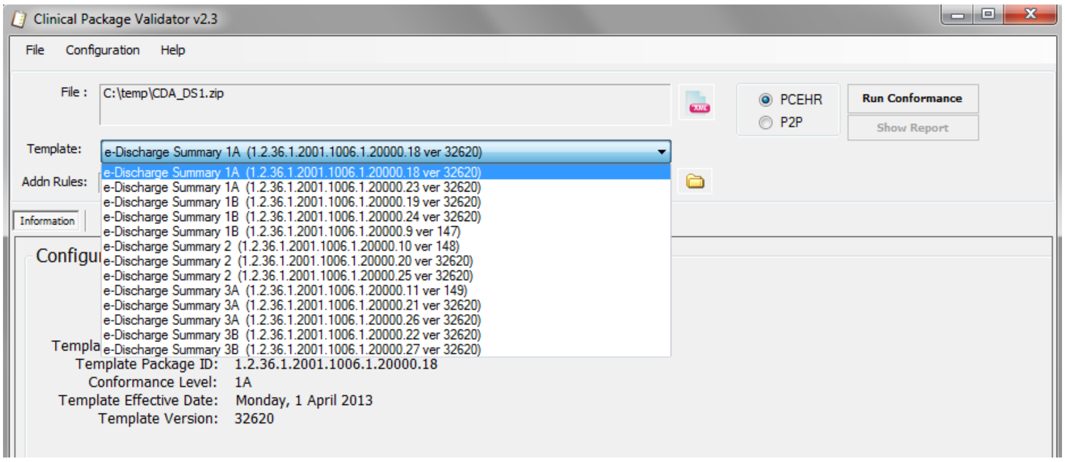
Addn Rules: Select additional rules template folder for validation

Figure 16: The 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 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 NEHTA 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).



File : C:\temp\CDA_DS1.zip

Template: e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)

e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)
e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.23 ver 32620)
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)
e-Discharge Summary 1B (1.2.36.1.2001.1006.1.20000.9 ver 147)
e-Discharge Summary 2 (1.2.36.1.2001.1006.1.20000.10 ver 148)
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)
e-Discharge Summary 3B (1.2.36.1.2001.1006.1.20000.22 ver 32620)
e-Discharge Summary 3B (1.2.36.1.2001.1006.1.20000.27 ver 32620)

Addn Rules:

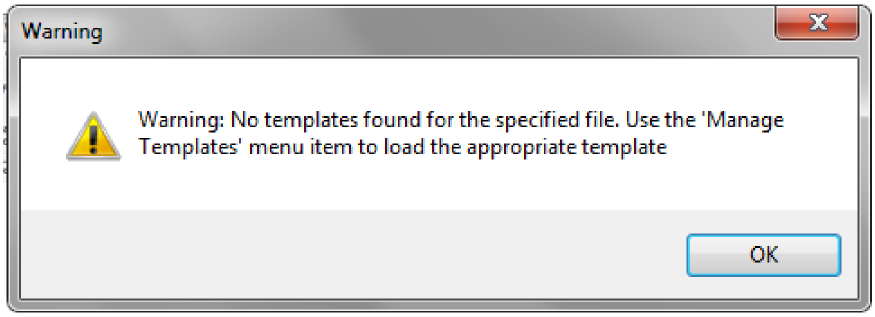
Template Package ID: 1.2.36.1.2001.1006.1.20000.18
Conformance Level: 1A
Template Effective Date: Monday, 1 April 2013
Template Version: 32620

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).

[4] https://www.nehta.gov.au/implementation-resources/clinical-documents/EP-1962-2014/NEHTA-1849-2014



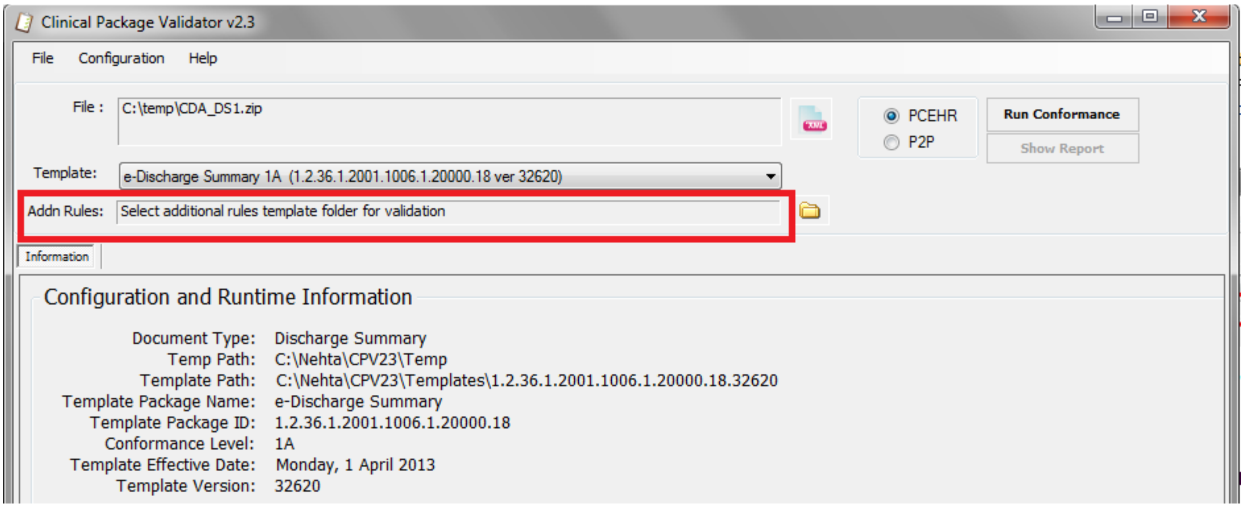
Warning

Warning: No templates found for the specified file. Use the 'Manage Templates' menu item to load the appropriate template

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 : C:\temp\CDA_DS1.zip

● PCEHR
○ P2P

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

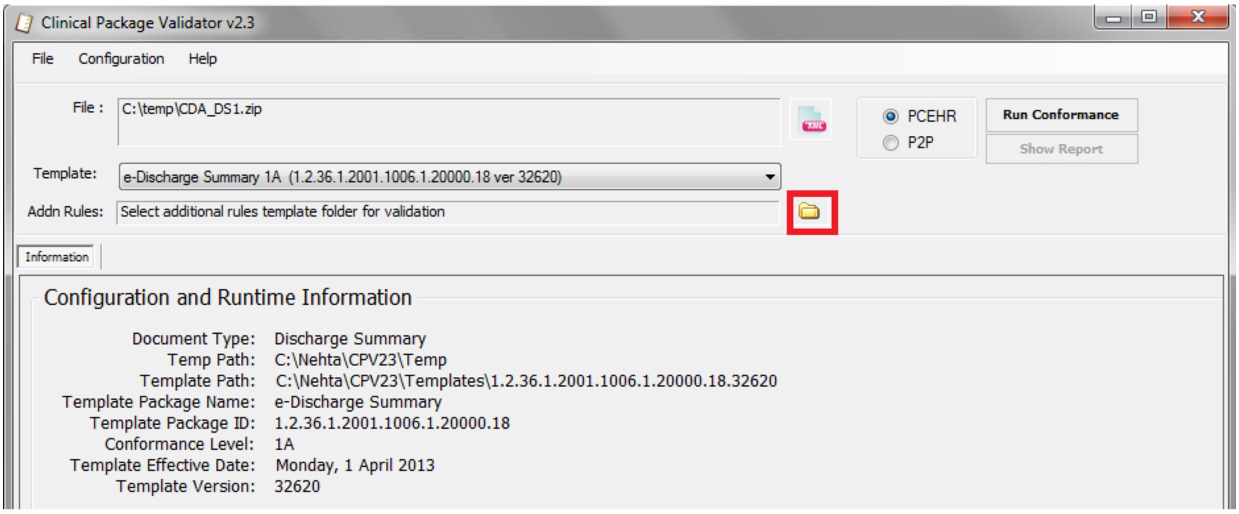
Configuration and Runtime Information

Document Type: Discharge Summary
Temp Path: C:\Nehta\CPV23\Temp
Template Path: C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.20000.18.32620
Template Package Name: e-Discharge Summary
Template Package ID: 1.2.36.1.2001.1006.1.20000.18
Conformance Level: 1A
Template Effective Date: Monday, 1 April 2013
Template Version: 32620

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 : C:\temp\CDA_DS1.zip

Template: e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)

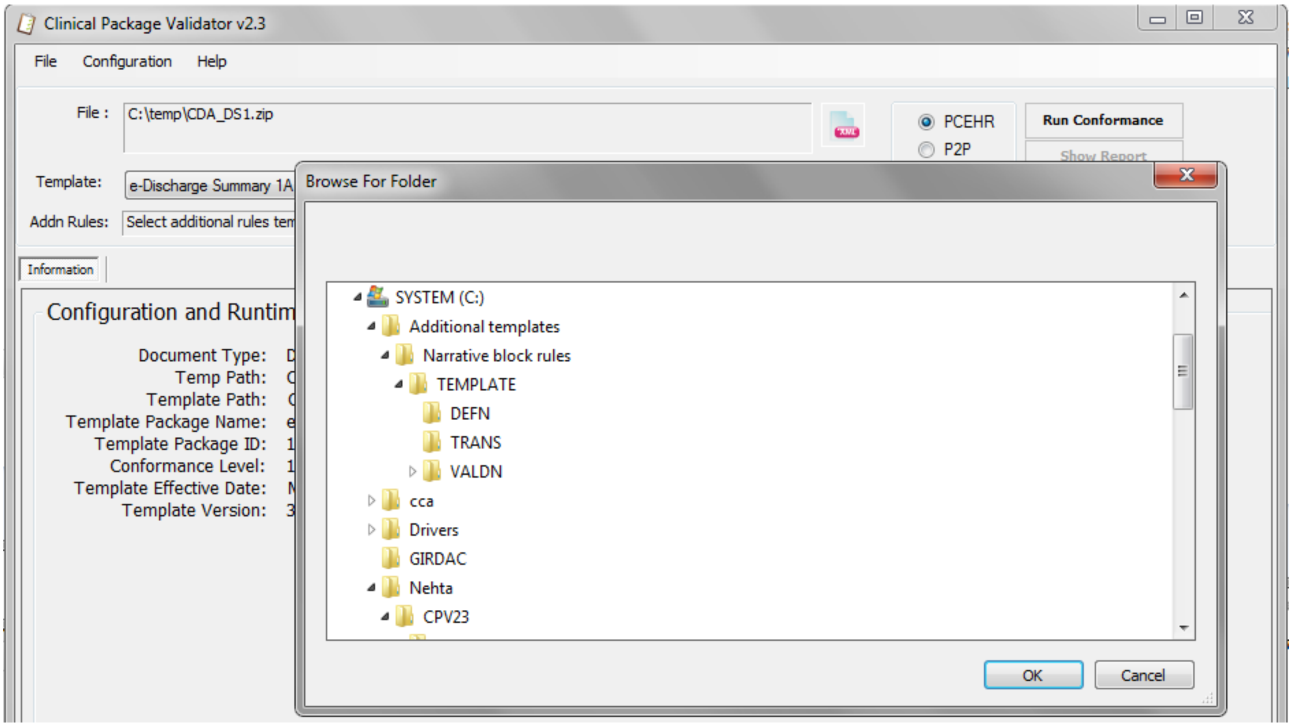
Addn Rules: Select additional rules template folder for validation

Configuration and Runtime Information

Document Type:	Discharge Summary
Temp Path:	C:\Nehta\CPV23\Temp
Template Path:	C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.20000.18.32620
Template Package Name:	e-Discharge Summary
Template Package ID:	1.2.36.1.2001.1006.1.20000.18
Conformance Level:	1A
Template Effective Date:	Monday, 1 April 2013
Template Version:	32620

Figure 20: Selecting the folder button

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



File : C:\temp\CDA_DS1.zip

Template: e-Discharge Summary 1A

Addn Rules: Select additional rules tem

Configuration and Runtim

Document Type: D
Temp Path: C
Template Path: C
Template Package Name: e
Template Package ID: 1
Conformance Level: 1
Template Effective Date: M
Template Version: 3

Figure 21: Navigating to the directory containing the additional template

3 Select the additional template (Figure 22).

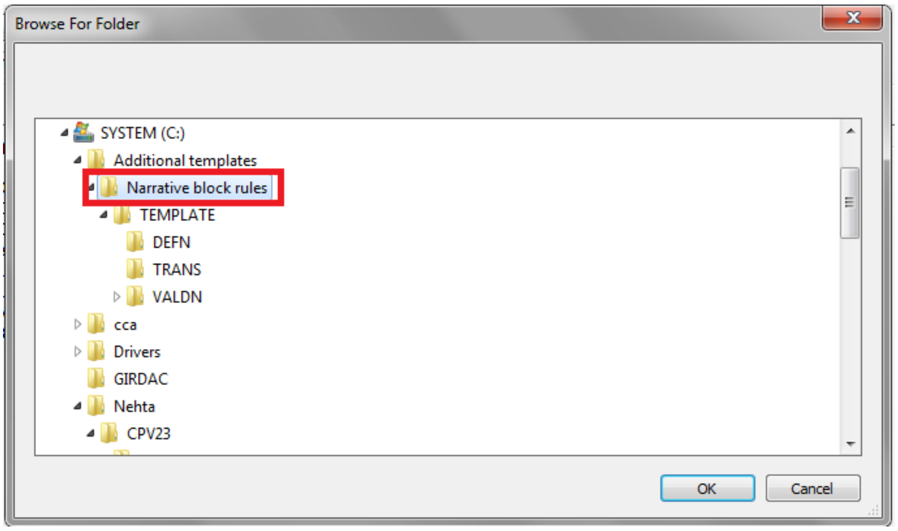
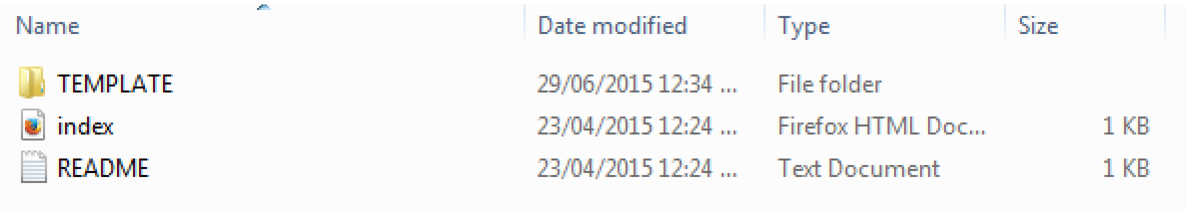


Figure 22: Locating and selecting the additional template

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

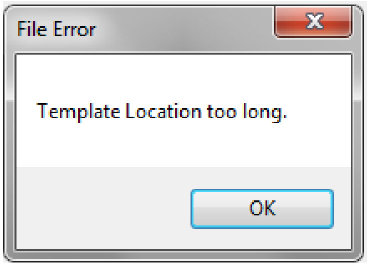
It is important to select the 'Additional templates\Narrative block rules' subdirectory rather than the 'Additional templates\Narrative block rules\TEMPLATE' subdirectory. The 'Additional templates\Narrative block rules' subdirectory is referred to as a *template package*. It contains the additional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



Name	Date modified	Type	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

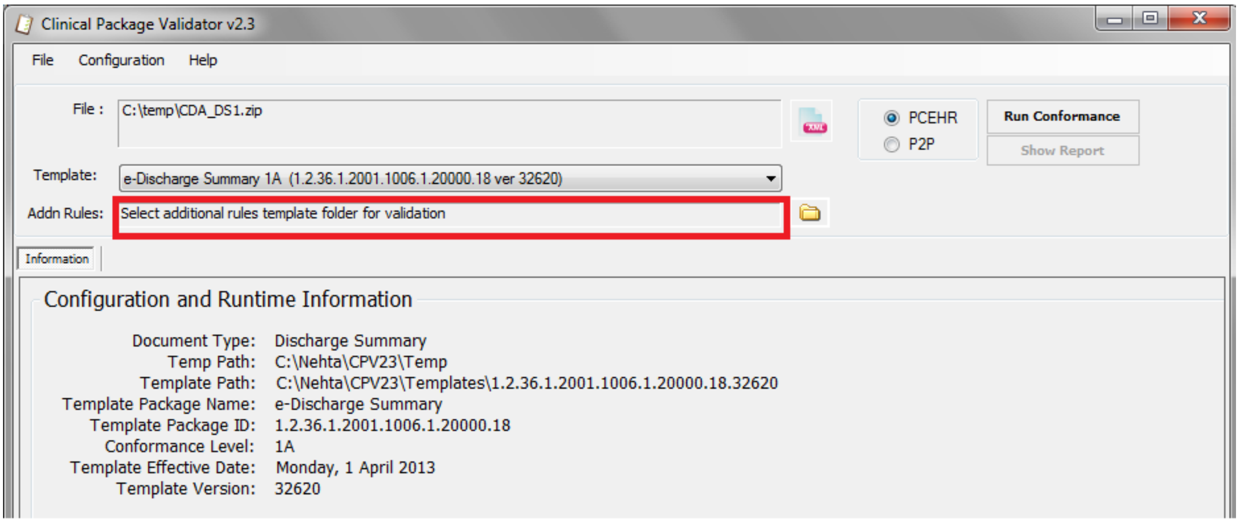
An error message is displayed if the combined length of the template location and folder name is more than 80 characters (Figure 24).



Template Location too long.

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 : C:\temp\CDA_DS1.zip

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

Configuration and Runtime Information

Document Type:	Discharge Summary
Temp Path:	C:\Nehta\CPV23\Temp
Template Path:	C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.20000.18.32620
Template Package Name:	e-Discharge Summary
Template Package ID:	1.2.36.1.2001.1006.1.20000.18
Conformance Level:	1A
Template Effective Date:	Monday, 1 April 2013
Template Version:	32620

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

3.2.4 Context parameter

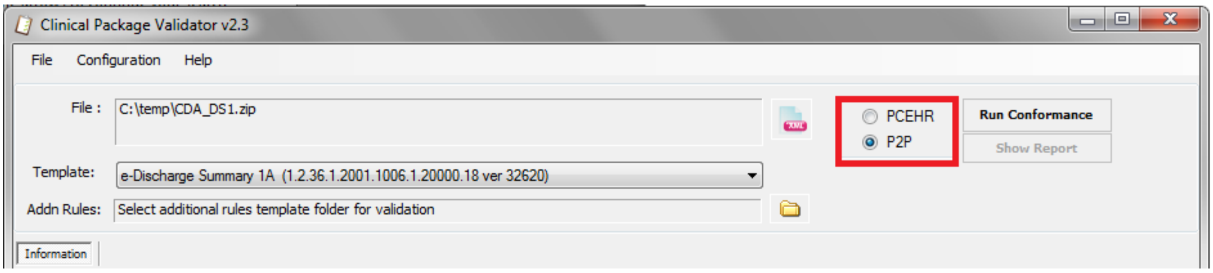
The Validator requires a user to select the context for validating a clinical package. The selection of context determines which tests will be applied when a clinical package is validated (Section 2.1).

The Validator supports the **PCEHR** and **P2P** contexts:

- The **PCEHR** context is the set of tests that apply to a clinical package sent to the PCEHR 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 **PCEHR**.

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 PCEHR system does not support HL7® MDM. For all other types of files the **P2P** context must be explicitly selected (Figure 26).



File : C:\temp\CDA_DS1.zip

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

*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 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 PCEHR end product published on the NEHTA website[5] (e.g. the event summary conformance profile is part of the Event Summary end product).

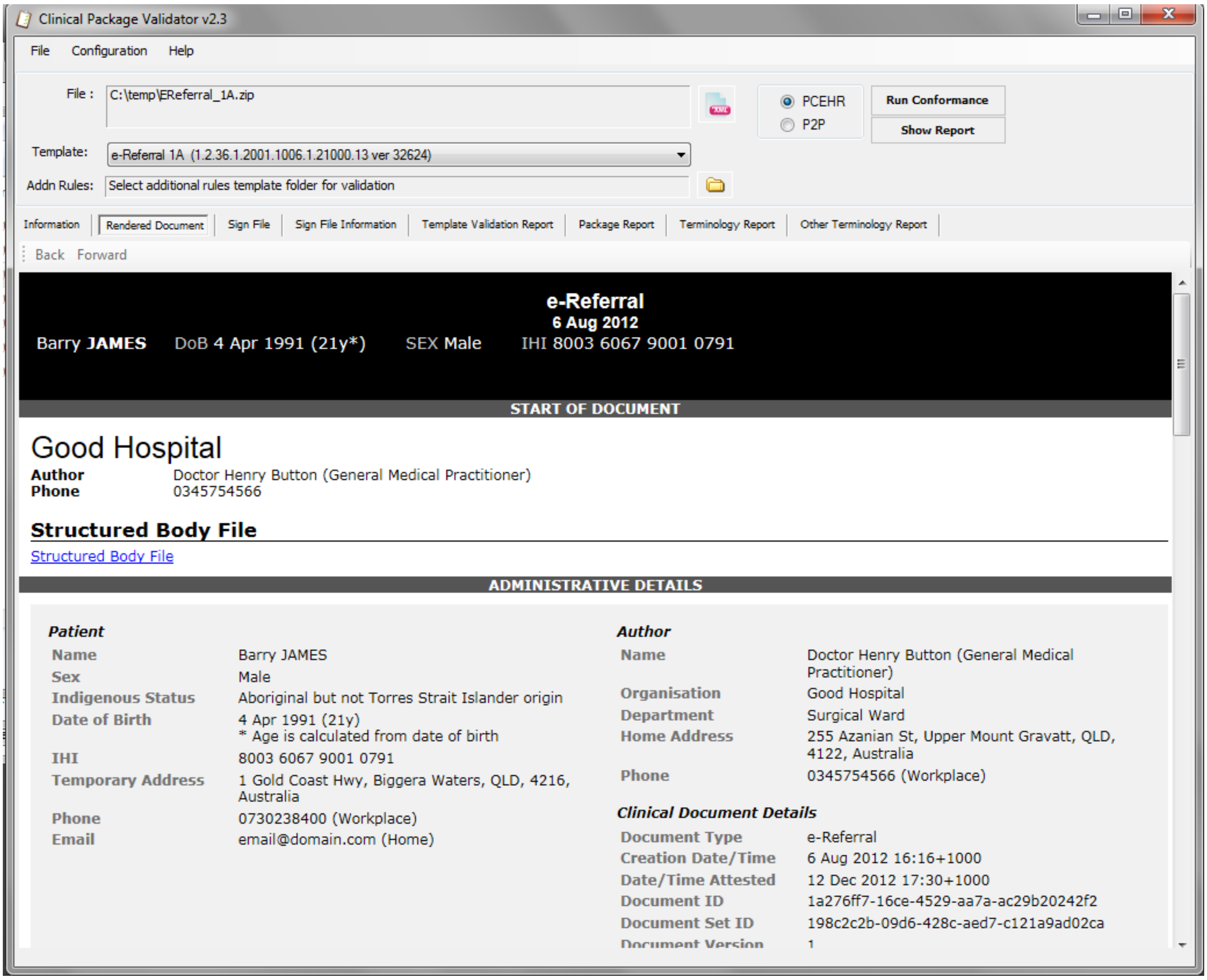
3.3.1 Conformance level 1A

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.

