

# Clinical Package Validator Release Note

16 June 2023 v3.3 Approved for external use Document ID: DH-3778:2023

## Related end product identifier: EP-3776:2023

### **Release rationale**

Version 3.3 of the Clinical Package Validator (the Validator) address couple of bug fixes and enhancements to support latest version of 'Ontoserver v6.2.0' and Agency's Information Quality Rule (IQ Rules) tool.

For other changes and defect fixes included in this release, please refer to the Change details section below.

Before formally declaring conformity to the System Operator of the My Health Record system, developers need to perform additional tests to ensure full coverage of all requirements.

Please refer to the *Clinical Package Validator Product Data Sheet* for more detailed information about the Validator's coverage of requirements and conformance test cases.

## Package inclusions

### New

None

## Updated (supersedes previous version)

| Identifier   | Name and version   |  |
|--------------|--|--|
| DH-3777:2023 | Clinical Package Validator – Product Data Sheet v3.3           |  |
| DH-3778:2023 | Clinical Package Validator – Release Note v3.3 (this document) |  |
| DH-3779:2023 | Clinical Package Validator – Software Package v3.3             |  |

### No change

| Identifier   | Name and version   |  |  |
|--------------|--|--|--|
| DH-3354:2020 | Clinical Package Validator – Installation Guide v3.2           |  |  |
| DH-3350:2020 | Clinical Package Validator – User and Configuration Guide v3.2 |  |  |

## Removed (archived or withdrawn)

None

## Change details

The following subsections provide additional details about the changes included in this release.

### Changes to CDA validation

This release of the Validator provides the following changes to the CDA validation functionality:

| Туре        | Change    |   |  |
|-------------|-----------|---|--|
| Enhancement | CCTT-1120 | LatestDateForPreferredTerm was revised to return NoDisplayName for inactive codes.  |  |
| Enhancement | CCTT-1110 | Support the API change in Ontoserver 6 that the calls <b>"\$expand"</b> operation used to use the " <b>identifier</b> " parameter (back in DSTU2_1 days) to specify the ValueSet of interest, but it was switched to using the parameter "URL".   |  |
| Enhancement | CCTT-1111 | Following enhancement to support Ontoserver 6:  |  |
|             |           | The results of the <b>\$translate</b> operation will now include any dependencies or products of the matches  |  |
|             |           | Support added for the <b>:not</b> modifier for the <b>url</b> search parameter  |  |
|             |           | Language Reference Sets support has been enhanced   |  |
|             |           | Added support for <b>\$expand</b>   |  |
|             |           | Ontoserver health check support has been enhanced with the <b>-s</b> parameter in the healthcheck.sh script   |  |
|             |           | Added extra validation of LOINC codes (We need to find if it is their internal change or if it extends to users outside!)   |  |
|             |           | The logs for rejected FHIR requests has been included   |  |
|             |           | Support added for SNOMED CT post-coordinated expressions with <b>\$subsumes,</b><br><b>\$closure</b> and <b>\$lookup</b>  |  |
| Enhancement | CCTT-1107 | Based on the comparative analysis between Ontoserver 5 and Ontoserver 6 and CSIRO's advice applicable for our Validator to migrate from Ontoserver 5 (using FHIR STU3) to Ontoserver 6 (using FHIR R4): Updated the ontoserver version in the CPV |  |
| Enhancement | CCTT-1104 | Function to dynamically obtain the system dateTime  |  |
| Enhancement | CCTT-1103 | Support latest version of ontoserver 6.2.0, to take advantage of bug fixes and performance improvements.  |  |
| Bug         | CCTT-1118 | Reduced the number of calls to onto server  |  |
| Bug         | CCTT-1116 | Improved the Logging to capture terminology server access   |  |
| Bug         | CCTT-1114 | Error searching PBS code due to older PBS Value set in the validator  |  |
| Bug         | CCTT-1106 | Validator throwing an exception while opening a user guide from the tool  |  |
| Bug         | CCTT-1112 | Fetching the template packages from SVT is throwing a template list error due to update in SVT URL  |  |
| Bug         | CCTT-1105 | 5 Exception error when we click COLL show report in tool  |  |

### Audience

This document is intended for:

- developers and implementers of clinical information systems
- the System Operator of the My Health Record system
- the National Infrastructure Operator.

