My Health Record

Conformance Vendor Declaration Form

13 December 2023 v20231213

Approved for external use

Document ID: DH-3873:2023

**My Health Record**

**Conformance Vendor Declaration Form**

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| The Australian Digital Health Agency (the **Agency**) issues this Agency approved form (**the Conformance Vendor Declaration Form**) which comprises the details in Part A and the Vendor Deed Poll in Part B, for software vendors to declare that their software system, including Software Product and Software Components (**Software System**), conforms to the mandatory requirements stated in Part A section 2 and published under the [My Health Record Conformance Assessment Scheme](https://developer.digitalhealth.gov.au/specifications/national-infrastructure/ep-2156-2015/nehta-1294-2012) (also known as the **CAS**).  This Vendor Declaration Form is a declaration that states software products comply with all applicable My Health Record technical specifications and conformance points and have undergone the necessary internal testing. Submitting this form is one of the requirements for software developed by vendors to be granted connection to the My Health Record system.  For further information, refer to the *Conformance Vendor Declaration form instructions and the Software Vendor Guide to the connection process.* |
| **Instructions** |
| * Please refer to the *Conformance Vendor Declaration Form Instructions* document to assist you in completing this form. * Keep your conformance test report confirming that the Software System conforms with the Conformance Profile (see above, Part A and Part B clause D). * In this Declaration of Conformance:   + enter details in Part A and send the completed, unsigned and unwitnessed form to the Agency [help@digitalhealth.gov.au](mailto:help@digitalhealth.gov.au) for a review and await feedback.   + Once feedback given, the Agency will invite you to have the form signed and witnessed. Ensure the Vendor Deed Poll in Part B is signed by a person or people with legal authority and witnessed. |

**PART A**

# **Section 1 - Vendor, Contact and Software details**

## Vendor details

|  |  |  |  |
| --- | --- | --- | --- |
| **Software Vendor name**  (Name of legal entity) |  | | |
| **ABN/ CAN** |  | | |
| **Is the Vendor making the Deed Poll as a trustee of any Trust?**  NO  YES, as trustee of (please specify the name of the trust): | | | |
| If yes, please provide the following documents to the Agency and await directions before completing this Declaration of Conformance:   * copy of the current trust deed including any amendments; and * written confirmation from a beneficiary that: * the trust deed and all amendments provided are current and complete; and * the Vendor is currently the appointed trustee. | | | |
| **Contact number** |  | | |
| **Address** |  | | |
| **Suburb**: | **State**: | **Postcode**: |

## Contact details – please provide direct numbers for each person.

|  |  |  |
| --- | --- | --- |
|  | **Primary contact** | **Secondary contact** |
| **Full name** |  |  |
| **Position** |  |  |
| **Email** |  |  |
| **Phone/mobile** |  |  |

## Software product details

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of software product** | Clinical Information System (CIS)  Contracted Service Provider (CSP) | | |
| **Description of software product or changes to the software** |  | | |
| **Type of request** | New software product.  Add new function or version number.  Update to function or conformance level. | | |
| **Software component name** | | **Version number** | **Function** |
|  | |  |  |
|  | |  |  |
| *Add more rows as needed* | |  |  |
| **Please insert extract of SOAP message as per the following example**  <productType>                 <vendor>Software Pty Ltd</vendor>                 <productName>New Health Software</productName>                 <productVersion>1.1</productVersion>                 <platform>Windows</platform>  </productType> | | | |
| Is the software product approved for connection to the Healthcare Identifiers (HI) Service?  (HI Service connection is a prerequisite to My Health Record production access)  YES  NO | | | |

## Terminology in Clinical Documents

|  |
| --- |
| **Does the software product include clinical terminology in clinical documents?**  N/A (Go to next question)  YES (please specify below)  **What terminology is included?**  Australian Medicines Terminology (AMT) or SNOMED CT® Australian Release (SNOMED CT-AU)  Version:  Clinical Terminology Guidance for Use of Medical Nomenclature in Information Exchange  Version:  Other terminology (please specify below)  Version:  Provide any additional Information about the scope of inclusion of terminology: |

## Special conditions

|  |
| --- |
| **Note that any special conditions must be first agreed in principle by the System Operator.** |
| Are there any special conditions that your organisation would like to consider when applying for production access to the My Health Record system?  (Include proposed exemptions from mandatory requirements here: title, date approved and date of exemption expiry. My Health Record NOC test case exemptions do not have to be listed here.) Note that the System Operator does not guarantee that any proposed special conditions will be acceptable.  N/A (Go to next question)  YES (please specify below)  Description: |