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.

[5] http://www.nehta.gov.au/implementation-resources/clinical-documents



File : C:\temp\EReferral_1A.zip

Template: e-Referral 1A (1.2.36.1.2001.1006.1.21000.13 ver 32624)

Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

e-Referral
6 Aug 2012

Barry **JAMES** DoB 4 Apr 1991 (21y*) SEX Male IHI 8003 6067 9001 0791

START OF DOCUMENT

Good Hospital

Author Doctor Henry Button (General Medical Practitioner)
Phone 0345754566

Structured Body File

Structured Body File

ADMINISTRATIVE DETAILS

Patient

Name	Barry JAMES
Sex	Male
Indigenous Status	Aboriginal but not Torres Strait Islander origin
Date of Birth	4 Apr 1991 (21y) * Age is calculated from date of birth
IHI	8003 6067 9001 0791
Temporary Address	1 Gold Coast Hwy, Biggera Waters, QLD, 4216, Australia
Phone	0730238400 (Workplace)
Email	email@domain.com (Home)

Author

Name	Doctor Henry Button (General Medical Practitioner)
Organisation	Good Hospital
Department	Surgical Ward
Home Address	255 Azanian St, Upper Mount Gravatt, QLD, 4122, Australia
Phone	0345754566 (Workplace)

Clinical Document Details

Document Type	e-Referral
Creation Date/Time	6 Aug 2012 16:16+1000
Date/Time Attested	12 Dec 2012 17:30+1000
Document ID	1a276ff7-16ce-4529-aa7a-ac29b20242f2
Document Set ID	198c2c2b-09d6-428c-aed7-c121a9ad02ca
Document Version	1

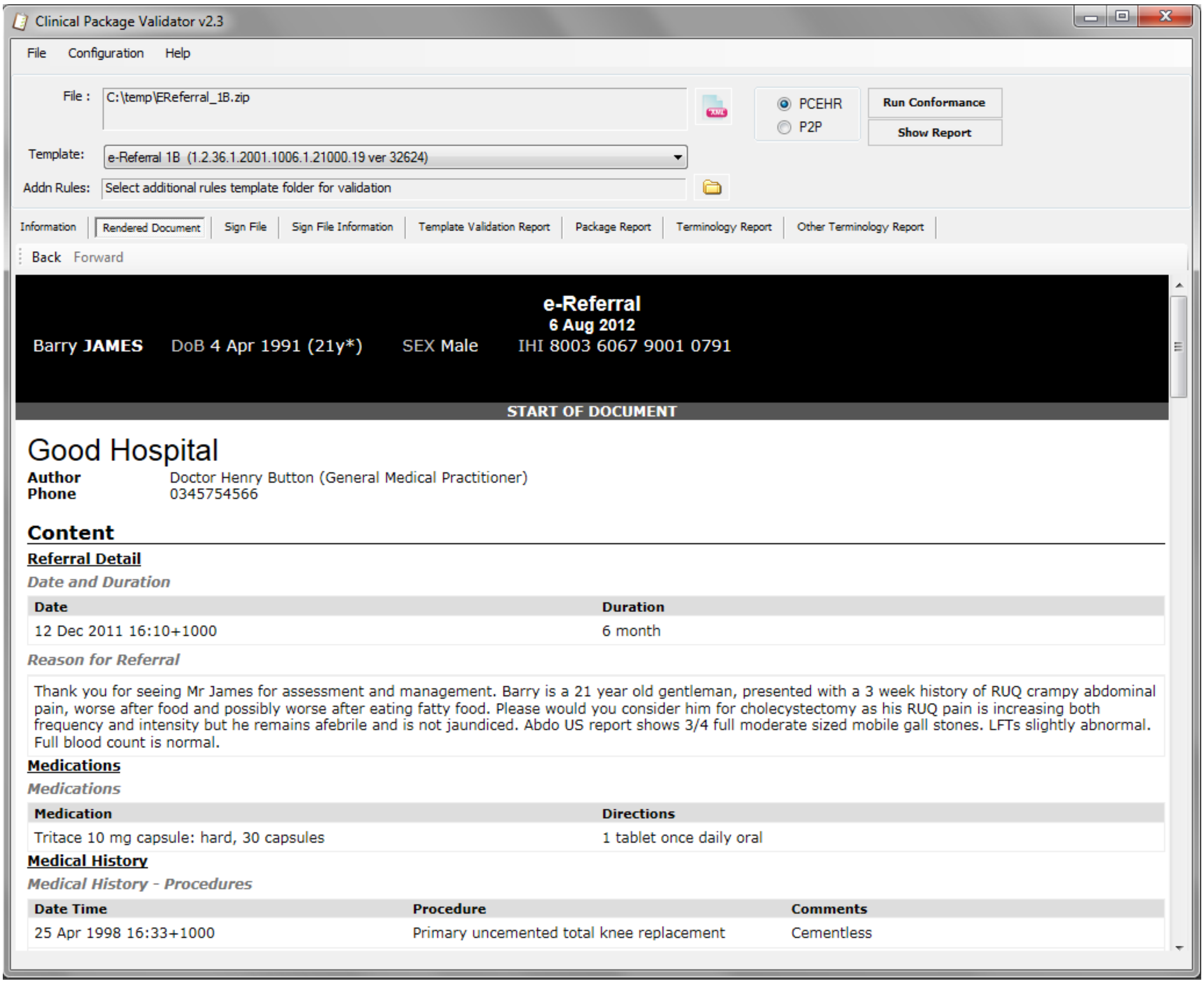
Figure 27: Rendered view of a level 1A eReferral

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 **Content** and the text below the label is the rendered text from the narrative block.



File : C:\temp\EReferral_1B.zip

● PCEHR
○ P2P

Template: e-Referral 1B (1.2.36.1.2001.1006.1.21000.19 ver 32624)

Addn Rules: Select additional rules template folder for validation

e-Referral
6 Aug 2012

Barry **JAMES** DoB 4 Apr 1991 (21y*) SEX Male IHI 8003 6067 9001 0791

START OF DOCUMENT

Good Hospital

Author Doctor Henry Button (General Medical Practitioner)
Phone 0345754566

Content

Referral Detail

Date and Duration

Date	Duration
12 Dec 2011 16:10+1000	6 month

Reason for Referral

Thank you for seeing Mr James for assessment and management. Barry is a 21 year old gentleman, presented with a 3 week history of RUQ crampy abdominal pain, worse after food and possibly worse after eating fatty food. Please would you consider him for cholecystectomy as his RUQ pain is increasing both frequency and intensity but he remains afebrile and is not jaundiced. Abdo US report shows 3/4 full moderate sized mobile gall stones. LFTs slightly abnormal. Full blood count is normal.

Medications

Medications

Medication	Directions
Tritace 10 mg capsule: hard, 30 capsules	1 tablet once daily oral

Medical History

Medical History - Procedures

Date Time	Procedure	Comments
25 Apr 1998 16:33+1000	Primary uncemented total knee replacement	Cementless

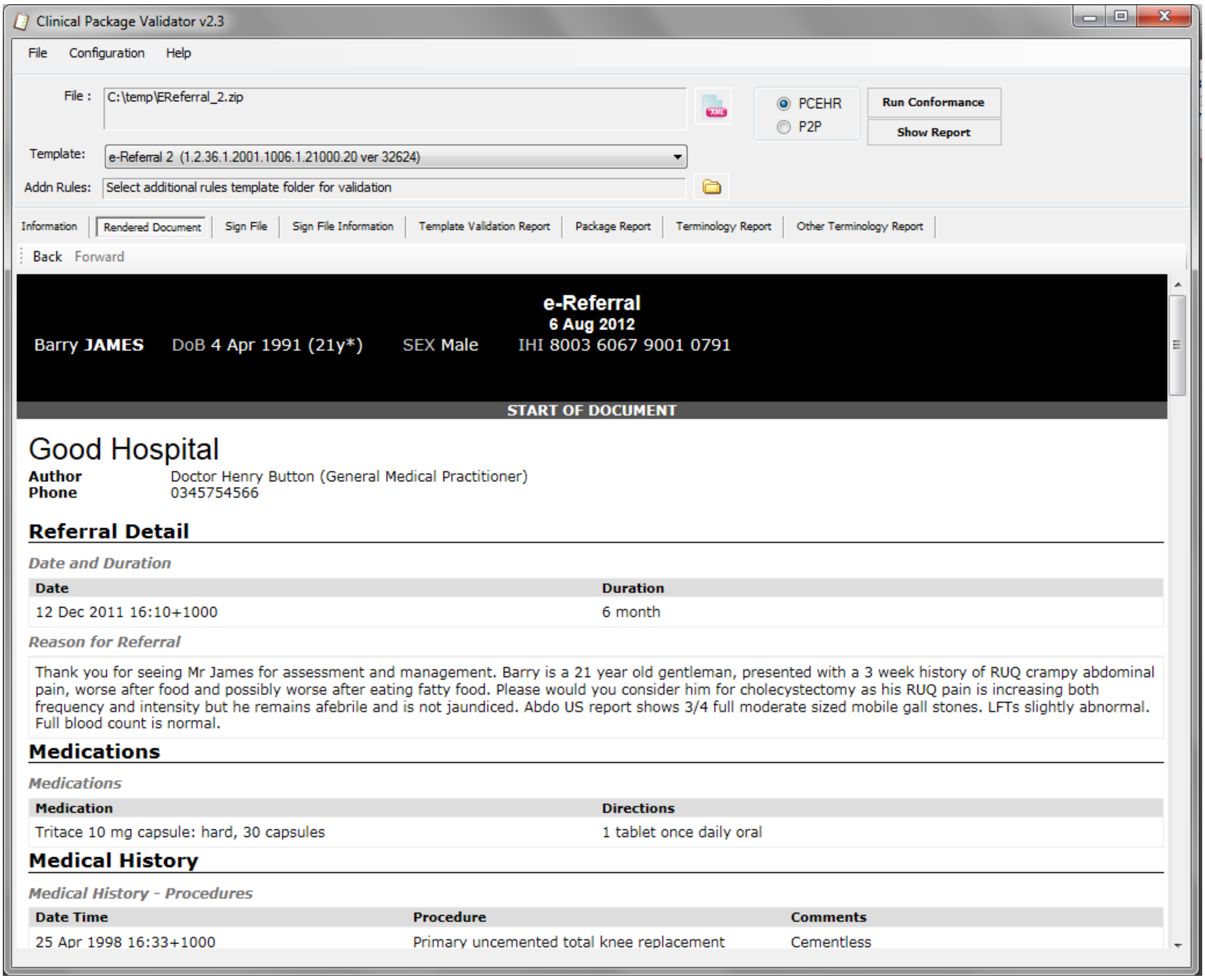
Figure 28: Rendered view of a level 1B eReferral

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 : C:\temp\EReferral_2.zip

Template: e-Referral 2 (1.2.36.1.2001.1006.1.21000.20 ver 32624)

Addn Rules: Select additional rules template folder for validation

e-Referral
6 Aug 2012

Barry **JAMES** DoB 4 Apr 1991 (21y*) SEX Male IHI 8003 6067 9001 0791

START OF DOCUMENT

Good Hospital

Author Doctor Henry Button (General Medical Practitioner)
Phone 0345754566

Referral Detail

Date and Duration

Date	Duration
12 Dec 2011 16:10+1000	6 month

Reason for Referral

Thank you for seeing Mr James for assessment and management. Barry is a 21 year old gentleman, presented with a 3 week history of RUQ crampy abdominal pain, worse after food and possibly worse after eating fatty food. Please would you consider him for cholecystectomy as his RUQ pain is increasing both frequency and intensity but he remains afebrile and is not jaundiced. Abdo US report shows 3/4 full moderate sized mobile gall stones. LFTs slightly abnormal. Full blood count is normal.

Medications

Medications

Medication	Directions
Tritace 10 mg capsule: hard, 30 capsules	1 tablet once daily oral

Medical History

Medical History - Procedures

Date Time	Procedure	Comments
25 Apr 1998 16:33+1000	Primary uncemented total knee replacement	Cementless

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.

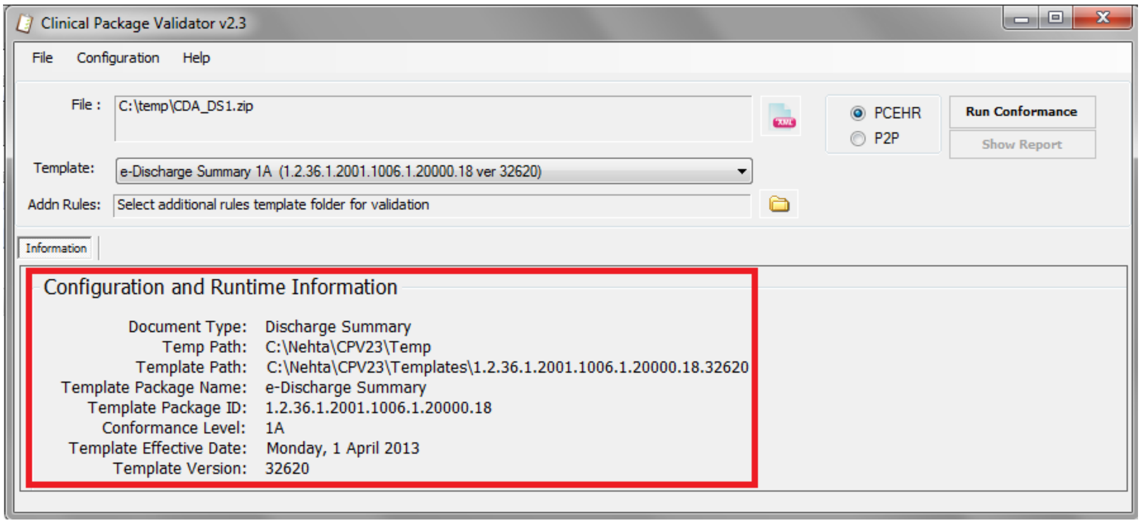
A conformance level 3B clinical document must contain codes from specified code systems, which is optional for lower levels of conformance. Terminology codes such as AMT, SNOMED CT-AU, or PBS must be present wherever they are allowed in the level 3B clinical document. The Validator will check whether 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).



File : C:\temp\CDA_DS1.zip

● PCEHR
○ P2P

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

Configuration and Runtime Information

Document Type: Discharge Summary
Temp Path: C:\Nehta\CPV23\Temp
Template Path: C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.20000.18.32620
Template Package Name: e-Discharge Summary
Template Package ID: 1.2.36.1.2001.1006.1.20000.18
Conformance Level: 1A
Template Effective Date: Monday, 1 April 2013
Template Version: 32620

Figure 30: Configuration and runtime information

The information displayed is described in Table 4.

*Table 4 – Configuration and runtime information displayed in the **Information** tab*

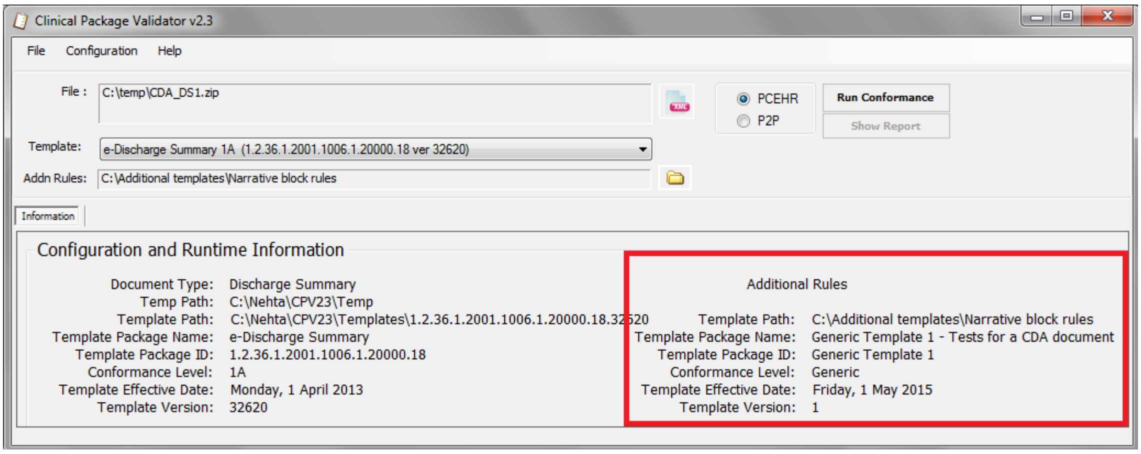
Label	Description
Document Type	The type of the clinical document to be validated.
Temp Path	The location used by the Validator to store temporary files.
Template Path	The location of the template package.
Template Package Name	The name of the template package as recorded in the template package metadata.
Template Package ID	The identifier of the template package as recorded in the template package metadata.

Label	Description
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.

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).



File : C:\temp\CDA_DS1.zip

● PCEHR
○ P2P

Template: e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)

Addn Rules: C:\Additional templates\Narrative block rules

Configuration and Runtime Information

Document Type: Discharge Summary
Temp Path: C:\Nehta\CPV23\Temp
Template Path: C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.20000.18.32620
Template Package Name: e-Discharge Summary
Template Package ID: 1.2.36.1.2001.1006.1.20000.18
Conformance Level: 1A
Template Effective Date: Monday, 1 April 2013
Template Version: 32620

Additional Rules

Template Path: C:\Additional templates\Narrative block rules
Template Package Name: Generic Template 1 - Tests for a CDA document
Template Package ID: Generic Template 1
Conformance Level: Generic
Template Effective Date: Friday, 1 May 2015
Template Version: 1

Figure 31: Information about an additional template

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

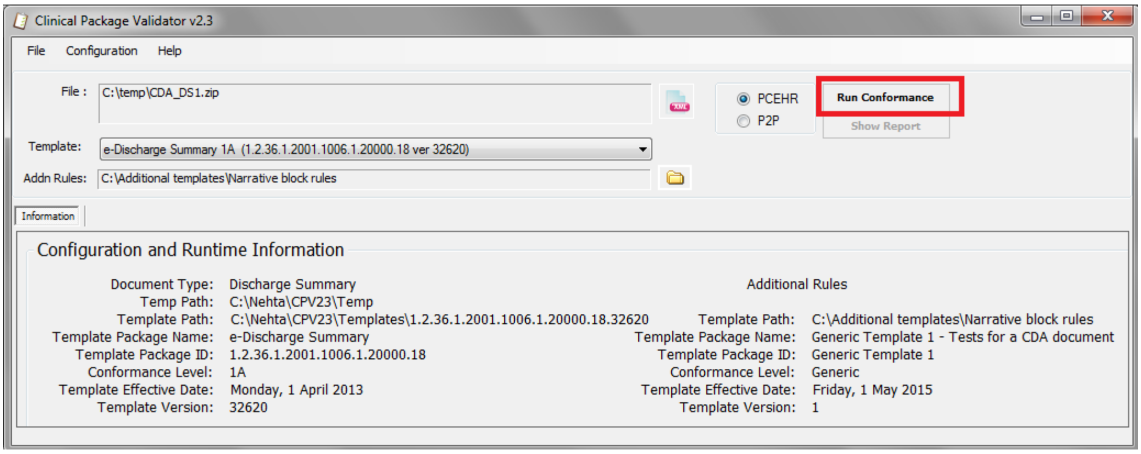
Table 5 –Information about the additional template

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

Label	Description
Template Version	The version number of the additional template package as recorded in the template package metadata.

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 Release Note*.



File : C:\temp\CDA_DS1.zip

Template: e-Discharge Summary 1A (1.2.36.1.2001.1006.1.20000.18 ver 32620)

Addn Rules: C:\Additional templates\Narrative block rules

● PCEHR
○ P2P

Configuration and Runtime Information

		Additional Rules	
Document Type:	Discharge Summary		
Temp Path:	C:\Nehta\CPV23\Temp		
Template Path:	C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.20000.18.32620	Template Path:	C:\Additional templates\Narrative block rules
Template Package Name:	e-Discharge Summary	Template Package Name:	Generic Template 1 - Tests for a CDA document
Template Package ID:	1.2.36.1.2001.1006.1.20000.18	Template Package ID:	Generic Template 1
Conformance Level:	1A	Conformance Level:	Generic
Template Effective Date:	Monday, 1 April 2013	Template Effective Date:	Friday, 1 May 2015
Template Version:	32620	Template Version:	1

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:

1 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.

2 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.

3 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 3.6).

3.6 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).

3.6.1 Information tab

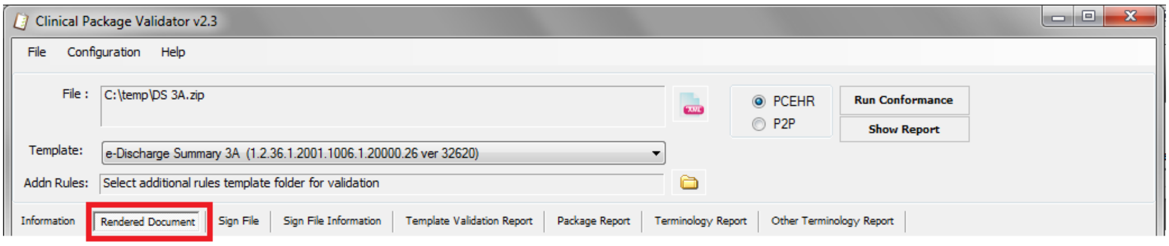
In addition to displaying the information listed in section 3.4, the **Information** tab also contains a summary of the validation results.

*Table 6 – Summary of validation results displayed in the **Information** tab*

Label	Description
Template Results	The total number of errors reported by template validation.
CDA® Package Results	The total number of errors reported by package validation. This information is only included if a clinical package was validated.
Terminology Results	The total number of errors and warnings reported by validation of codes where the CDA implementation guide requires a specific code system must be used.
Other Terminology Results	The total number of errors and warnings reported by validation of codes from 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.

3.6.2 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).