#### Licence

The Agency provides the Clinical Package Validator end product subject to the Software Licence Terms and Conditions contained in the Software Package product component.

### Support

For further support or to provide feedback, please email the Agency Help Centre at <u>help@digitalhealth.gov.au</u> or phone 1300 901 001.

## Previous releases

| Version   | Date            | Comment   |
|-----------|-----------------|---|
| 3.2       | 12 January 2021 | EP-3352:2020 Clinical Package Validator v3.2  |
|           |                 | Release Note  |
|           |                 | Release rationale   |
|           |                 | Version 3.2 of the Clinical Package Validator (the Validator) introduces validation capabilities for messages in addition to clinical packages: |
|           |                 | Validation of HL7 v2 messages   |
|           |                 | <ul> <li>Referral messages (REF_I12)</li> </ul>   |
|           |                 | • Order messages (ORM_O01)  |
|           |                 | <ul> <li>Observation result messages (ORU_R01)</li> </ul>   |
|           |                 | • MDM messages (MDM_T02)  |
|           |                 | <ul> <li>Referral acknowledgement messages (ACK_I12)</li> </ul>   |
|           |                 | <ul> <li>Referral response messages (RRI_I12)</li> </ul>  |
|           |                 | <ul> <li>Order acknowledgement messages (ACK_001)</li> </ul>  |
|           |                 | <ul> <li>Order response messages (ORR_O02)</li> </ul>   |
|           |                 | <ul> <li>Observation result acknowledgement messages (ACK_R01)</li> </ul>   |
|           |                 | <ul> <li>MDM acknowledgement messages (ACK_T02)</li> </ul>  |
|           |                 | Details about all supported HL7 v2 messages and the validations performed on them are listed in the <i>Product Data Sheet</i> .                 |
|           |                 | For other changes and defect fixes included in this release, please refer to the Change details section below.                                  |
| 2.9 - 3.1 | -               | Controlled releases only  |

| Version | Date           | Comment  |  |  |
|---------|----------------|--|--|--|
| 2.8     | 7 January 2020 | EP-2903:2020 Clinical Package Validator v2.8   |  |  |
|         |                | Release Note   |  |  |
|         |                | Release rationale  |  |  |
|         |                | Version 2.8 of the Clinical Package Validator (the Validator) provides important<br>enhancements to external functions used by the Agency's Information Quality Rules<br>(IQ Rules).   |  |  |
|         |                | Developers and implementers of clinical information systems planning to use the Agency's IQ Rules for the validation of their clinical documents should upgrade to thi version of the Validator. This version is required for the execution of IQ Rules from version 1.6.  |  |  |
|         |                | IQ Rules can be used to perform an in-depth analysis of clinical documents. This complements the structural analysis performed by My Health Record template packages. The Validator supports the parallel execution of IQ Rules and My Health Record template packages. The Agency publishes IQ Rules separately.  |  |  |
|         |                | For a comprehensive list of all changes and defect fixes, please refer to Change details, below.   |  |  |
|         |                | Before formally declaring conformity to the System Operator of the My Health<br>Record system, developers need to perform additional tests to ensure full coverage<br>of all requirements. Please refer to the <i>Clinical Package Validator Product Data Shee</i><br>for more detailed information about the Validator's coverage of requirements and<br>conformance test cases.  |  |  |
| 2.7     | 1 June 2018    | EP-2684:2018 Clinical Package Validator v2.7   |  |  |
|         |                | Release Note   |  |  |
|         |                | Release rationale  |  |  |
|         |                | Version 2.7 of the Clinical Package Validator (i.e., Validator) enables software developers to improve the depth and automation of clinical document conformance testing.  |  |  |
|         |                | The new release includes a number of defect fixes and enhancements which will<br>improve the Validator's ability to effectively support implementers in their<br>conformance assessment activities.  |  |  |
|         |                | Additional updates have been added to the Validator's documentation.   |  |  |
|         |                | The Validator introduces call back functions required by advanced Information<br>Quality Rules (IQ Rules). Developers can perform more thorough conformance tests<br>of clinical documents using the latest version of the Agency's IQ Rules. IQ Rules<br>enable developers to perform in-depth analysis of clinical documents that<br>complements the structural analysis performed by standard template packages. The<br>Validator supports the parallel execution of IQ Rules and standard template<br>packages. IQ Rules are published separately by the Agency. |  |  |

| Version | Date        | Comment   |
|---------|-------------|---|
| 2.6.1   | -           | Not released.   |
|         |             | EP-2489:2017 Clinical Package Validator v2.6.1  |
|         |             | Release Note  |
|         |             | Release rationale   |
|         |             | Version 2.6.1 of the Clinical Package Validator (Validator) introduces call back<br>functions required by advanced Information Quality Rules (IQ Rules). Developers can<br>perform more thorough conformance tests of clinical documents using the latest<br>version of the Agency's IQ Rules.  |
|         |             | IQ Rules enable developers to perform in-depth analysis of clinical documents that<br>complements the structural analysis performed by standard template packages. The<br>Validator supports the parallel execution of IQ Rules and standard template<br>packages. IQ Rules are published separately by the Agency.   |
| 2.5     | 20 May 2016 | EP-2489:2017 Clinical Package Validator v2.5  |
|         |             | Release Note  |
|         |             | Release rationale   |
|         |             | Version 2.5 of the Clinical Package Validator (Validator) provides software developers<br>with enhanced capabilities to achieve a greater degree of automation and depth of<br>their conformance tests of clinical documents.   |
|         |             | The new release helps developers reduce efforts for manual conformance testing and increase their confidence about their targeted test coverage when declaring conformance. This is achieved through new types of validation checks, greater depth of document inspections and improved automation features.  |
|         |             | The new Validator supports:   |
|         |             | <ul> <li>More powerful validations through additional validation languages:</li> </ul>  |
|         |             | <ul> <li>ISO Schematron</li> </ul>  |
|         |             | • XSLT v2.0   |
|         |             | <ul> <li>XPath v2.0</li> </ul>  |
|         |             | <ul> <li>XQuery v1.0</li> </ul>   |
|         |             | <ul> <li>Improved batch operation and reporting.</li> </ul>   |
|         |             | Australian Immunisation Register (AIR) documents.   |
|         |             | For a comprehensive list of all changes and defect fixes, please refer to release note.   |
|         |             | Before formally declaring conformance of a software product to the System Operato<br>of the My Health Record system, developers need to perform additional tests to<br>ensure full coverage of all requirements. Please refer to the <i>Product Data Sheet</i> for<br>more detailed information about the Validator's coverage of requirements and<br>conformance test cases. |