Clinical Package Validator v2.3

File : C:\temp\DS 3A.zip

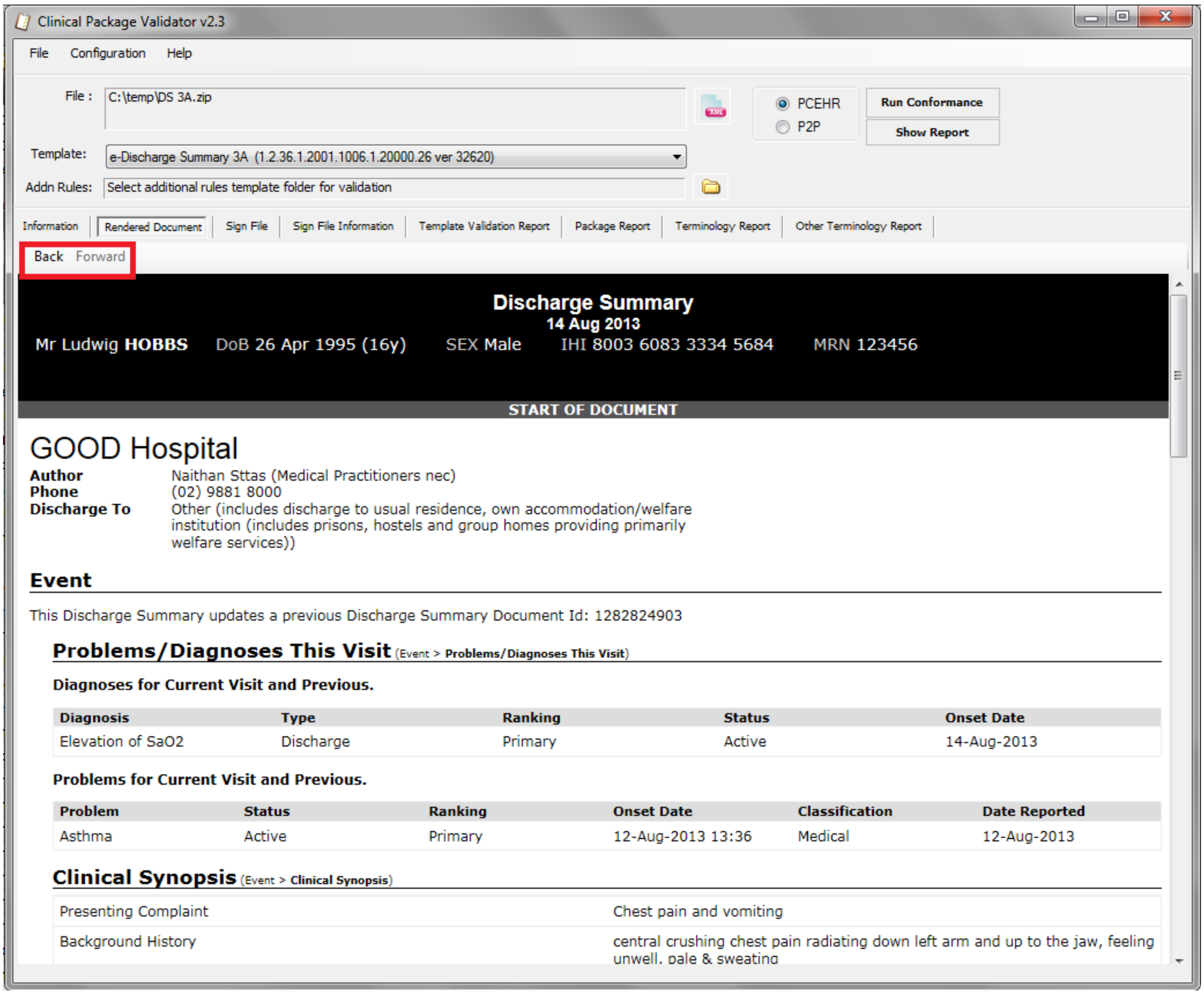
Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

Figure 33: Rendered Document tab

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 : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Discharge Summary
14 Aug 2013
Mr Ludwig **HOBBS** DoB 26 Apr 1995 (16y) SEX Male IHI 8003 6083 3334 5684 MRN 123456

START OF DOCUMENT

GOOD Hospital

Author	Naithan Sttas (Medical Practitioners nec)
Phone	(02) 9881 8000
Discharge To	Other (includes discharge to usual residence, own accommodation/welfare institution (includes prisons, hostels and group homes providing primarily welfare services))

Event

This Discharge Summary updates a previous Discharge Summary Document Id: 1282824903

Problems/Diagnoses This Visit (Event > **Problems/Diagnoses This Visit**)

Diagnoses for Current Visit and Previous.

Diagnosis	Type	Ranking	Status	Onset Date
Elevation of SaO2	Discharge	Primary	Active	14-Aug-2013

Problems for Current Visit and Previous.

Problem	Status	Ranking	Onset Date	Classification	Date Reported
Asthma	Active	Primary	12-Aug-2013 13:36	Medical	12-Aug-2013

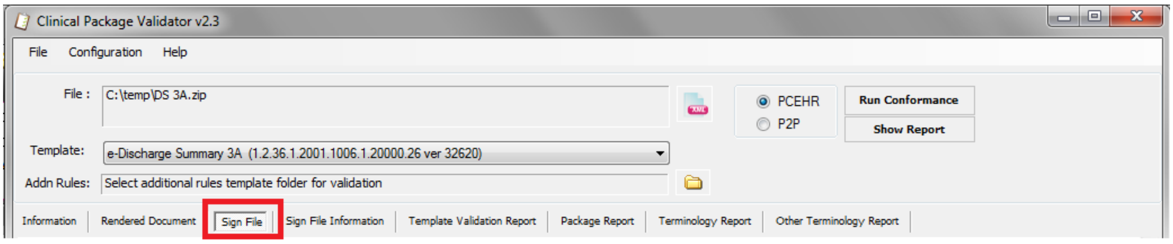
Clinical Synopsis (Event > **Clinical Synopsis**)

Presenting Complaint	Chest pain and vomiting
Background History	central crushing chest pain radiating down left arm and up to the jaw, feeling unwell, pale & sweating

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

3.6.3 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.



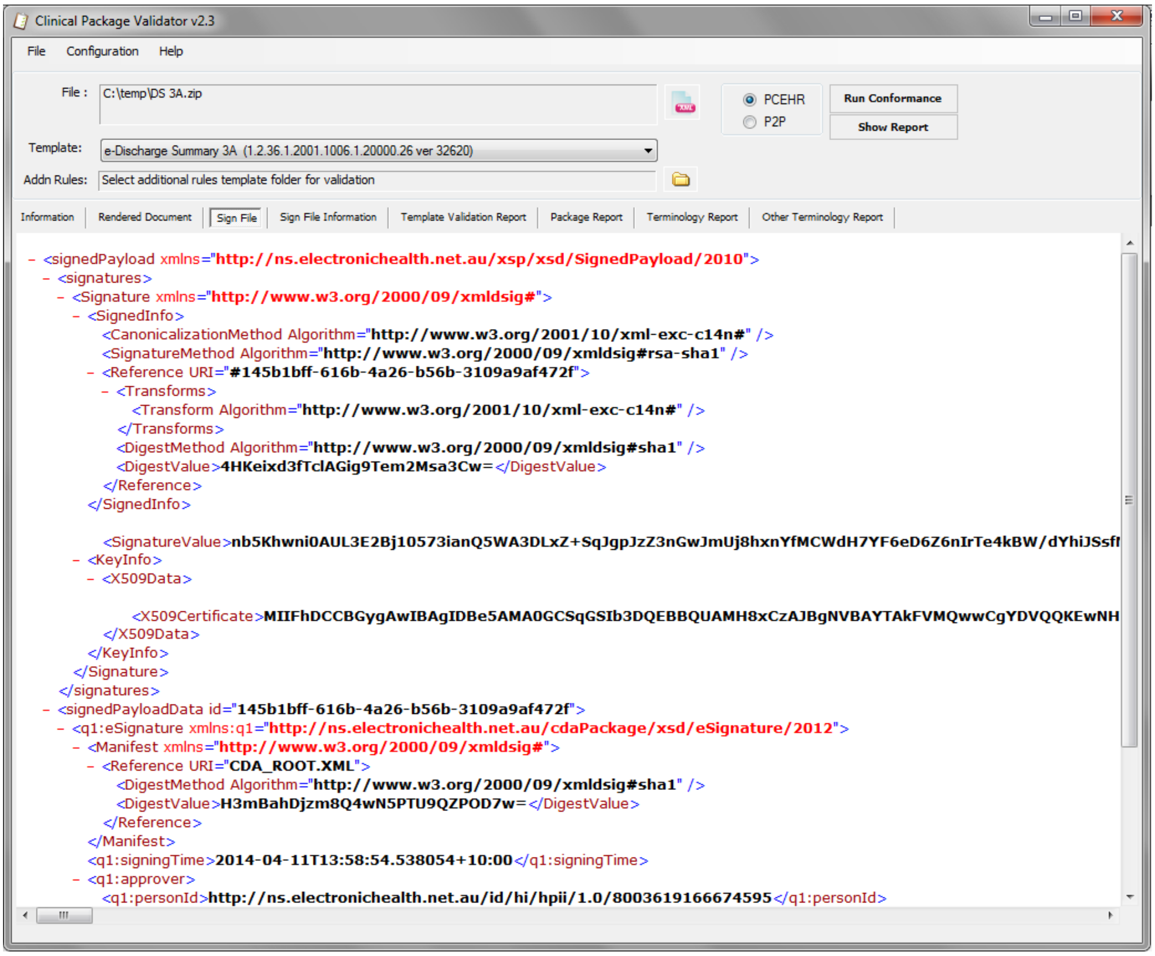
File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Figure 35: Sign File tab

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



File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

● PCEHR ○ P2P

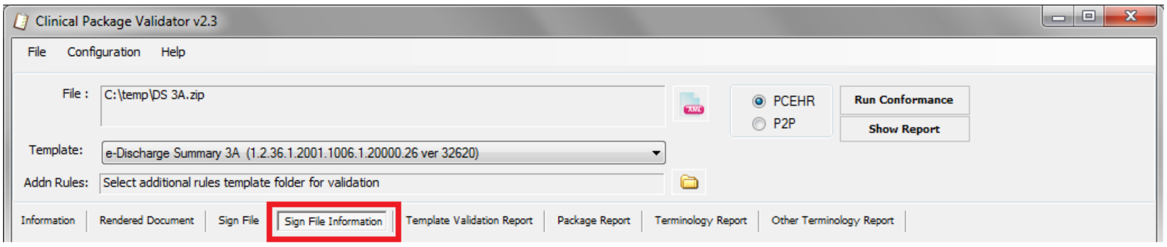
```
- <signedPayload xmlns="http://ns.electronichealth.net.au/xsp/xsd/SignedPayload/2010">
  - <signatures>
    - <Signature xmlns="http://www.w3.org/2000/09/xmldsig#">
      - <SignedInfo>
          <CanonicalizationMethod Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#" />
          <SignatureMethod Algorithm="http://www.w3.org/2000/09/xmldsig#rsa-sha1" />
        - <Reference URI="#145b1bff-616b-4a26-b56b-3109a9af472f">
          - <Transforms>
              <Transform Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#" />
            </Transforms>
            <DigestMethod Algorithm="http://www.w3.org/2000/09/xmldsig#sha1" />
            <DigestValue>4HKeixd3fTclAGig9Tem2Msa3Cw=</DigestValue>
          </Reference>
        </SignedInfo>

          <SignatureValue>nb5Khwni0AUL3E2Bj10573ianQ5WA3DLxZ+SqJgpJzZ3nGwJmUj8hxnYfMCWdH7YF6eD6Z6nIrTe4kBW/dYhiJSsf
      - <KeyInfo>
        - <X509Data>

              <X509Certificate>MIIFhDCCBGygAwIBAgIDBe5AMA0GCSqGSIb3DQEBBQUAMH8xCzAJBgNVBAYTAkFVMQwwCgYDVQQKEwNH
          </X509Data>
        </KeyInfo>
      </Signature>
    </signatures>
  - <signedPayloadData id="145b1bff-616b-4a26-b56b-3109a9af472f">
    - <q1:eSignature xmlns:q1="http://ns.electronichealth.net.au/cdaPackage/xsd/eSignature/2012">
      - <Manifest xmlns="http://www.w3.org/2000/09/xmldsig#">
        - <Reference URI="CDA_ROOT.XML">
            <DigestMethod Algorithm="http://www.w3.org/2000/09/xmldsig#sha1" />
            <DigestValue>H3mBahDjzm8Q4wN5PTU9QZPOD7w=</DigestValue>
          </Reference>
        </Manifest>
        <q1:signingTime>2014-04-11T13:58:54.538054+10:00</q1:signingTime>
      - <q1:approver>
          <q1:personId>http://ns.electronichealth.net.au/id/hi/hpii/1.0/8003619166674595</q1:personId>
```

Figure 36: Display of a CDA_SIGN.XML file

3.6.4 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 : C:\temp\DS 3A.zip

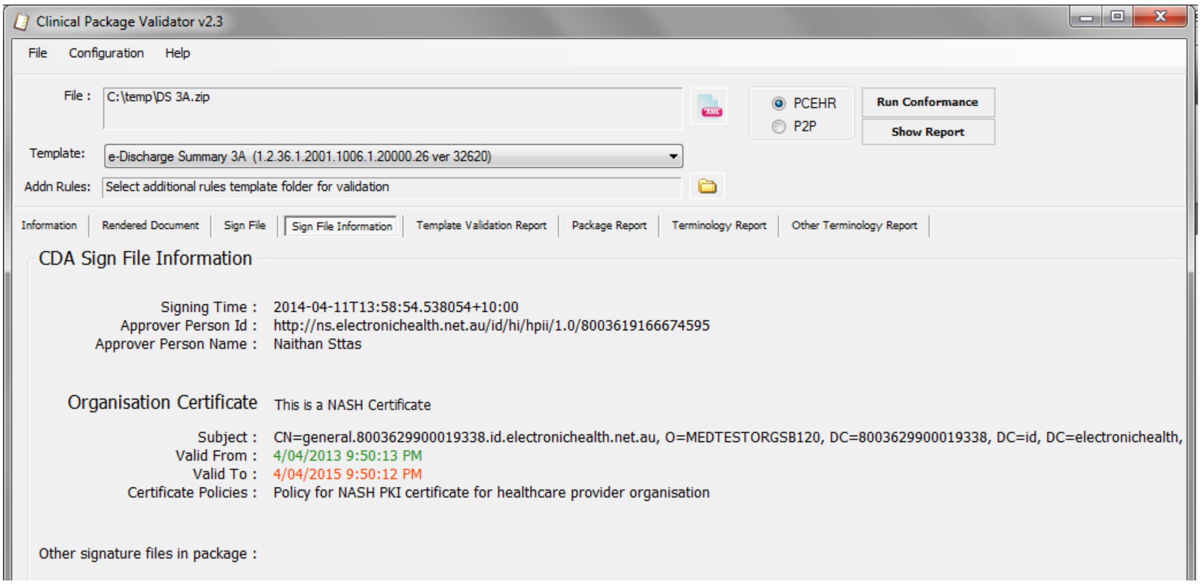
Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

● PCEHR ○ P2P

Figure 37: Sign File Information tab

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



File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

CDA Sign File Information

Signing Time : 2014-04-11T13:58:54.538054+10:00
Approver Person Id : http://ns.electronichealth.net.au/id/hi/hpii/1.0/8003619166674595
Approver Person Name : Naithan Sttas

Organisation Certificate This is a NASH Certificate

Subject : CN=general.8003629900019338.id.electronichealth.net.au, O=MEDTESTORGSB120, DC=8003629900019338, DC=id, DC=electronichealth,
Valid From : 4/04/2013 9:50:13 PM
Valid To : 4/04/2015 9:50:12 PM
Certificate Policies : Policy for NASH PKI certificate for healthcare provider organisation

Other signature files in package :

Figure 38: Display of eSignature file information

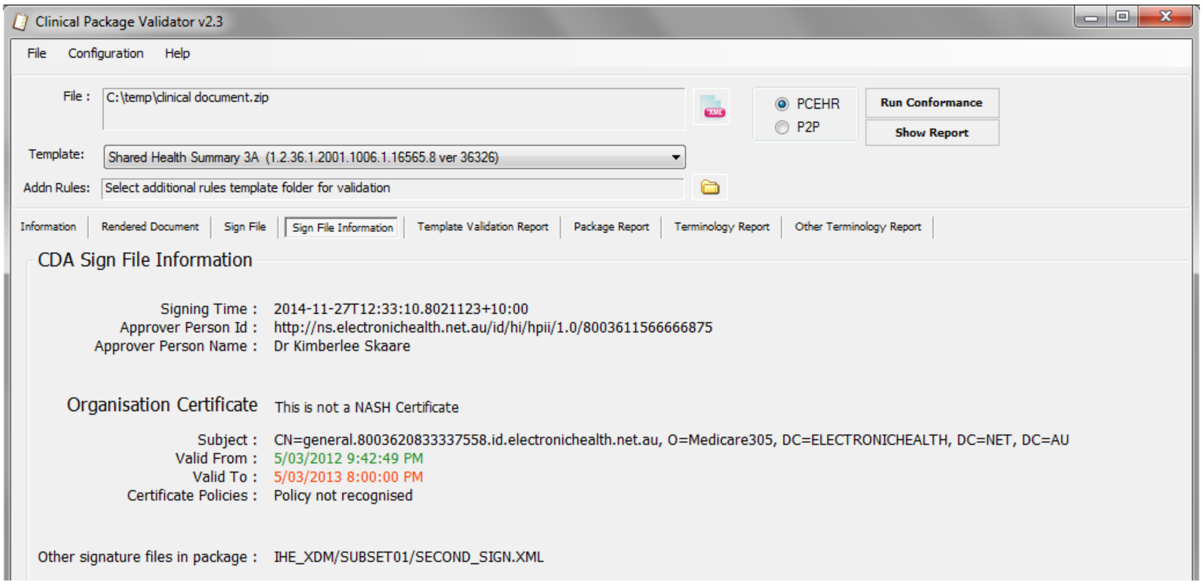
The information displayed is listed in Table 7.

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

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.

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.
Subject Alternative Name	An alternative representation of the organisation that was assigned the PKI certificate, in the Uniform Resource Identifier (URI) format. The URI includes the national healthcare identifier of the organisation and the identifier type. Subject Alternative Name is an optional element so it may not be displayed.
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:\temp\clinical document.zip

● PCEHR
○ P2P

Template: Shared Health Summary 3A (1.2.36.1.2001.1006.1.16565.8 ver 36326)

Addn Rules: Select additional rules template folder for validation

CDA Sign File Information

Signing Time : 2014-11-27T12:33:10.8021123+10:00
Approver Person Id : http://ns.electronichealth.net.au/id/hi/hpii/1.0/8003611566666875
Approver Person Name : Dr Kimberlee Skaare

Organisation Certificate This is not a NASH Certificate

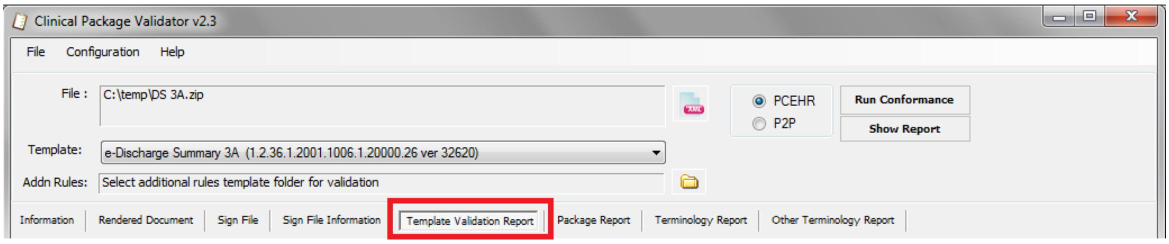
Subject : CN=general.8003620833337558.id.electronichealth.net.au, O=Medicare305, DC=ELECTRONICHEALTH, DC=NET, DC=AU
Valid From : 5/03/2012 9:42:49 PM
Valid To : 5/03/2013 8:00:00 PM
Certificate Policies : Policy not recognised

Other signature files in package : IHE_XDM/SUBSET01/SECOND_SIGN.XML

Figure 39: An unrecognised type of certificate and a second eSignature

3.6.5 Template Validation Report tab

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



File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

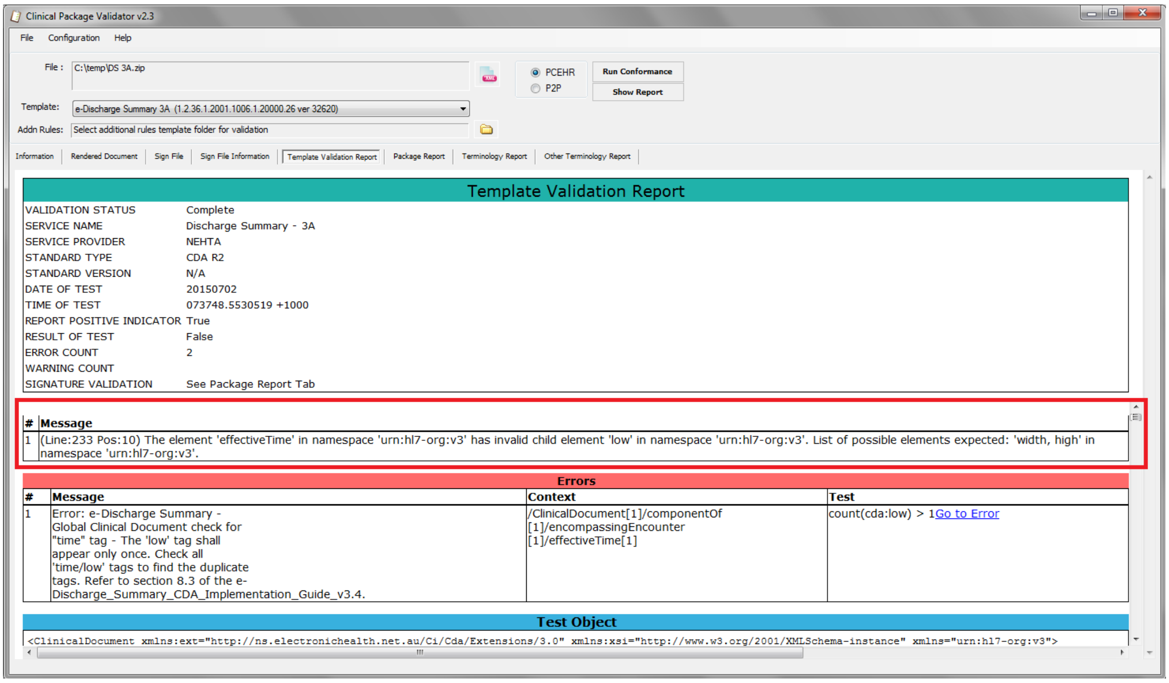
Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

Figure 40: Template Validation Report tab

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

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



File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

Template Validation Report

VALIDATION STATUS	Complete
SERVICE NAME	Discharge Summary - 3A
SERVICE PROVIDER	NEHTA
STANDARD TYPE	CDA R2
STANDARD VERSION	N/A
DATE OF TEST	20150702
TIME OF TEST	073748.5530519 +1000
REPORT POSITIVE INDICATOR	True
RESULT OF TEST	False
ERROR COUNT	2
WARNING COUNT	
SIGNATURE VALIDATION	See Package Report Tab

#	Message
1	(Line:233 Pos:10) The element 'effectiveTime' in namespace 'urn:hl7-org:v3' has invalid child element 'low' in namespace 'urn:hl7-org:v3'. List of possible elements expected: 'width, high' in namespace 'urn:hl7-org:v3'.

Errors

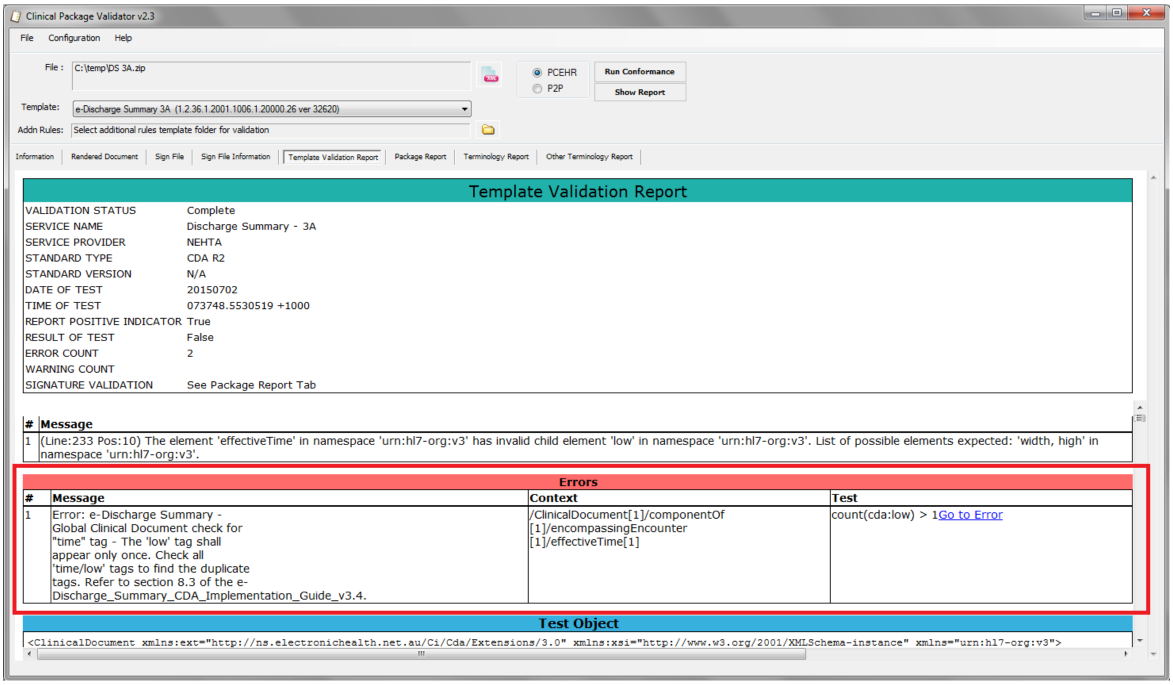
#	Message	Context	Test
1	Error: e-Discharge Summary - Global Clinical Document check for "time" tag - The 'low' tag shall appear only once. Check all 'time/low' tags to find the duplicate tags. Refer to section 8.3 of the e-Discharge_Summary_CDA_Implementation_Guide_v3.4.	/ClinicalDocument[1]/componentOf [1]/encompassingEncounter [1]/effectiveTime[1]	count(cda:low) > 1Go to Error

Test Object

```
<ClinicalDocument xmlns:ext="http://ns.electronichealth.net.au/Ci/Cda/Extensions/3.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3">
```

Figure 41: Template Validation Report tab with schema error highlighted

Figure 42 shows the report with Schematron errors highlighted.



File : C:\temp\DS 3A.zip

● PCEHR
○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Template Validation Report

VALIDATION STATUS	Complete
SERVICE NAME	Discharge Summary - 3A
SERVICE PROVIDER	NEHTA
STANDARD TYPE	CDA R2
STANDARD VERSION	N/A
DATE OF TEST	20150702
TIME OF TEST	073748.5530519 +1000
REPORT POSITIVE INDICATOR	True
RESULT OF TEST	False
ERROR COUNT	2
WARNING COUNT	
SIGNATURE VALIDATION	See Package Report Tab

#	Message
1	(Line:233 Pos:10) The element 'effectiveTime' in namespace 'urn:hl7-org:v3' has invalid child element 'low' in namespace 'urn:hl7-org:v3'. List of possible elements expected: 'width, high' in namespace 'urn:hl7-org:v3'.

Errors

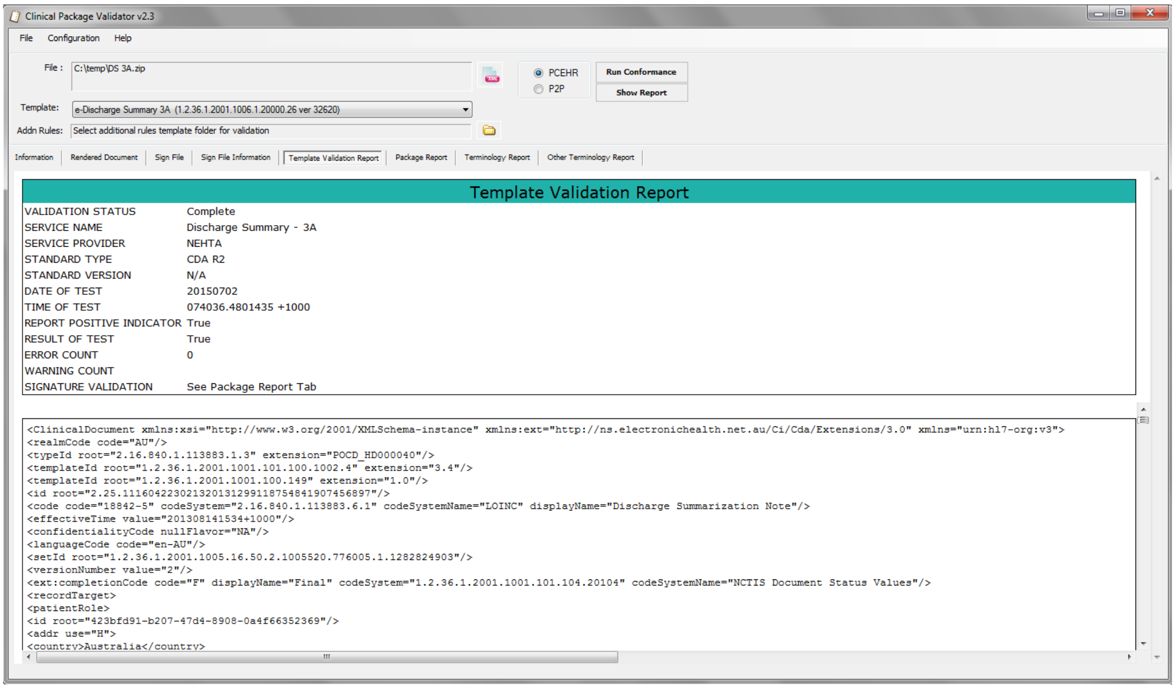
#	Message	Context	Test
1	Error: e-Discharge Summary - Global Clinical Document check for "time" tag - The 'low' tag shall appear only once. Check all 'time/low' tags to find the duplicate tags. Refer to section 8.3 of the e-Discharge_Summary_CDA_Implementation_Guide_v3.4.	/ClinicalDocument[1]/componentOf[1]/encompassingEncounter[1]/effectiveTime[1]	count(cda:low) > 1Go to Error

Test Object

```
<ClinicalDocument xmlns:ext="http://ns.electronichealth.net.au/Ci/Cda/Extensions/3.0" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns="urn:hl7-org:v3">
```

Figure 42: Template Validation Report tab with Schematron errors highlighted

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



File : C:\temp\DS 3A.zip

● PCEHR
○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Template Validation Report

VALIDATION STATUS	Complete
SERVICE NAME	Discharge Summary - 3A
SERVICE PROVIDER	NEHTA
STANDARD TYPE	CDA R2
STANDARD VERSION	N/A
DATE OF TEST	20150702
TIME OF TEST	074036.4801435 +1000
REPORT POSITIVE INDICATOR	True
RESULT OF TEST	True
ERROR COUNT	0
WARNING COUNT	
SIGNATURE VALIDATION	See Package Report Tab

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:ext="http://ns.electronichealth.net.au/Ci/Cda/Extensions/3.0" xmlns="urn:hl7-org:v3">
<realmCode code="AU"/>
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<templateId root="1.2.36.1.2001.1001.101.100.1002.4" extension="3.4"/>
<templateId root="1.2.36.1.2001.1001.100.149" extension="1.0"/>
<id root="2.25.111604223021320131299118754841907456897"/>
<code code="18842-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Discharge Summarization Note"/>
<effectiveTime value="201308141534+1000"/>
<confidentialityCode nullFlavor="NA"/>
<languageCode code="en-AU"/>
<setId root="1.2.36.1.2001.1005.16.50.2.1005520.776005.1.1282824903"/>
<versionNumber value="2"/>
<ext:completionCode code="F" displayName="Final" codeSystem="1.2.36.1.2001.1001.101.104.20104" codeSystemName="NCTIS Document Status Values"/>
<recordTarget>
<patientRole>
<id root="423bfd91-b207-47d4-8908-0a4f66352369"/>
<addr use="H">
<country>Australia</country>
```

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	NEHTA
Standard type	HL7 CDA R2 indicates the clinical document specifications are based on release 2 of the HL7® Clinical Document Architecture [HL72004].
Standard version	This field is not used.
Date of test	The date in the yyyymmdd format.
Time of test	The time when the test was run.
Report positive indicator	The **Report positive indicator** is currently always set to **True**.
Result of test	The overall result of the validation. The result is **True** if template validation found no errors, and **False** if errors were found during template validation.
Error count	The total number of schema and Schematron errors.
Warning count	The total number of warnings.
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.

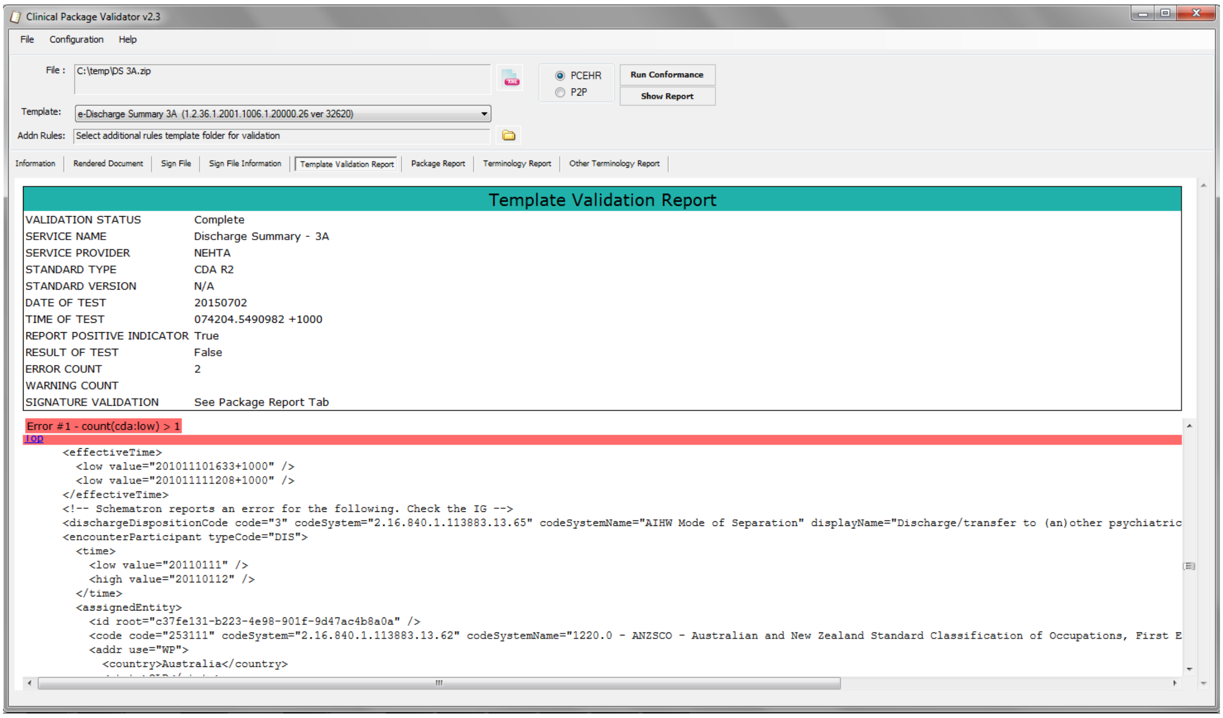
If schema errors are found, the middle portion of the report contains the XML line number where the error is located, the position of the error within the line, and a description of the error (Figure 41).

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

Table 9 - Schematron error information

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

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



File : C:\temp\DS 3A.zip

● PCEHR ○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Template Validation Report

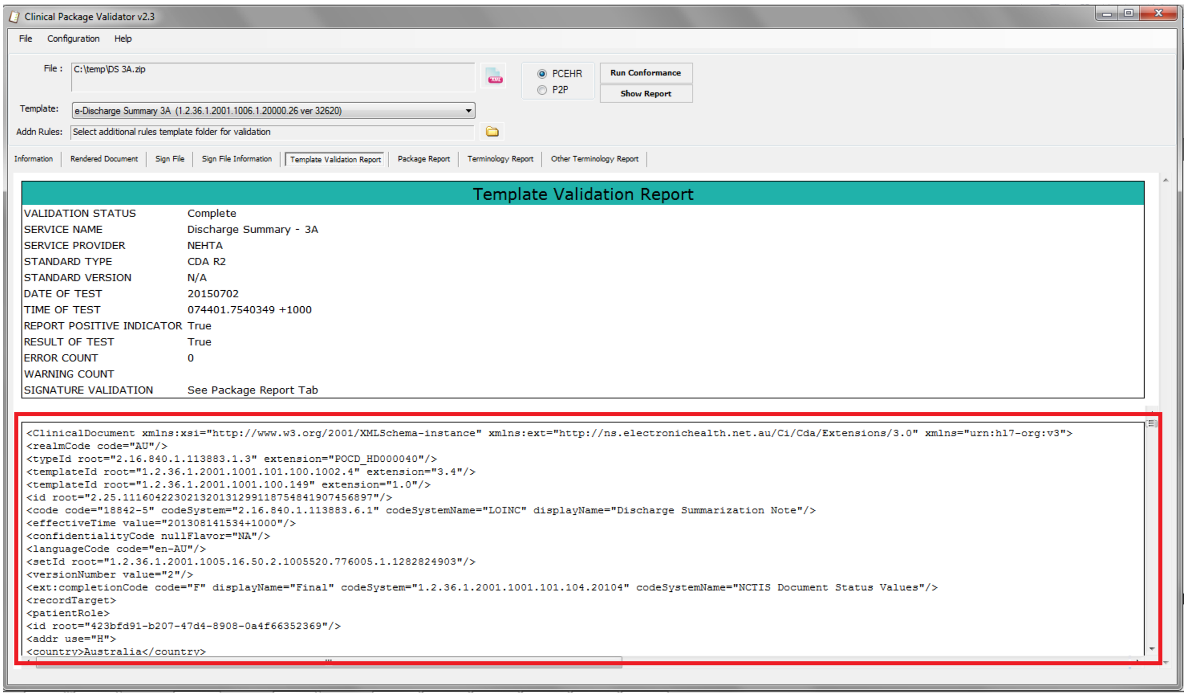
VALIDATION STATUS	Complete
SERVICE NAME	Discharge Summary - 3A
SERVICE PROVIDER	NEHTA
STANDARD TYPE	CDA R2
STANDARD VERSION	N/A
DATE OF TEST	20150702
TIME OF TEST	074204.5490982 +1000
REPORT POSITIVE INDICATOR	True
RESULT OF TEST	False
ERROR COUNT	2
WARNING COUNT	
SIGNATURE VALIDATION	See Package Report Tab

Error #1 - count(cda:low) > 1
Top

```
      <effectiveTime>
        <low value="201011101633+1000" />
        <low value="201011111208+1000" />
      </effectiveTime>
      <!-- Schematron reports an error for the following. Check the IG -->
      <dischargeDispositionCode code="3" codeSystem="2.16.840.1.113883.13.65" codeSystemName="AIHW Mode of Separation" displayName="Discharge/transfer to (an)other psychiatric
      <encounterParticipant typeCode="DIS">
        <time>
          <low value="20110111" />
          <high value="20110112" />
        </time>
        <assignedEntity>
          <id root="c37fe131-b223-4e98-901f-9d47ac4b8a0a" />
          <code code="253111" codeSystem="2.16.840.1.113883.13.62" codeSystemName="1220.0 - ANZSCO - Australian and New Zealand Standard Classification of Occupations, First E
          <addr use="WP">
            <country>Australia</country>
```

*Figure 44: Template Validation Report tab when a **Go to Error** 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 errors.



File : C:\temp\DS 3A.zip

● PCEHR ○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Template Validation Report

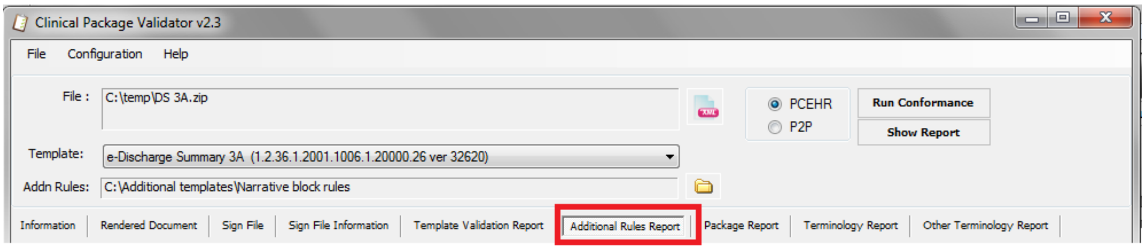
VALIDATION STATUS	Complete
SERVICE NAME	Discharge Summary - 3A
SERVICE PROVIDER	NEHTA
STANDARD TYPE	CDA R2
STANDARD VERSION	N/A
DATE OF TEST	20150702
TIME OF TEST	074401.7540349 +1000
REPORT POSITIVE INDICATOR	True
RESULT OF TEST	True
ERROR COUNT	0
WARNING COUNT	
SIGNATURE VALIDATION	See Package Report Tab

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xmlns:ext="http://ns.electronichealth.net.au/Ci/Cda/Extensions/3.0" xmlns="urn:hl7-org:v3">
<realmCode code="AU"/>
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<templateId root="1.2.36.1.2001.1001.101.100.1002.4" extension="3.4"/>
<templateId root="1.2.36.1.2001.1001.100.149" extension="1.0"/>
<id root="2.25.111604223021320131299118754841907456897"/>
<code code="18842-5" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Discharge Summarization Note"/>
<effectiveTime value="201308141534+1000"/>
<confidentialityCode nullFlavor="NA"/>
<languageCode code="en-AU"/>
<setId root="1.2.36.1.2001.1005.16.50.2.1005520.776005.1.1282824903"/>
<versionNumber value="2"/>
<ext:completionCode code="F" displayName="Final" codeSystem="1.2.36.1.2001.1001.101.104.20104" codeSystemName="NCTIS Document Status Values"/>
<recordTarget>
<patientRole>
<id root="423bfd91-b207-47d4-8908-0a4f66352369"/>
<addr use="H">
<country>Australia</country>
```

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

3.6.6 Additional Rules Report tab

The **Additional Rules Report** tab displays selected information from the CDA_SIGN.XML file in a clinical package (for which the Validator may be used) (Figure 46). This tab is only displayed if an additional template package was imported into the Validator (Section 3.2.3).


Clinical Package Validator v2.3

File : C:\temp\DS 3A.zip

● PCEHR ○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

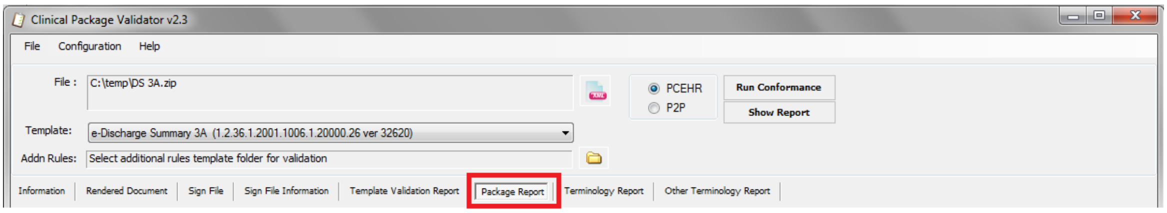
Addn Rules: C:\Additional templates\Narrative block rules

Figure 46: Additional Rules Report tab

Information is displayed in the **Additional Rules Report** tab in the same way as information is displayed in the **Template Validation Report** tab (Section 3.6.5).

3.6.7 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).