| Version | Date        | Comment   |  |  |
|---------|-------------|---|--|--|
| 2.4     | 20 May 2016 | <ul> <li><u>EP-2257:2016 Clinical Package Validator v2.4</u></li> <li><u>Release Note</u></li> <li><b>Release rationale</b></li> <li>Version 2.4 of the Clinical Package Validator ("the Validator") has been released to provide the following functional improvements:</li> </ul> |  |  |
|         |             | ID  | Change   |  |
|         |             | CCTT-704  | Support added for loading combined SNOMED CT-AU and AMT v3 code sets.  |  |
|         |             |   | AMT v3 and SNOMED CT-AU are now published by the<br>Australian Digital Health Agency as combined code sets. The<br>Validator supports the loading of additional combined<br>SNOMED CT-AU and AMT v3 code sets. This allows users to<br>perform validations against versions of these combined<br>code sets that are released after the publication of this<br>Validator release. |  |
|         |             | CCTT-703  | Support removed for loading AMT v2 code sets:  |  |
|         |             |   | AMT v2 has been deprecated more than 18 months ago and<br>no more updates will be published for AMT v2. The<br>Validator continues to support validations against the latest<br>version of the AMT v2 code set, which is preinstalled with<br>the Validator and does not need to be loaded by the user.  |  |
|         |             | CCTT-618  | Improved usability of report tabs for terminology validations:   |  |
|         |             |   | User feedback suggested that the previous naming of these report tabs could be misleading. Tabs have been renamed and User Guide improved.   |  |
|         |             | CCTT-606  | Improved highlighting of overrides in test reports   |  |
|         |             | This release cont   | ains the following new product component:  |  |
|         |             | • The <i>Product Data Sheet</i> provides all release-independent information about Clinical Package Validator end product. This information was previously incluin this release note, which is now focused on information about this release.                                       |  |  |
| 2.3     | 17 Jul 2015 | <u>EP-2134:2015 Cli</u>   | inical Package Validator v2.3  |  |
|         |             | Release Note  |  |  |
|         |             | Release rationale   |  |  |
|         |             | • Support the validation of eHealth Diagnostic Imaging Reports that reference clinical information outside the clinical package (e.g., a diagnostic image on a website), through the automation of version 1.5 of the <i>Conformance Test Specification for CDA Packaging</i> .     |  |  |
|         |             | test scenarios  | tform that enables the automation of conformance test cases and s, through the application of Schematron rules that are in addition t nplate package.  |  |
| 2.2     | _           | Not released  |  |  |

| Version Date |              | Comment  |  |  |
|--------------|--------------|--|--|--|
| 2.1          | 20 Jan 2015  | New and more consistent user interface with summary screen, drag and drop functionality, better handling of files, user management of terminology database, inclusion of version 1.2.9 of the generic style sheet. |  |  |
| 2.0          | 22 Aug 2014  | New package validation function built; Schematron libraries removed; added abilit to load template packages for the validation of clinical documents and CDA packag  |  |  |
| 1.12.8       | 08 Jan 2014  | Support for both HPI-I relaxation and HPI-I enforcement by Schematron libraries in alignment with PCEHR release 4 (patch for v1.12, to replace v1.12.5a).  |  |  |
| 1.12.7       | 08 Jan 2014  | Support for HPI-I relaxation by Schematron libraries in alignment with PCEHR releas<br>4 (patch for v1.12, to replace v1.12.5a).   |  |  |
| 1.12.5a      | 15 May 2013  | Revised validation rules (patch for v1.12, to replace v1.12.5).  |  |  |
| 1.12.5       | 20 Mar 2013  | Revised validation rules (patch for v1.12).  |  |  |
| 1.12.2       | 20 Aug 2012  | Validation rules aligned with PCEHR R1c (patch for v1.12).   |  |  |
| 1.12         | 15 July 2012 | Functionality, validation rules and terminology aligned with PCEHR R1b.  |  |  |
| 2.1          | 20 Jan 2015  | New and more consistent user interface with summary screen, drag and drop functionality, better handling of files, user management of terminology database, inclusion of version 1.2.9 of the generic style sheet. |  |  |
| 2.0          | 22 Aug 2014  | New package validation function built; Schematron libraries removed; added ability to load template packages for the validation of clinical documents and CDA packages.  |  |  |
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| 1.12.7       | 08 Jan 2014  | Support for HPI-I relaxation by Schematron libraries in alignment with PCEHR releas<br>4 (patch for v1.12, to replace v1.12.5a).   |  |  |
| 1.12.5a      | 15 May 2013  | Revised validation rules (patch for v1.12, to replace v1.12.5).  |  |  |
| 1.12.5       | 20 Mar 2013  | Revised validation rules (patch for v1.12).  |  |  |
| 1.12.2       | 20 Aug 2012  | Validation rules aligned with PCEHR R1c (patch for v1.12).   |  |  |
| 1.12         | 15 July 2012 | Functionality, validation rules and terminology aligned with PCEHR R1b.  |  |  |

#### Publication date: 16 June 2023

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#### Acknowledgements

The Australian Digital Health Agency is jointly funded by the Australian Government and all state and territory governments.