Clinical Package Validator v2.3

File : C:\temp\DS 3A.zip

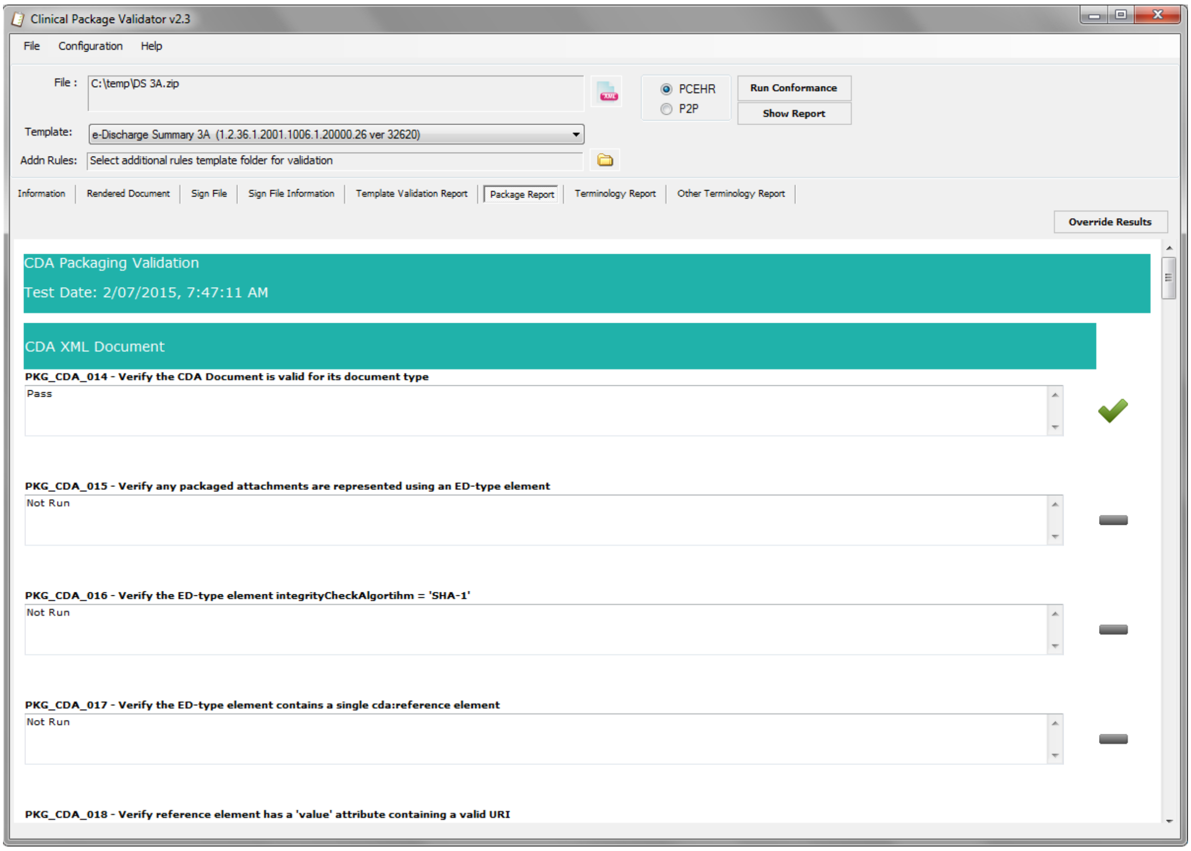
● PCEHR ○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

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 : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

CDA Packaging Validation

Test Date: 2/07/2015, 7:47:11 AM

CDA XML Document

PKG_CDA_014 - Verify the CDA Document is valid for its document type
Pass ✓

PKG_CDA_015 - Verify any packaged attachments are represented using an ED-type element
Not Run ▬

PKG_CDA_016 - Verify the ED-type element integrityCheckAlgortihm = 'SHA-1'
Not Run ▬

PKG_CDA_017 - Verify the ED-type element contains a single cda:reference element
Not Run ▬

PKG_CDA_018 - Verify reference element has a 'value' attribute containing a valid URI

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

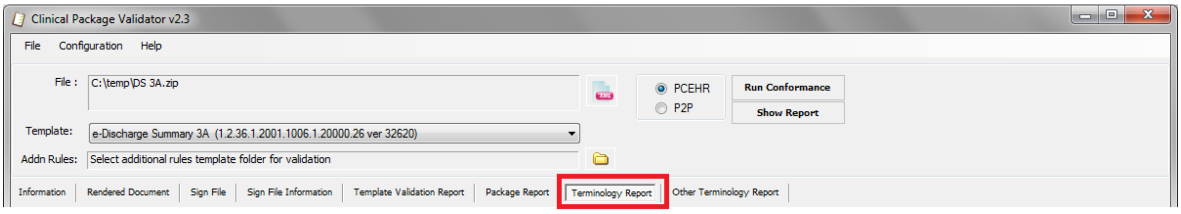
Package validation symbols and their meanings are listed in Table 10.

Table 10 - Package validation symbols

Symbol	Explanation	Usage
✓	Pass	The Validator determined a definite pass for the test case.
✖	Fail	The Validator determined a definite 'Fail' for the test case.
🚩	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.

3.6.8 Terminology Report tab

The **Terminology Report** tab (Figure 49) displays the results of applying additional code validation (for which the Validator may be used) (Section 2.3.1).



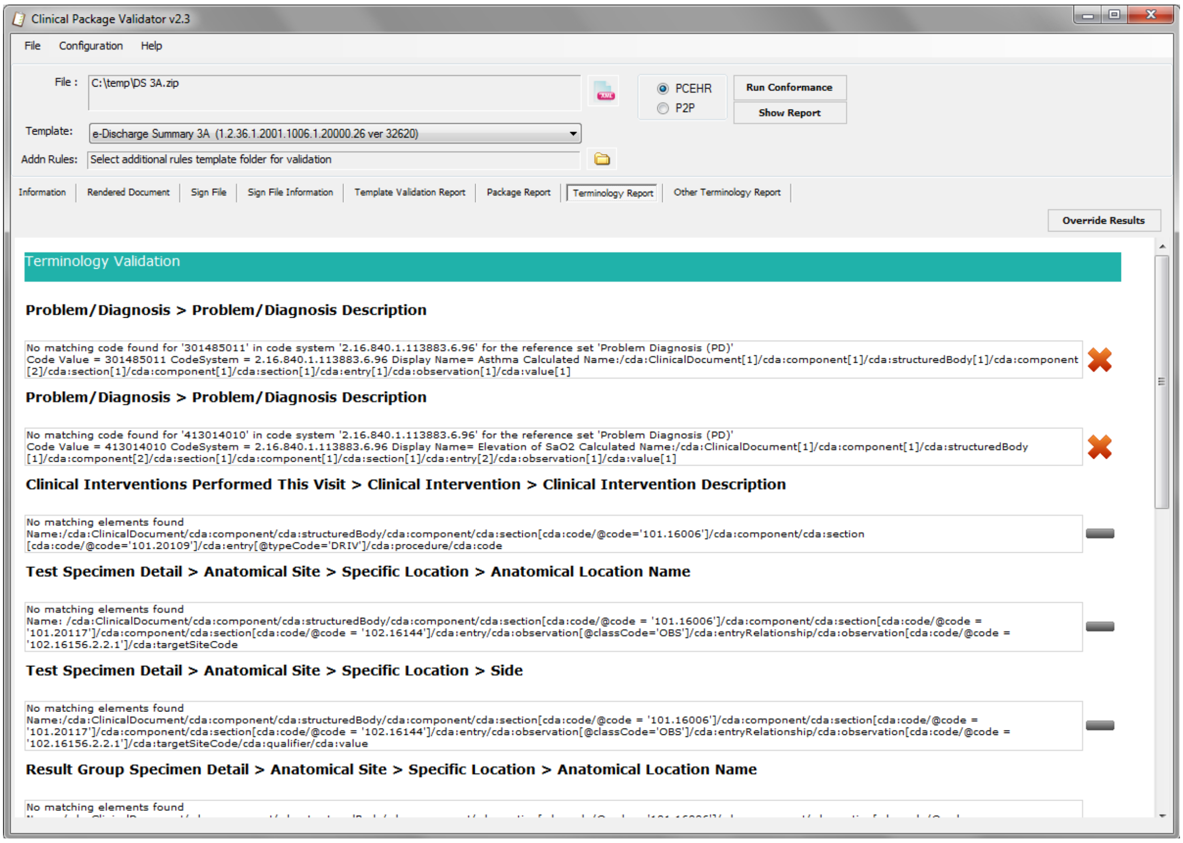
File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Figure 49: Terminology Report tab

Terminology code validation results are displayed for every data element that is a target of code validation. They include information that describes the validation result and a symbol that summarises that result (Figure 50).



File : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

Terminology Validation

Problem/Diagnosis > Problem/Diagnosis Description

```
No matching code found for '301485011' in code system '2.16.840.1.113883.6.96' for the reference set 'Problem Diagnosis (PD)'
Code Value = 301485011 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Asthma Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component
[2]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:value[1]
```
✖

Problem/Diagnosis > Problem/Diagnosis Description

```
No matching code found for '413014010' in code system '2.16.840.1.113883.6.96' for the reference set 'Problem Diagnosis (PD)'
Code Value = 413014010 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Elevation of SaO2 Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody
[1]/cda:component[2]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[2]/cda:observation[1]/cda:value[1]
```
✖

Clinical Interventions Performed This Visit > Clinical Intervention > Clinical Intervention Description

```
No matching elements found
Name:/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code='101.16006']/cda:component/cda:section
[cda:code/@code='101.20109']/cda:entry[@typeCode='DRIV']/cda:procedure/cda:code
```
▬

Test Specimen Detail > Anatomical Site > Specific Location > Anatomical Location Name

```
No matching elements found
Name: /cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code = '101.16006']/cda:component/cda:section[cda:code/@code =
'101.20117']/cda:component/cda:section[cda:code/@code = '102.16144']/cda:entry/cda:observation[@classCode='OBS']/cda:entryRelationship/cda:observation[cda:code/@code =
'102.16156.2.2.1']/cda:targetSiteCode
```
▬

Test Specimen Detail > Anatomical Site > Specific Location > Side

```
No matching elements found
Name:/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code = '101.16006']/cda:component/cda:section[cda:code/@code =
'101.20117']/cda:component/cda:section[cda:code/@code = '102.16144']/cda:entry/cda:observation[@classCode='OBS']/cda:entryRelationship/cda:observation[cda:code/@code =
'102.16156.2.2.1']/cda:targetSiteCode/cda:qualifier/cda:value
```
▬

Result Group Specimen Detail > Anatomical Site > Specific Location > Anatomical Location Name

```
No matching elements found
```

Figure 50: Terminology Report tab showing results of code validation

Terminology code validation symbols and their meanings are listed in Table 11.

Table 11 – Terminology code validation symbols

Symbol	Explanation	Usage
✓	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.

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 (✖) if:

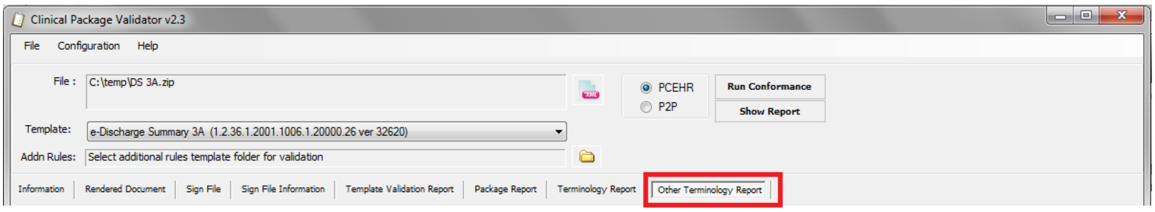
- the value of a code does not exist in the terminology reference set specified in the relevant CDA implementation guide; or
- the display name of a code in a clinical document does not match that code's display name in the terminology reference set.

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.

3.6.9 Other Terminology Report tab

The **Other Terminology Report** 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:\temp\DS 3A.zip

● PCEHR
○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

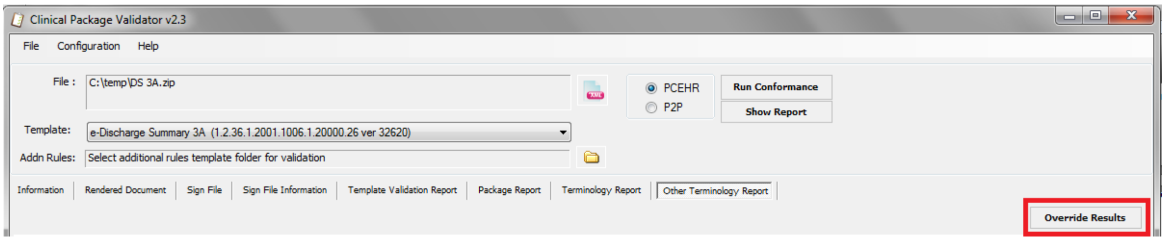
Addn Rules: Select additional rules template folder for validation

Figure 51: Other Terminology Report tab

Information is displayed in the **Other Terminology Report** tab in the same way as information is displayed in the **Terminology Report** tab (Section 3.6.8).

3.7 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 : C:\temp\DS 3A.zip

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

● PCEHR

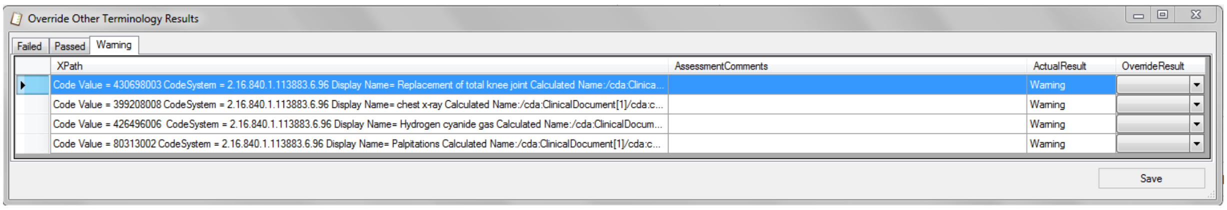
○ P2P

Figure 52: Override results command displayed in Terminology Report 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 PCEHR 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).



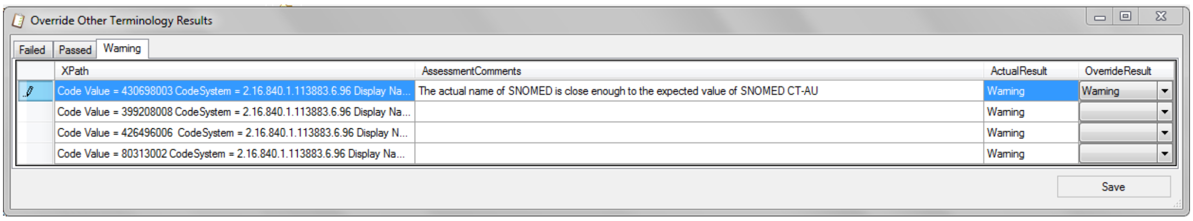
XPath	AssessmentComments	ActualResult	OverrideResult
Code Value = 430698003 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Replacement of total knee joint Calculated Name:/cda:Clinica...		Warning	
Code Value = 399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Name= chest x-ray Calculated Name:/cda:ClinicalDocument[1]/cda:c...		Warning	
Code Value = 426496006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Hydrogen cyanide gas Calculated Name:/cda:ClinicalDocum...		Warning	
Code Value = 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’.



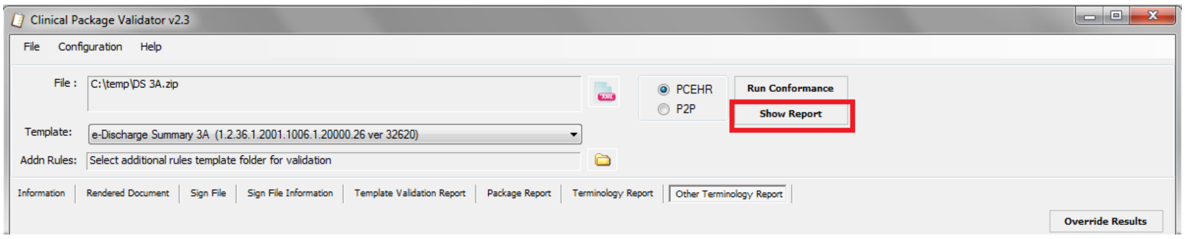
XPath	AssessmentComments	ActualResult	OverrideResult
Code Value = 430698003 CodeSystem = 2.16.840.1.113883.6.96 Display Na...	The actual name of SNOMED is close enough to the expected value of SNOMED CT-AU	Warning	Warning
Code Value = 399208008 CodeSystem = 2.16.840.1.113883.6.96 Display Na...		Warning	
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 3.6.1).

3.8 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:\temp\DS 3A.zip

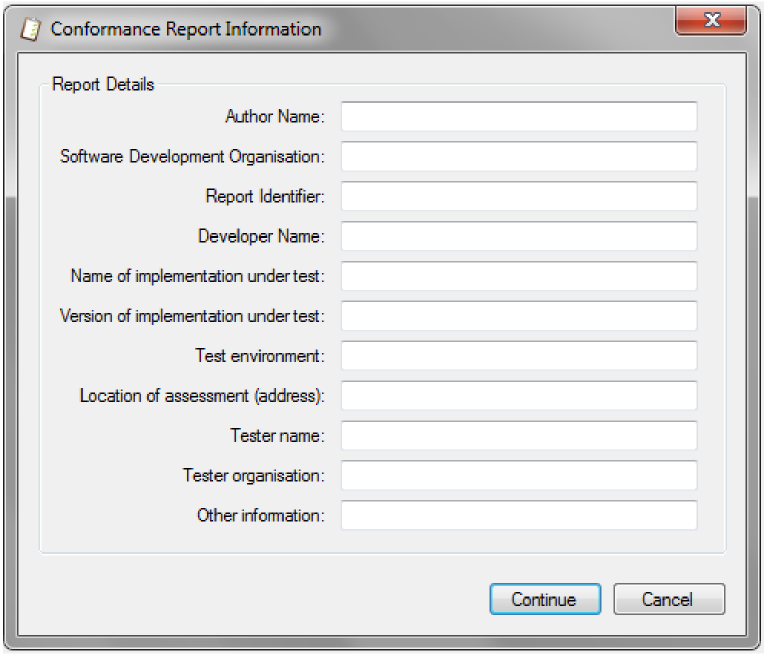
● PCEHR
○ P2P

Template: e-Discharge Summary 3A (1.2.36.1.2001.1006.1.20000.26 ver 32620)

Addn Rules: Select additional rules template folder for validation

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.



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:

Figure 56: Recording information about the tests performed

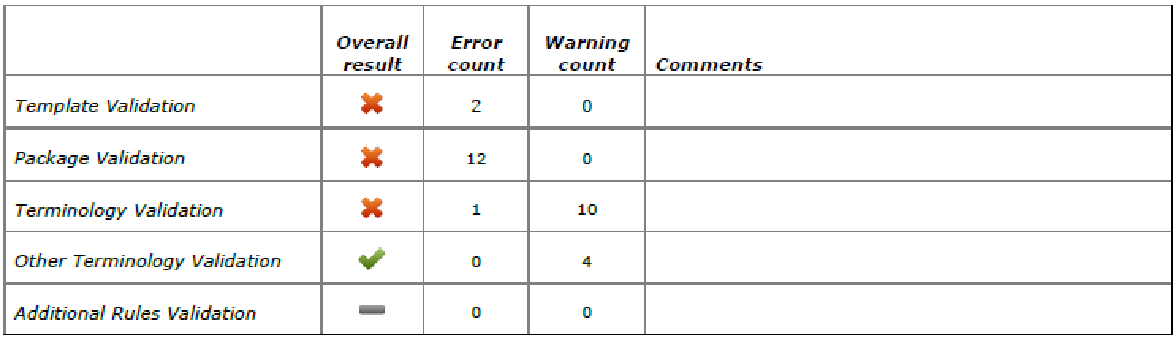
The test report is in Adobe PDF format and contains:

- 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 clinical document XML file.

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

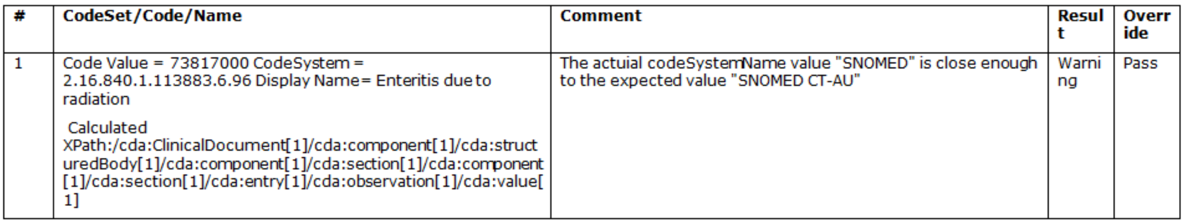
Note: If there are warnings but no errors, the overall test result recorded is a 'Pass', as shown in the 'Overall result' for the 'Other Terminology Validation' in Figure 57.



	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	

Figure 57: Test report showing a summary of the validation results

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**	**Result**	**Override**
1	Code Value = 73817000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Enteritis due to radiation Calculated XPath:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[1]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:value[1]	The actuial codeSystemName value "SNOMED" is close enough to the expected value "SNOMED CT-AU"	Warning	Pass

Figure 58: Record of an overridden test result in a test report

3.9 Cumulative report of test results

The Validator creates a cumulative report of test results in the file C:\Nehta\CPV23\report.csv. 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.

Table 12 – Information in the report.csv file

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.

Label	Description
Template Name	The name of the template package as recorded in the template package metadata.
Template ID	The identifier of the template package as recorded in the template package metadata.
Template Version	The version number of the template package as recorded in the template package metadata.
Template Effective Date	The date the 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 ‘PCEHR’ 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 template package.
Template Warnings	The number of warnings reported by applying the template package. **Note:** template packages in the PCEHR system do not report warnings.
Additional Rules Errors	The number of errors reported by applying the additional template package.
Additional Rules Warnings	The number of warnings reported by applying the additional template package.
Terminology Errors	The number of errors reported by applying additional code validation (Section 2.3.1).
Terminology Warnings	The number of warnings reported by applying additional code 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.

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 Release Note* and confirm your intended use with the NEHTA Help Desk on 1300 901 001.

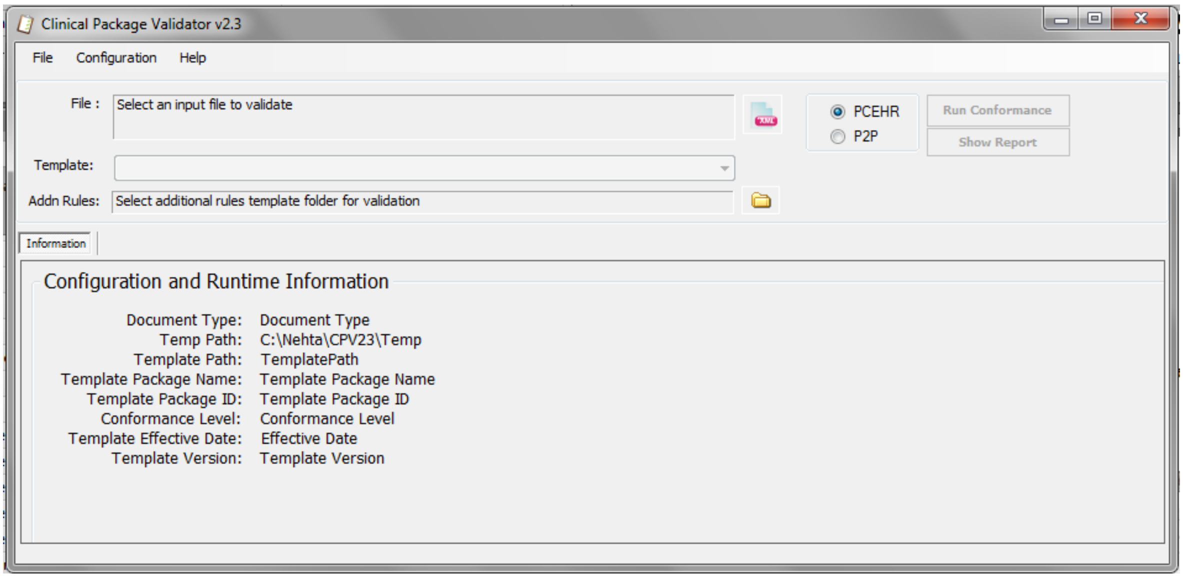
4.1 Validate a 3A eReferral clinical package, PCEHR context

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 **PCEHR** context.

1 If the Validator has been installed and configured but is not already launched, launch the Validator through:

Start > All Programs > Nehta > NEHTA CP Validator > Clinical Package Validator.

The default screen will appear (Figure 59).



File : Select an input file to validate

Template:

Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

Configuration and Runtime Information

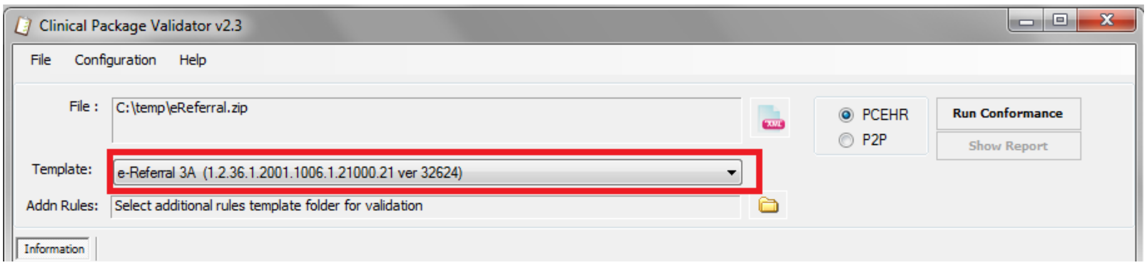
```
          Document Type:   Document Type
              Temp Path:   C:\Nehta\CPV23\Temp
          Template Path:   TemplatePath
  Template Package Name:   Template Package Name
    Template Package ID:   Template Package ID
      Conformance Level:   Conformance Level
Template Effective Date:   Effective Date
       Template Version:   Template Version
```

Figure 59: Default Validator screen

2 Click the XML button (XML) 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 60).

The default context for validating a clinical package is **PCEHR** (Section 3.2.4).



File : C:\temp\eReferral.zip

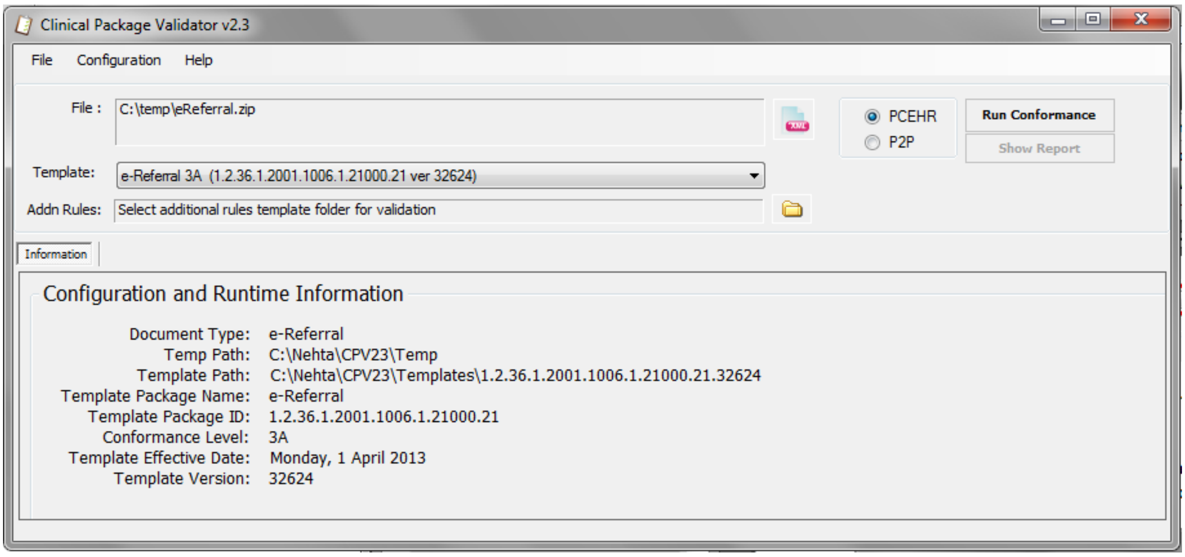
Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

● PCEHR
○ P2P

Figure 60: Template selection

Figure 61 shows the Validator **Information** tab, after the parameters for testing an eReferral for level 3A conformance in the **PCEHR** context have been selected.



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

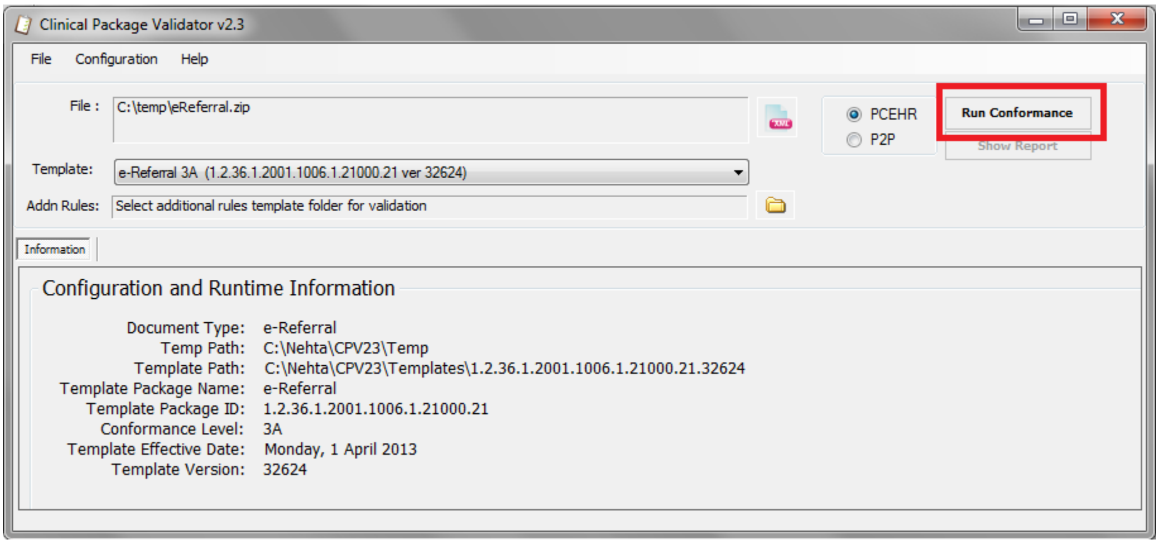
● PCEHR
○ P2P

Configuration and Runtime Information

Document Type:	e-Referral
Temp Path:	C:\Nehta\CPV23\Temp
Template Path:	C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.21000.21.32624
Template Package Name:	e-Referral
Template Package ID:	1.2.36.1.2001.1006.1.21000.21
Conformance Level:	3A
Template Effective Date:	Monday, 1 April 2013
Template Version:	32624

Figure 61: Information tab showing information about the clinical document and template package

4 Click the **Run Conformance** button to perform the validation (Figure 62).



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

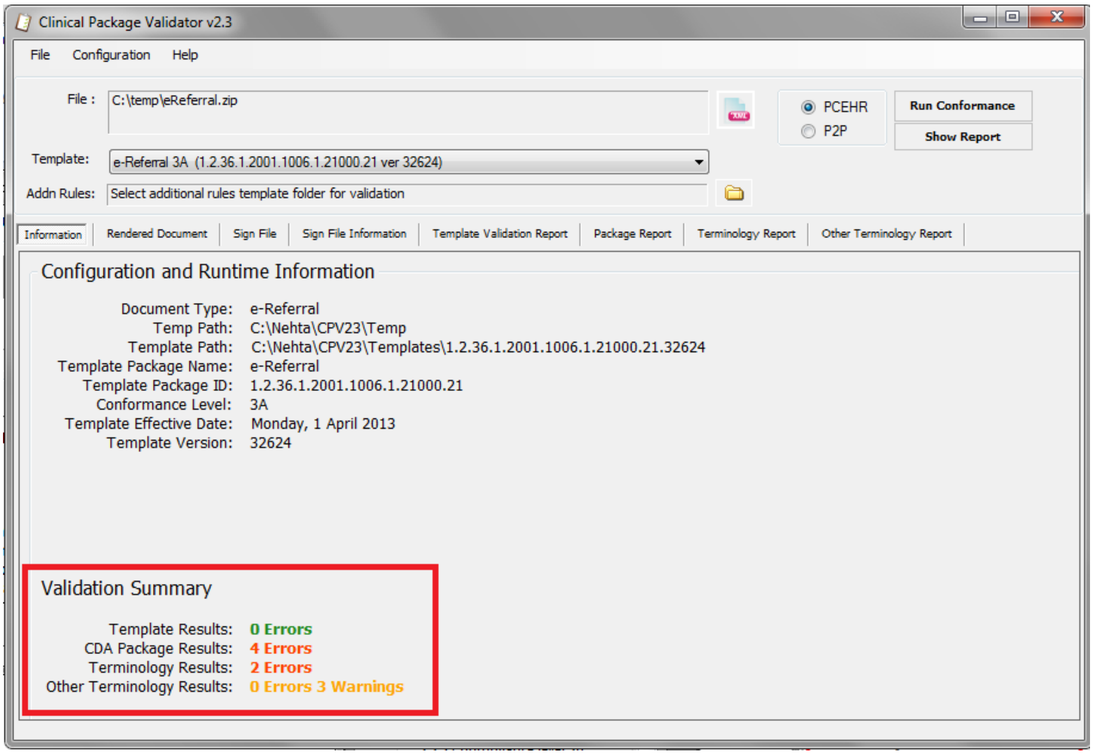
● PCEHR
○ P2P

Configuration and Runtime Information

Document Type:	e-Referral
Temp Path:	C:\Nehta\CPV23\Temp
Template Path:	C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.21000.21.32624
Template Package Name:	e-Referral
Template Package ID:	1.2.36.1.2001.1006.1.21000.21
Conformance Level:	3A
Template Effective Date:	Monday, 1 April 2013
Template Version:	32624

*Figure 62: Selecting the **Run Conformance** button*

The **Information** tab shows a summary of the validation results (Figure 63). In this example there are no template errors, four CDA® package errors, two terminology code errors and three warnings for other terminology codes.



File : C:\temp\eReferral.zip

● PCEHR
○ P2P

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

Configuration and Runtime Information

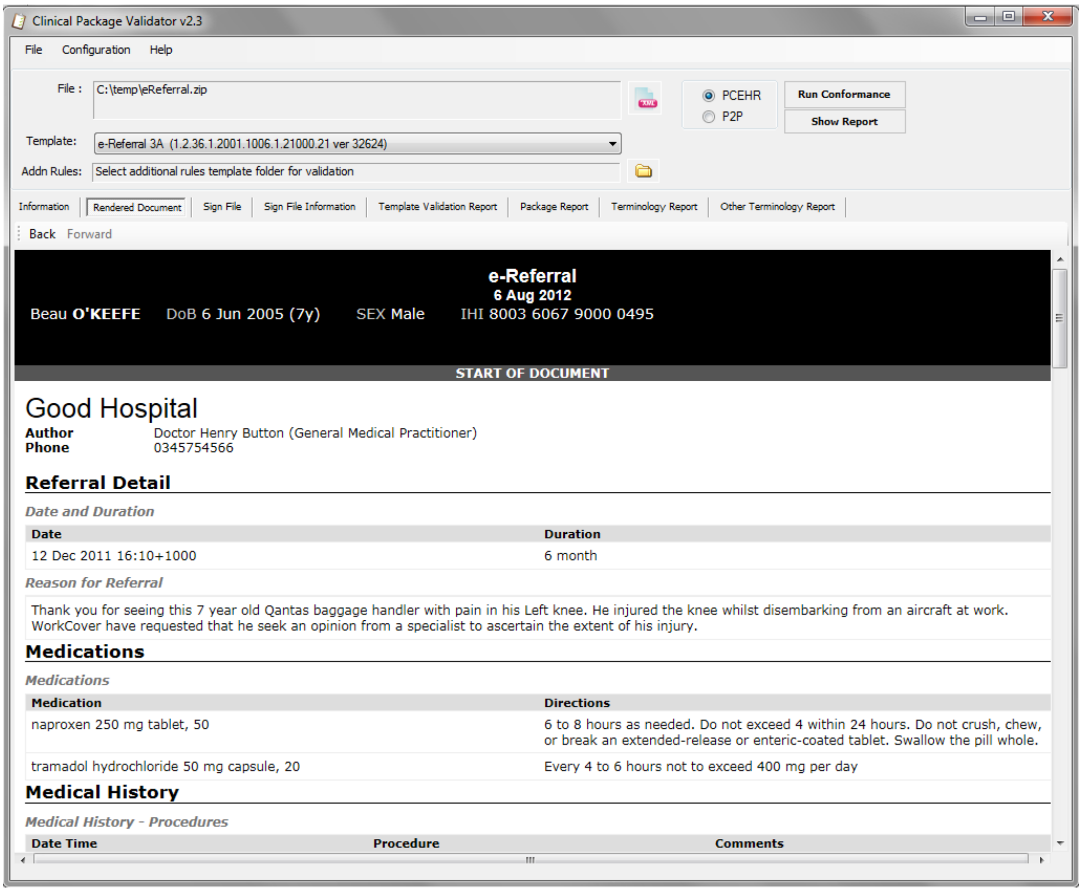
Document Type:	e-Referral
Temp Path:	C:\Nehta\CPV23\Temp
Template Path:	C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.21000.21.32624
Template Package Name:	e-Referral
Template Package ID:	1.2.36.1.2001.1006.1.21000.21
Conformance Level:	3A
Template Effective Date:	Monday, 1 April 2013
Template Version:	32624

Validation Summary

Template Results:	0 Errors
CDA Package Results:	4 Errors
Terminology Results:	2 Errors
Other Terminology Results:	0 Errors 3 Warnings

Figure 63: Information tab showing a summary of the validation results

The **Rendered Document** tab displays a rendered view of the eReferral that was validated (Figure 64).



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

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 Doctor Henry Button (General Medical Practitioner)
Phone 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

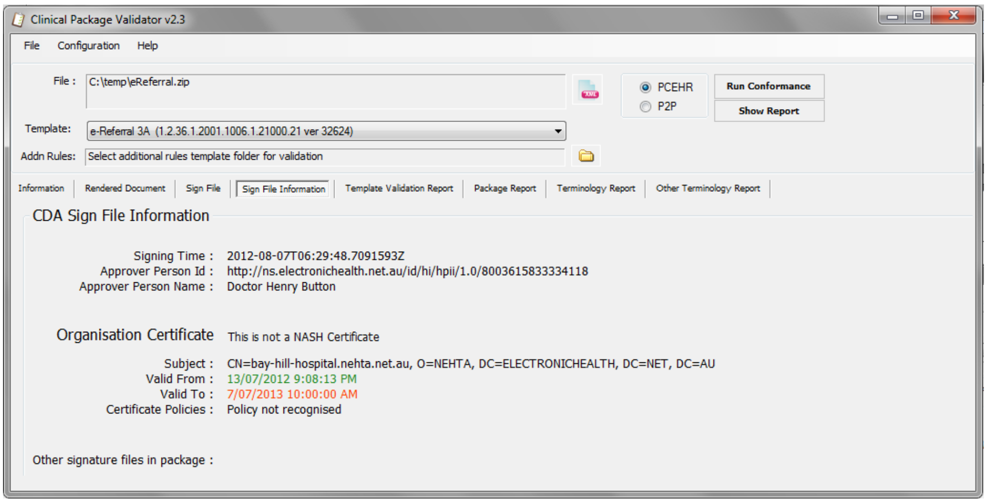
Medical History - Procedures

Date Time	Procedure	Comments

Figure 64: 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 65).



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

CDA Sign 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

Organisation Certificate This is not a NASH Certificate

Subject : CN=bay-hill-hospital.nehta.net.au, O=NEHTA, DC=ELECTRONICHEALTH, DC=NET, DC=AU
Valid From : 13/07/2012 9:08:13 PM
Valid To : 7/07/2013 10:00:00 AM
Certificate Policies : Policy not recognised

Other signature files in package :

Figure 65: 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.

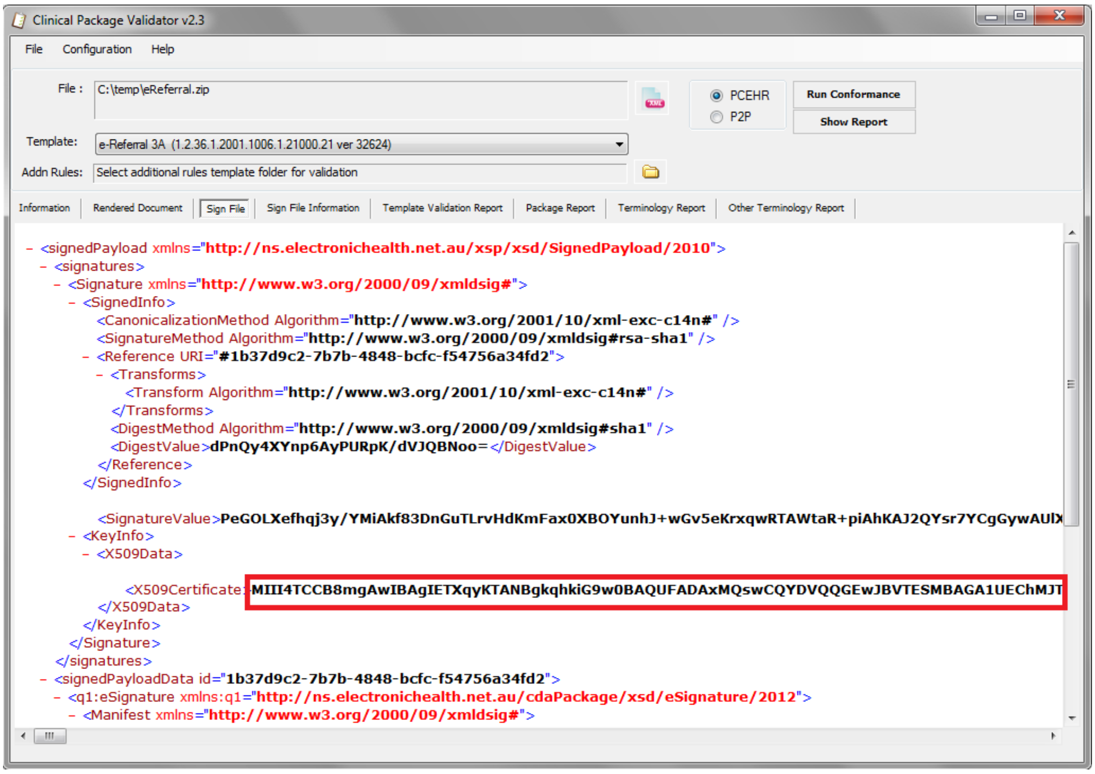
The approver's name and HPI-I reported by the Validator in this tab can be used to check whether the healthcare software system is recording the same person as the approver of the clinical document.

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 PKI Certificate was not a NASH certificate. It is a requirement that PKI certificates be NASH certificates. 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 66).



File : C:\temp\eReferral.zip

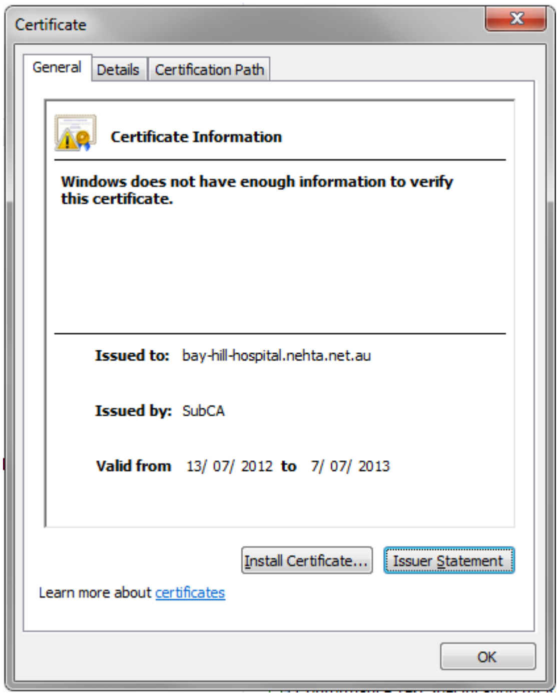
Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

```
- <signedPayload xmlns="http://ns.electronichealth.net.au/xsp/xsd/SignedPayload/2010">
  - <signatures>
    - <Signature xmlns="http://www.w3.org/2000/09/xmldsig#">
      - <SignedInfo>
          <CanonicalizationMethod Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#" />
          <SignatureMethod Algorithm="http://www.w3.org/2000/09/xmldsig#rsa-sha1" />
        - <Reference URI="#1b37d9c2-7b7b-4848-bcfc-f54756a34fd2">
          - <Transforms>
              <Transform Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#" />
            </Transforms>
            <DigestMethod Algorithm="http://www.w3.org/2000/09/xmldsig#sha1" />
            <DigestValue>dPnQy4XYnp6AyPURpK/dVJQBNoo=</DigestValue>
          </Reference>
        </SignedInfo>

          <SignatureValue>PeGOLXefhqj3y/YMiAkf83DnGuTLrvHdKmFax0XBOYunhJ+wGv5eKrxqwRTAWtaR+piAhKAJ2QYsr7YCgGywAUlX
      - <KeyInfo>
        - <X509Data>

            <X509Certificate>MIII4TCCB8mgAwIBAgIETXqyKTANBgkqhkiG9w0BAQUFADAxMQswCQYDVQQGEwJBVTESMBAGA1UEChMJT
          </X509Data>
        </KeyInfo>
      </Signature>
    </signatures>
  - <signedPayloadData id="1b37d9c2-7b7b-4848-bcfc-f54756a34fd2">
    - <q1:eSignature xmlns:q1="http://ns.electronichealth.net.au/cdaPackage/xsd/eSignature/2012">
      - <Manifest xmlns="http://www.w3.org/2000/09/xmldsig#">
```

Figure 66: 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 67 and Figure 68).



Windows does not have enough information to verify this certificate.

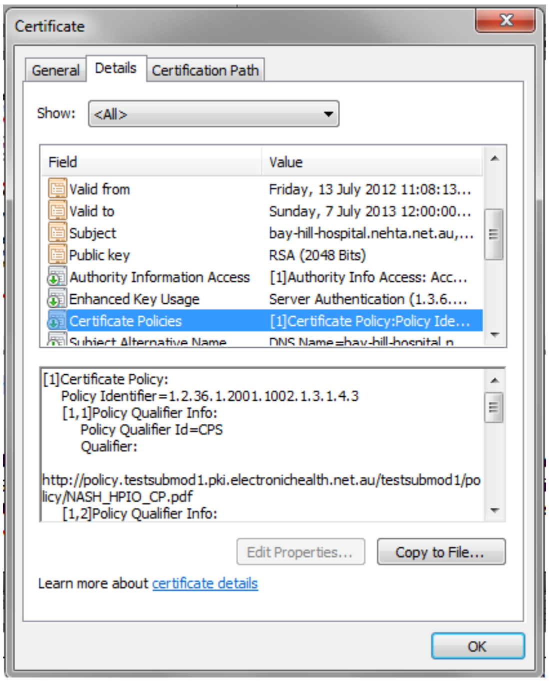
Issued to: bay-hill-hospital.nehta.net.au

Issued by: SubCA

Valid from 13/ 07/ 2012 **to** 7/ 07/ 2013

Learn more about certificates

Figure 67: A view of the PKI certificate



Show: <All>

Field	Value
Valid from	Friday, 13 July 2012 11:08:13...
Valid to	Sunday, 7 July 2013 12:00:00...
Subject	bay-hill-hospital.nehta.net.au,...
Public key	RSA (2048 Bits)
Authority Information Access	[1]Authority Info Access: Acc...
Enhanced Key Usage	Server Authentication (1.3.6....
Certificate Policies	[1]Certificate Policy:Policy Ide...
Subject Alternative Name	DNS Name=bay-hill-hospital.n

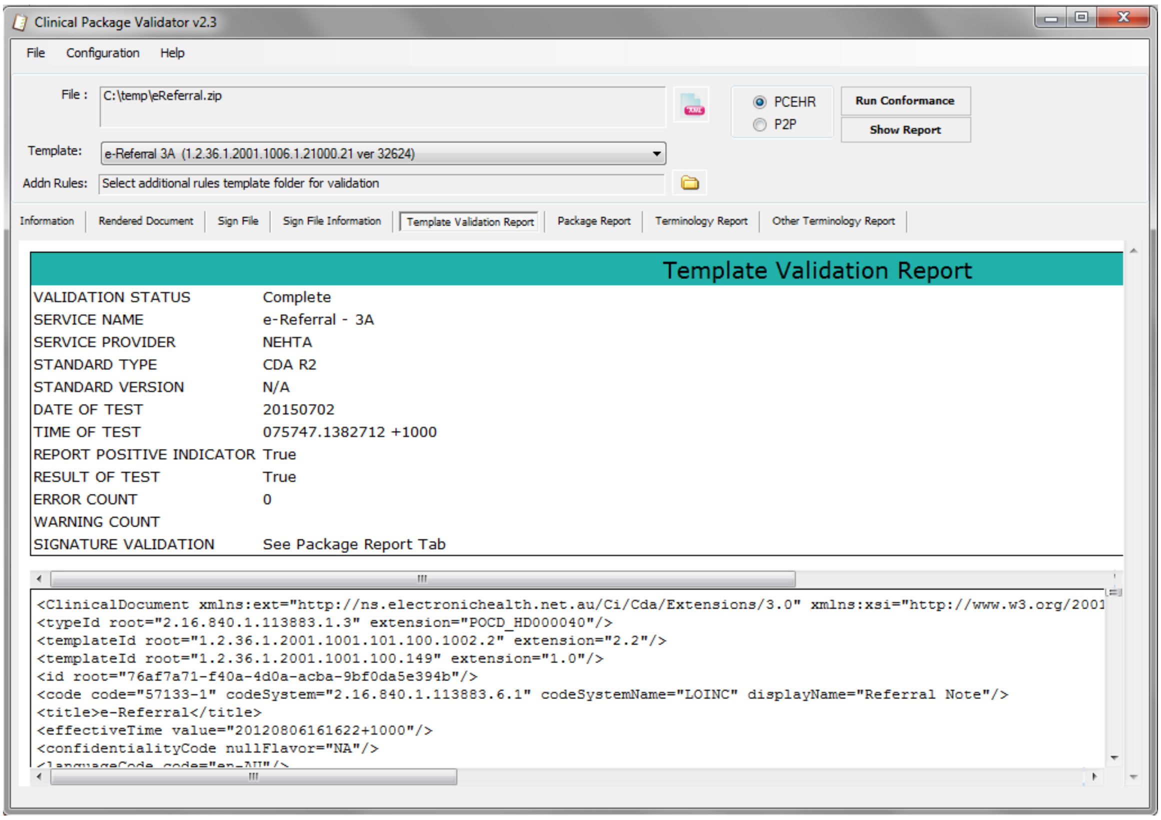
```
[1]Certificate Policy:
   Policy Identifier=1.2.36.1.2001.1002.1.3.1.4.3
   [1,1]Policy Qualifier Info:
      Policy Qualifier Id=CPS
      Qualifier:

http://policy.testsubmod1.pki.electronichealth.net.au/testsubmod1/po
licy/NASH_HPIO_CP.pdf
   [1,2]Policy Qualifier Info:
```

Learn more about certificate details

Figure 68: PKI certificate details

4.1.2 Display template validation results

To view the detailed template validation results, click the **Template Validation Report** tab (Figure 69). In this example, the error count was zero as no errors were found during template validation. The clinical document still needs to bemanually inspected for conformance to requirements because not all conformance tests can be specified in a template (Section 2.2.1).



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

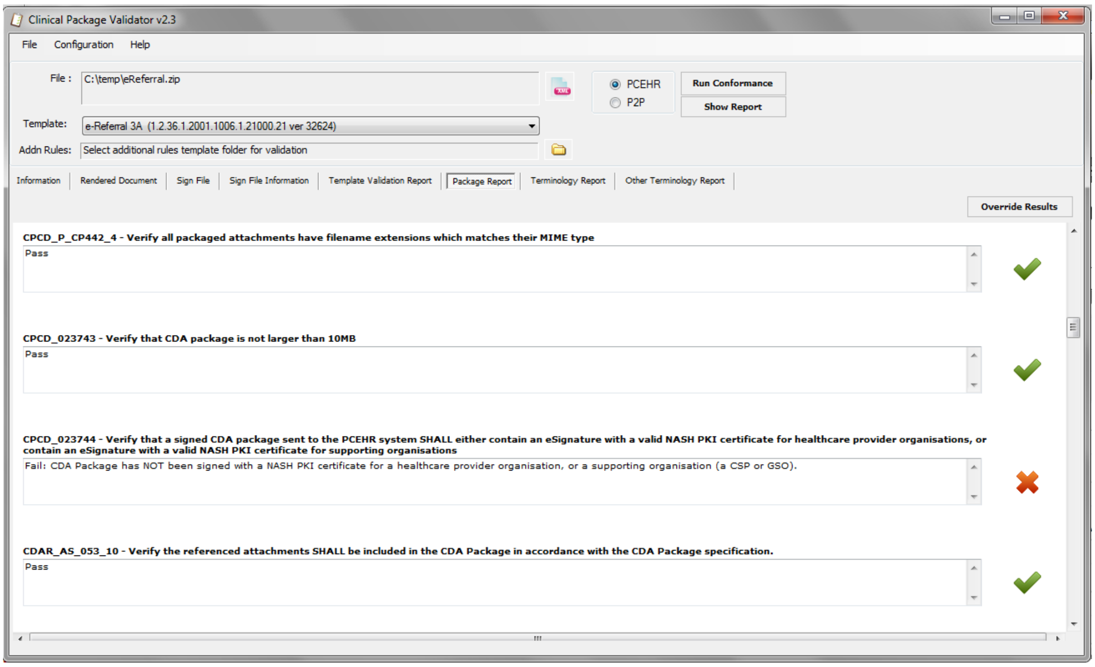
Template Validation Report	
VALIDATION STATUS	Complete
SERVICE NAME	e-Referral - 3A
SERVICE PROVIDER	NEHTA
STANDARD TYPE	CDA R2
STANDARD VERSION	N/A
DATE OF TEST	20150702
TIME OF TEST	075747.1382712 +1000
REPORT POSITIVE INDICATOR	True
RESULT OF TEST	True
ERROR COUNT	0
WARNING COUNT	
SIGNATURE VALIDATION	See Package Report Tab

```
<ClinicalDocument xmlns:ext="http://ns.electronichealth.net.au/Ci/Cda/Extensions/3.0" xmlns:xsi="http://www.w3.org/2001
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<templateId root="1.2.36.1.2001.1001.101.100.1002.2" extension="2.2"/>
<templateId root="1.2.36.1.2001.1001.100.149" extension="1.0"/>
<id root="76af7a71-f40a-4d0a-acba-9bf0da5e394b"/>
<code code="57133-1" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Referral Note"/>
<title>e-Referral</title>
<effectiveTime value="20120806161622+1000"/>
<confidentialityCode nullFlavor="NA"/>
<languageCode code="en-AU"/>
```

Figure 69: 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 70). The Validator reports some errors with the clinical package in this example, including the absence of a valid NASH certificate.



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

CPCD_P_CP442_4 - Verify all packaged attachments have filename extensions which matches their MIME type

Pass ✓

CPCD_023743 - Verify that CDA package is not larger than 10MB

Pass ✓

CPCD_023744 - Verify that a signed CDA package sent to 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

Fail: CDA Package has NOT been signed with a NASH PKI certificate for a healthcare provider organisation, or a supporting organisation (a CSP or GSO). ✗

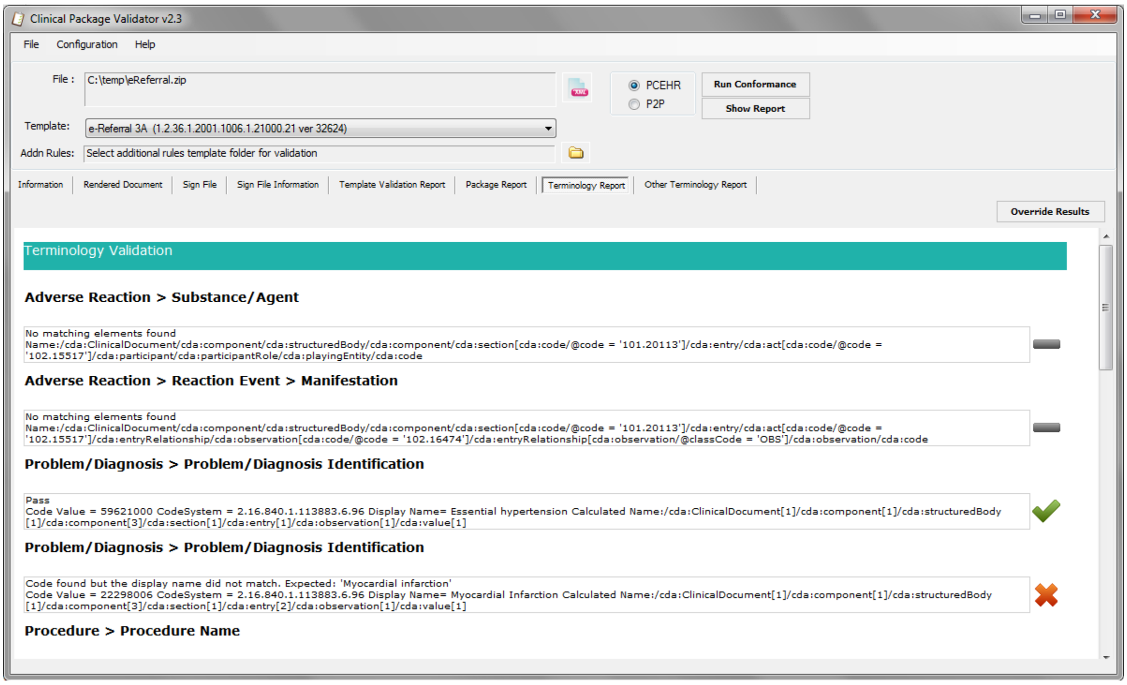
CDAR_AS_053_10 - Verify the referenced attachments SHALL be included in the CDA Package in accordance with the CDA Package specification.

Pass ✓

Figure 70: Package Report tab showing package validation results

4.1.4 Display code validation results

To view the detailed code validation results, click the **Terminology Report** tab (Figure 71) and the click the **Other Terminology Report** tab (Figure 72). 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 3.7).



File : C:\temp\eReferral.zip

Template: e-Referral 3A (1.2.36.1.2001.1006.1.21000.21 ver 32624)

Addn Rules: Select additional rules template folder for validation

Terminology Validation

Adverse Reaction > Substance/Agent

```
No matching elements found
Name:/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code = '101.20113']/cda:entry/cda:act[cda:code/@code =
'102.15517']/cda:participant/cda:participantRole/cda:playingEntity/cda:code
```

Adverse Reaction > Reaction Event > Manifestation

```
No matching elements found
Name:/cda:ClinicalDocument/cda:component/cda:structuredBody/cda:component/cda:section[cda:code/@code = '101.20113']/cda:entry/cda:act[cda:code/@code =
'102.15517']/cda:entryRelationship/cda:observation[cda:code/@code = '102.16474']/cda:entryRelationship[cda:observation/@classCode = 'OBS']/cda:observation/cda:code
```

Problem/Diagnosis > Problem/Diagnosis Identification

```
Pass
Code Value = 59621000 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Essential hypertension Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody
[1]/cda:component[3]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:value[1]
```

✓

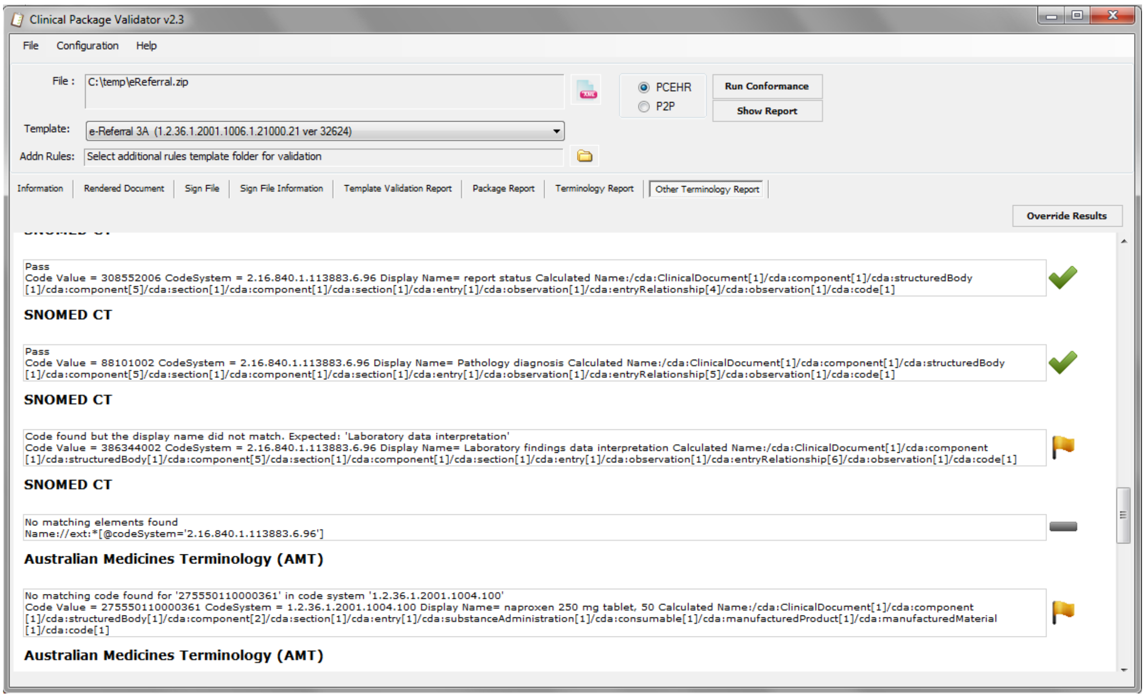
Problem/Diagnosis > Problem/Diagnosis Identification

```
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]
```

✗

Procedure > Procedure Name

Figure 71: Terminology Report tab showing code validation results



Pass
Code Value = 308552006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= report status Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:entryRelationship[4]/cda:observation[1]/cda:code[1] ✓

SNOMED CT

Pass
Code Value = 88101002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Pathology diagnosis Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:entryRelationship[5]/cda:observation[1]/cda:code[1] ✓

SNOMED CT

Code found but the display name did not match. Expected: 'Laboratory data interpretation'
Code Value = 386344002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Laboratory findings data interpretation Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:entryRelationship[6]/cda:observation[1]/cda:code[1] ⚑

SNOMED CT

No matching elements found
Name://ext:*[@codeSystem='2.16.840.1.113883.6.96'] —

Australian Medicines Terminology (AMT)

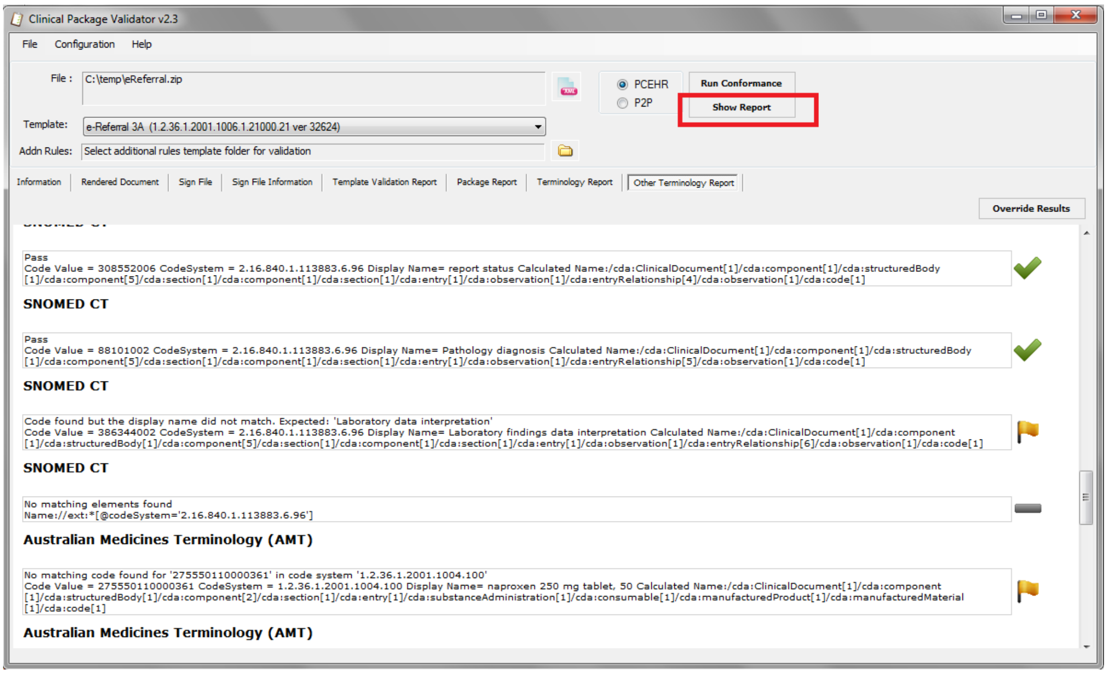
No matching code found for '275550110000361' in code system '1.2.36.1.2001.1004.100'
Code Value = 275550110000361 CodeSystem = 1.2.36.1.2001.1004.100 Display Name= naproxen 250 mg tablet, 50 Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1] ⚑

Australian Medicines Terminology (AMT)

Figure 72: Other Terminology Report tab showing code validation results

4.1.5 Generate a test report

To generate a test report in Adobe PDF format, click the **Show Report** button (Figure 73). Enter details of information to be included in the report and then click the **Continue** button (Figure 74).



Pass
Code Value = 308552006 CodeSystem = 2.16.840.1.113883.6.96 Display Name= report status Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:entryRelationship[4]/cda:observation[1]/cda:code[1] ✓

SNOMED CT

Pass
Code Value = 88101002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Pathology diagnosis Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:entryRelationship[5]/cda:observation[1]/cda:code[1] ✓

SNOMED CT

Code found but the display name did not match. Expected: 'Laboratory data interpretation'
Code Value = 386344002 CodeSystem = 2.16.840.1.113883.6.96 Display Name= Laboratory findings data interpretation Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[5]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:entryRelationship[6]/cda:observation[1]/cda:code[1] ⚑

SNOMED CT

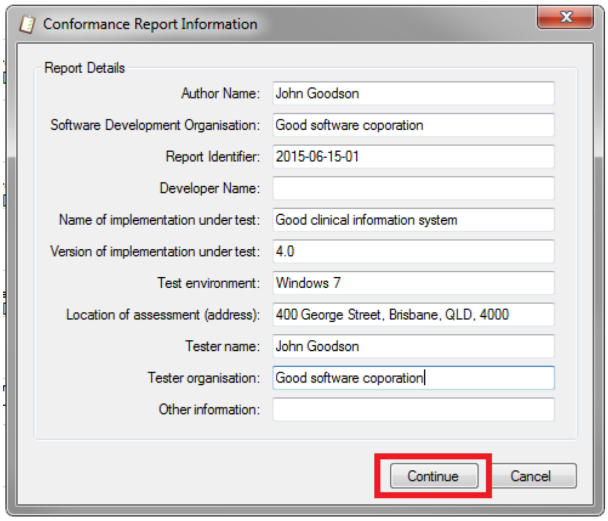
No matching elements found
Name://ext:*[@codeSystem='2.16.840.1.113883.6.96'] —

Australian Medicines Terminology (AMT)

No matching code found for '275550110000361' in code system '1.2.36.1.2001.1004.100'
Code Value = 275550110000361 CodeSystem = 1.2.36.1.2001.1004.100 Display Name= naproxen 250 mg tablet, 50 Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:substanceAdministration[1]/cda:consumable[1]/cda:manufacturedProduct[1]/cda:manufacturedMaterial[1]/cda:code[1] ⚑

Australian Medicines Terminology (AMT)

Figure 73: Generating a test report



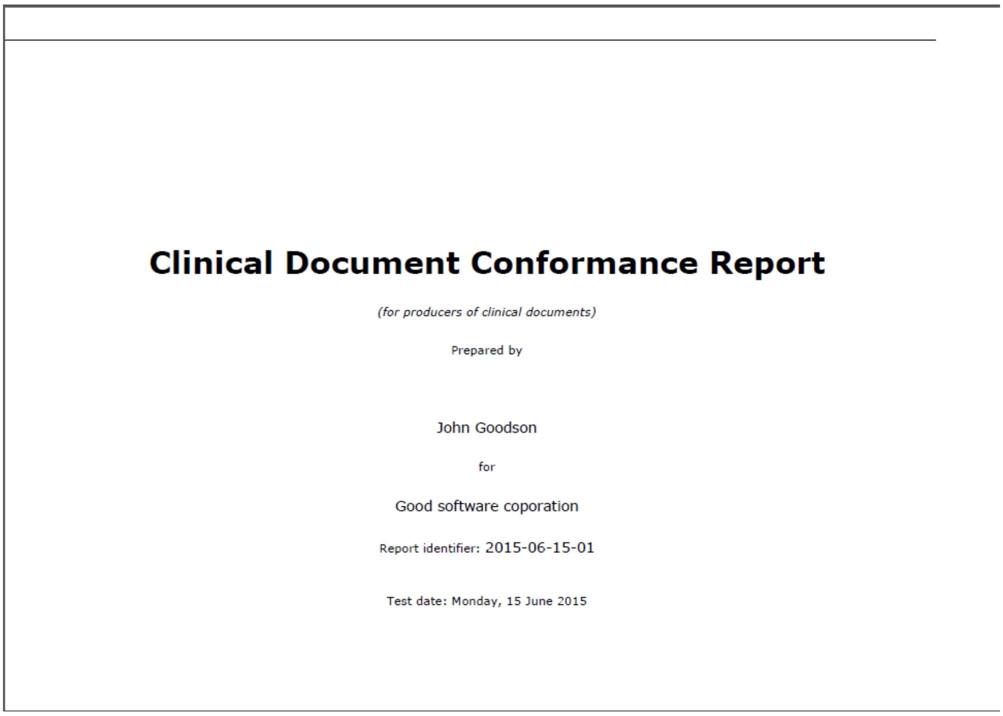
Conformance Report Information

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:	

Figure 74: Adding test report information

The test report is now complete (Figure 75).



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 75: 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.

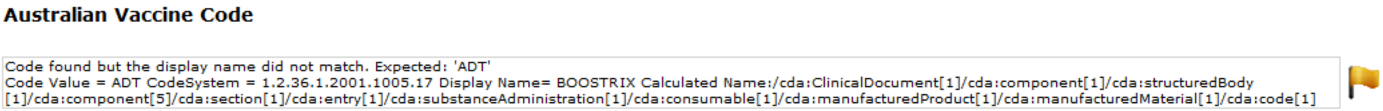
Please refer to Section 4.2 of the *Clinical Package Validator Release Note* for further details on the scope of tests for clinical terminology validation.

4.2.1 Australian Vaccine code error

Figure 76 shows a 'Warning' reported in the **Other Terminology Report** tab because the value of the displayName attribute for an Australian Vaccine code in a clinical document was not the expected name.

An examination of the list of Australian Vaccine codes (in the Australian Vaccine codes website[6]) 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]
```

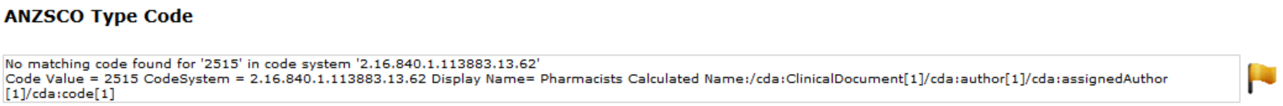
Figure 76: Other Terminology Report tab showing a warning for an Australian Vaccine code

4.2.2 ANZSCO code error

Figure 77 shows a 'Warning' reported in the **Other Terminology Report** 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'.

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



ANZSCO Type Code

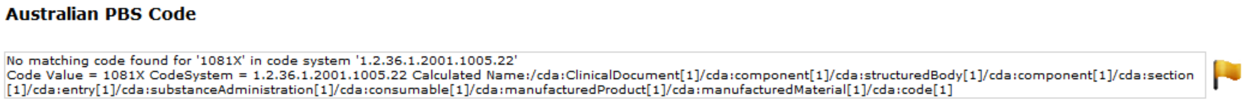
```
No matching code found for '2515' in code system '2.16.840.1.113883.13.62'
Code Value = 2515 CodeSystem = 2.16.840.1.113883.13.62 Display Name= Pharmacists Calculated Name:/cda:ClinicalDocument[1]/cda:author[1]/cda:assignedAuthor
[1]/cda:code[1]
```

Figure 77: Other Terminology Report tab showing a warning for an ANZSCO code

4.2.3 Australian PBS item code error

Figure 78 shows a ‘Warning’ reported in the **Other Terminology Report** 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’.



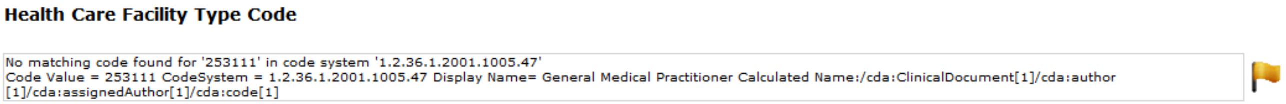
Australian PBS Code

```
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 78: Other Terminology Report tab showing a warning for an Australian PBS item code

4.2.4 Health Care Facility Type code error

Figure 79 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 79: Other Terminology Report tab showing a warning for a healthcare facility type code

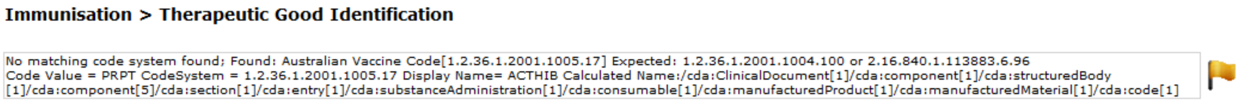
4.2.5 Valid Australian Vaccine code

Figure 80 shows a ‘Warning’ and Figure 81 shows a ‘Pass’ for an Australian Vaccine code in an event summary. The ‘Warning’ was displayed in the **Terminology Report** tab and the ‘Pass’ was displayed in the **Other Terminology Report** 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 **Terminology Report** 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 Report** 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 **Terminology Report** 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.

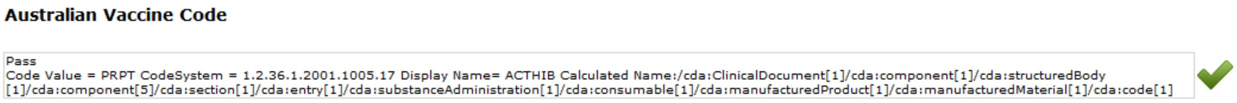


Immunisation > Therapeutic Good Identification

```
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: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 80: Terminology Report tab showing a warning for an Australian Vaccine code



Australian Vaccine Code

```
Pass
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]
```

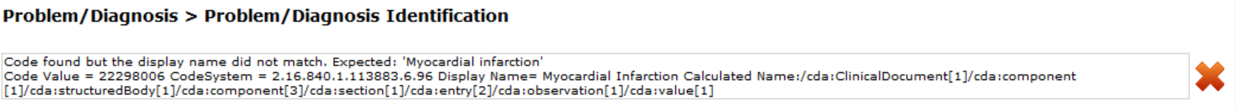
✓

Figure 81: Other Terminology Report tab showing a pass for an Australian Vaccine code

4.2.6 SNOMED CT-AU display name error

Figure 82 shows a ‘Fail’ reported in the **Terminology Report** 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 ’900000000000020002‘, 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.



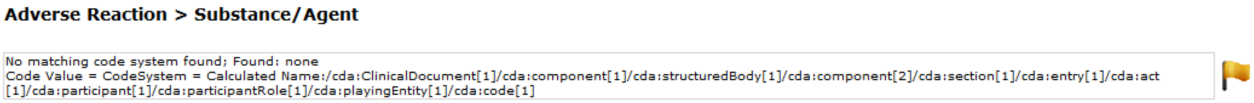
Problem/Diagnosis > Problem/Diagnosis Identification

```
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 82: Terminology Report tab showing a SNOMED CT-AU display name error

4.2.7 Valid omission of a code

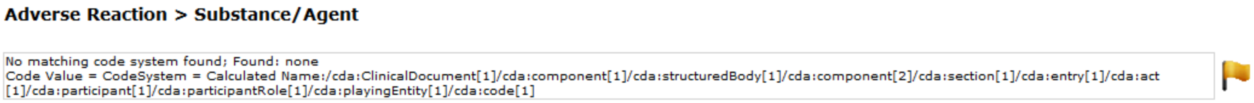


Adverse Reaction > Substance/Agent

```
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 83 shows a ‘Warning’ reported by the Validator in the **Terminology Report** 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

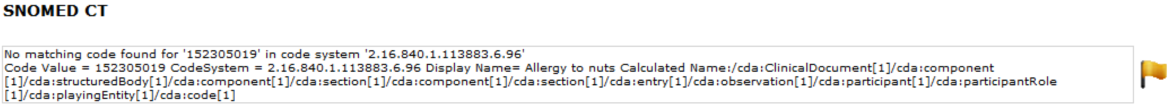
```
No matching code system found; Found: none
Code Value = CodeSystem = Calculated Name:/cda:ClinicalDocument[1]/cda:component[1]/cda:structuredBody[1]/cda:component[2]/cda:section[1]/cda:entry[1]/cda:act
[1]/cda:participant[1]/cda:participantRole[1]/cda:playingEntity[1]/cda:code[1]
```

⚑

Figure 83: Terminology Report tab showing a warning for an omitted code

4.2.8 SNOMED CT-AU code error

Figure 84 shows a warning reported by the Validator in the **Other Terminology Report** 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 identifer 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:structuredBody[1]/cda:component[1]/cda:section[1]/cda:component[1]/cda:section[1]/cda:entry[1]/cda:observation[1]/cda:participant[1]/cda:participantRole
[1]/cda:playingEntity[1]/cda:code[1]
```

Figure 84: Other Terminology Report tab showing a warning for a SNOMED CT-AU code

5 Batch validation

As an alternative to using the graphical user interface of Validator 2.3, 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 Release Note* and confirm the intended use with NEHTA Help Desk on 1300 901 001.

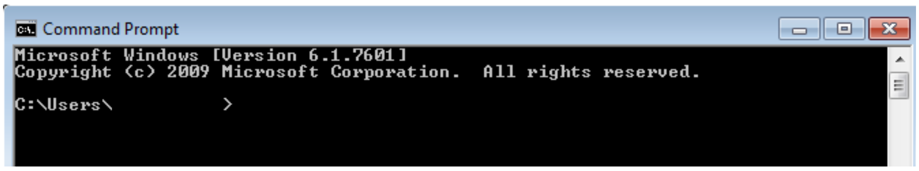
The Validator's command line interface is intended for use by software developers and testers who write scripts. For example, a software developer can create a script to command the Validator to validate a file, or to analyse test reports to determine whether any errors were found or if an expected error 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 85) by selecting **Start -> All programs -> Accessories**, and then clicking **Command Prompt**.

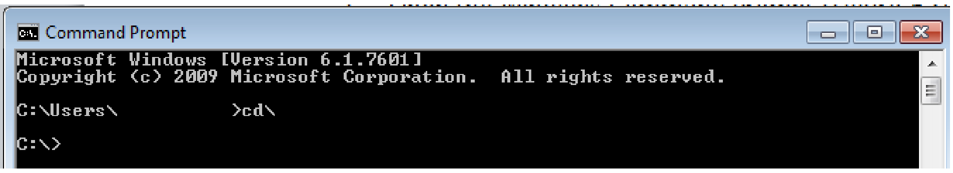
Note: The username that is displayed will vary from user to user.



```
Microsoft Windows [Version 6.1.7601]
Copyright (c) 2009 Microsoft Corporation.  All rights reserved.

C:\Users\          >
```

Figure 85: Command prompt

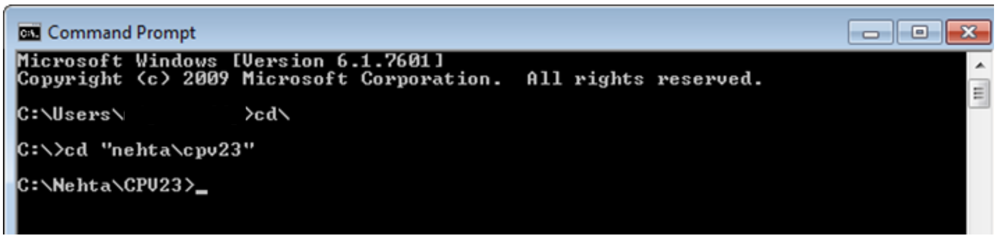
2 Navigate to the root directory by typing the command `cd\` and then press Enter (Figure 86).



```
Microsoft Windows [Version 6.1.7601]
Copyright (c) 2009 Microsoft Corporation.  All rights reserved.

C:\Users\          >cd\

C:\>
```

Figure 86: Root directory

3 Navigate to the Validator directory (i.e. 'CPV23') by typing the command `cd "nehta\cpv23"` and then press Enter (Figure 87).



```
Microsoft Windows [Version 6.1.7601]
Copyright (c) 2009 Microsoft Corporation.  All rights reserved.

C:\Users\          >cd\

C:\>cd "nehta\cpv23"

C:\Nehta\CPV23>_
```

Figure 87: Navigating to the Validator directory

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

```
CPvalidator.exe "TemplatePath" "FileToValidate" "Context”
“AdditionalRulesTemplatePath”
```

where:

a `TemplatePath` is the absolute path to the root directory that contains the standard template package;

b `FileToValidate` is the absolute path to the file to be validated;

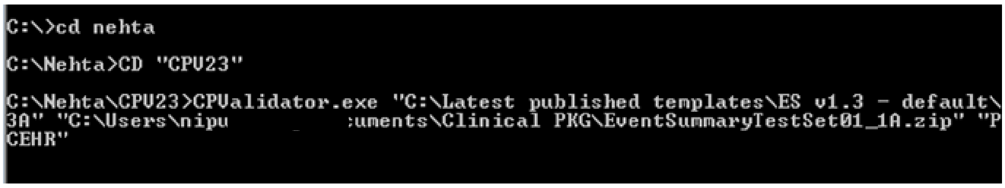
c `Context` is the context for package validation, i.e. PCEHR or P2P; and

d `AdditionalRulesTemplatePath` is the absolute path to the root directory that contains the template package with additional validation rules.

Then press Enter.

A template package imported into the Validator is stored in a folder with the filename “C:\Nehta\CPV23\Templates\[templateId].[version]”. For example, version 3471 of the template with ID “1.2.36.1.2001.1006.1.183.1” is stored in “C:\Nehta\CPV23\Templates\1.2.36.1.2001.1006.1.183.1.3471”.

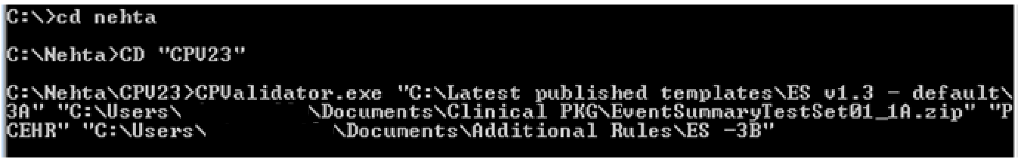
If no additional rules are to be applied during package validation, the “AdditionalRulesTemplatePath” can be excluded from the above command (Figure 88).



```
C:\>cd nehta

C:\Nehta>CD "CPV23"

C:\Nehta\CPV23>CPValidator.exe "C:\Latest published templates\ES v1.3 - default\
3A" "C:\Users\nipu[redacted]:uments\Clinical PKG\EventSummaryTestSet01_1A.zip" "P
CEHR"
```

Figure 88: 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 89).

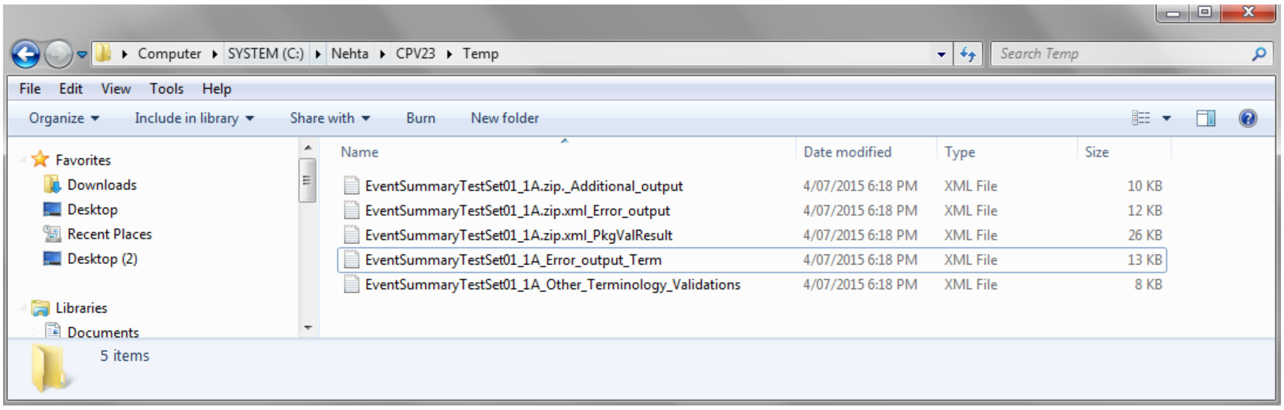


```
C:\>cd nehta

C:\Nehta>CD "CPV23"

C:\Nehta\CPV23>CPValidator.exe "C:\Latest published templates\ES v1.3 - default\
3A" "C:\Users\[redacted]\Documents\Clinical PKG\EventSummaryTestSet01_1A.zip" "P
CEHR" "C:\Users\[redacted]\Documents\Additional Rules\ES -3B"
```

Figure 89: Launching the Validator through the command line interface

5.2 Analysing validation results

Validation results are stored in XML files in the “C:\Nehta\CPV23\Temp” directory (Figure 90). If a script is written to validate a batch of clinical packages or clinical documents, it should contain instructions to copy these files to another directory after each validation because these files will be removed when another validation is performed.


Computer ▸ SYSTEM (C:) ▸ Nehta ▸ CPV23 ▸ Temp
Search Temp
File Edit View Tools Help
Organize ▾ Include in library ▾ Share with ▾ Burn New folder
Favorites
Downloads
Desktop
Recent Places
Desktop (2)
Libraries
Documents
5 items

Name	Date modified	Type	Size
EventSummaryTestSet01_1A.zip._Additional_output	4/07/2015 6:18 PM	XML File	10 KB
EventSummaryTestSet01_1A.zip.xml_Error_output	4/07/2015 6:18 PM	XML File	12 KB
EventSummaryTestSet01_1A.zip.xml_PkgValResult	4/07/2015 6:18 PM	XML File	26 KB
EventSummaryTestSet01_1A_Error_output_Term	4/07/2015 6:18 PM	XML File	13 KB
EventSummaryTestSet01_1A_Other_Terminology_Validations	4/07/2015 6:18 PM	XML File	8 KB

Figure 90: Storage of validation results including additional template validation results

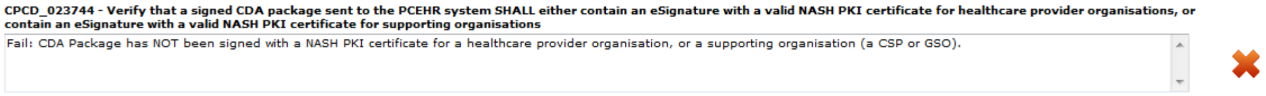
The XML files created by the Validator to store validation results are listed in Table 13, where <FileName> is the name of the file (i.e. clinical package or clinical document) that was validated.

Table 13 - Files created by the Validator to store validation results

File name	**Description**
<FileName>.xml_Error_output.xml	An XML report of template validation errors.
<FileName>.xml_PkgValResult.xml	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	An XML report of terminology validation errors.
<FileName>_Other_Terminology_Validations.xml	An XML report of other terminology validation errors.
<FileName>_Additional_output.xml	An XML report of additional template validation errors. ***Note:*** *This xml file only appears if the AdditionalRulesTemplatePath is used.*

The file "C:\Nehta\CPV23\report.csv" (Section 3.9) contains a cumulative summary of test results and the XML files listed in Table 13 contain detailed test results. The cumulative summary of test results may be used to complement analysis of the detailed test results.

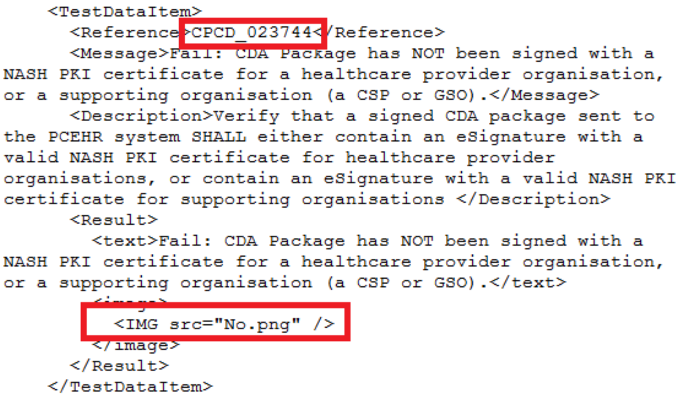
A user of the Validator may write a script to interrogate the test report XML files. Unlike the graphical user interface where an image is displayed for a test result (Figure 91), the test results in the XML files are stored as references to an image (Figure 92) i.e. the graphical user interface reports a 'Fail' as ✖ whereas the test result XML files report a 'Fail' as <IMG src="No.png" />.



CPCD_023744 - Verify that a signed CDA package sent to 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

Fail: 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 91: Graphical user interface with image reporting a 'Fail' for clinical packaging test case CPCD_023744



```
    <TestDataItem>
      <Reference>CPCD_023744</Reference>
      <Message>Fail: CDA Package has NOT been signed with a
NASH PKI certificate for a healthcare provider organisation,
or a supporting organisation (a CSP or GSO).</Message>
      <Description>Verify that a signed CDA package sent to
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 </Description>
      <Result>
        <text>Fail: CDA Package has NOT been signed with a
NASH PKI certificate for a healthcare provider organisation,
or a supporting organisation (a CSP or GSO).</text>
        <image>
          <IMG src="No.png" />
        </image>
      </Result>
    </TestDataItem>
```

Figure 92: 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 92).

Table 14 describes the image reference associated with each test result.

Table 14 – Test results and image references

Test result	**Image reference**
Pass	<IMG src="Accept.png" />
Fail	<IMG src="No.png" />
Warning	<IMG src="Warning.png" />
Not Run	<IMG src="NA.png" />

Acronyms

Acronym	Description
AMT	Australian Medicines Terminology
CDA®	Clinical Document Architecture. CDA is a registered trademark of HL7 International.
DVA	Department of Veterans' Affairs
HL7®	Health Level Seven. HL7 is a registered trademark of HL7 International.
HTML	HyperText Markup Language
JPEG	Joint Photographic Experts Group (image format)
MDM	Medical Document Management
NASH	National Authentication Service for Health
P2P	provider to provider
PBS	Pharmaceutical Benefits Scheme
PCEHR	personally controlled electronic health record
PKI	Public Key Infrastructure
SNOMED CT-AU	Systematized Nomenclature of Medicine Clinical Terms - Australia
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.
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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