# **Section 2 – Software compliance and conformance areas**

## My Health Record National Repository

|  |  |
| --- | --- |
| Does the software product support any of the following web services and use cases to access the My Health Record National Repository?  N/A (Go to next question)  YES (please specify below) | |
| **My Health Record Web Services** | **My Health Record Use Cases** |
| doesPCEHRExist via B2B – v1.1 | UC.CIS.001 – Check if an advertised PCEHR exists |
| gainPCEHRAccess via B2B – v1.1 | UC.CIS.002 – Gain access to PCEHR |
| ITI – 41 Provide & Register Document Set-b via B2B - v1.1 | UC.CIS.201 – Upload a clinical document |
|  | UC.CIS.202 – Supersede a clinical document |
| RemoveDocument/DeregisterDocument via B2B – v1.1 | UC.CIS.203 – Remove a clinical document |
| ITI – 43 Retrieve Document Set via B2B – v1.1 | UC.CIS.204 – Download a clinical document |
| ITI – 18 Registry Stored Query via B2B – v1.1 | UC.CIS.204 – Download a clinical document |
| RegisterPCEHR via B2B – v2.0 | UC.CIS.501 – Assisted PCEHR Registration (adult) |
|  | UC.CIS.502 – Assisted PCEHR Registration (child) |
| CIStoNPP | UC.CIStoNPP.001 – CIS to NPP direct access My Health Record from National Provider using web-browsers |
|  | UC.CIStoNPP.002 – CIS to NPP direct access My Health Record from National Provider using system browsers |
|  | UC.CIStoNPP.003 – CIS to NPP user configuration of vendor's CIS |
| getChangeHistoryView via B2B – v1.1 | UC.CIS.301 – Access a view service |
| getAuditView via B2B – v 1.1 | UC.CIS.301 – Access a view service |
| getRepresentativeListView via B2B– v1.1 | UC.CIS.301 – Access a view service |
| getIndividualDetailsView via B2B – v2.0 | UC.CIS.301 – Access a view service |
| getView via B2B – v1.0 | UC.CIS.301 – Access a view service |
| searchTemplate via B2B – v1.1 | UC.CIS.401 – Search for a template package |
| getTemplate via B2B – v1.1 | UC.CIS 402 – Retrieve a template package |
|  | UC.CIS 403 – Store template metadata/template package |

## Clinical Documents created by software

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Does the software product generate clinical documents in any of the Clinical Document Architecture (CDA) ® formats?  N/A (Go to next question)  YES (specify below the template package IDs for each document type)  Does the software product conform to the mandatory and relevant conditional requirements for CDA ® document producers listed in the following Conformance profiles?  N/A (Go to next question)  YES (specify below the template package IDs for each document type) | | | | | | | | |
| **Clinical Document** | **Conformance Level** | | | | | **Template Package ID** | **Conformance Profile version** | |
| Discharge Summary | 1A | 1B | 2 | 3A | 3B | 1.2.36.1.2001.1006.1.XXX |  |
| eReferral | 1A | 1B | 2 | 3A | 3B | 1.2.36.1.2001.1006.1.XXX |  |
| Specialist Letter | 1A | 1B | 2 | 3A | 3B | 1.2.36.1.2001.1006.1.XXX |  |
| Shared Health Summary | n/a | n/a | n/a | 3A | 3B | 1.2.36.1.2001.1006.1.XXX |  |
| Event Summary | n/a | n/a | n/a | 3A | 3B | 1.2.36.1.2001.1006.1.XXX |  |
| Advance Care Planning | n/a | n/a | n/a | 3A | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Goals of Care | n/a | n/a | n/a | 3A | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Prescription Record | n/a | n/a | n/a | 3A | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Dispense Record | n/a | n/a | n/a | 3A | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Pathology Report | n/a | n/a | n/a | 3A | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Diagnostic Imaging Report | n/a | n/a | n/a | 3A | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Pharmacist Shared Medicines List | 1A | n/a | n/a | n/a | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Residential Care Transfer Reason | n/a | 1B | n/a | n/a | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Residential Care  Health Summary | 1A | n/a | n/a | n/a | n/a | 1.2.36.1.2001.1006.1.XXX |  |
| Residential Care Medication Chart | 1A | n/a | n/a | n/a | n/a | 1.2.36.1.2001.1006.1.XXX |  |

## CDA document presentation

|  |  |
| --- | --- |
| Does the software product conform to the specifications for downloading and rendering CDA documents?  N/A (Go to next question)  YES (please specify below) | |
| **Conformance Profile** | **Version Number** |
| Clinical Documents – Common Conformance Profile |  |

## My Health Record Views

|  |  |
| --- | --- |
| Does the software product present My Health Record views?  N/A (Go to next question)  YES (Please tick and provide the version number of the Conformance Profile used for development). | |
| **Conformance Profile** | **Version Number** |
| Health Record Overview |  |
| Prescription and Dispense View |  |
| Observations View |  |
| Pathology Report View |  |
| Medicare Overview |  |
| Health Check Schedule View |  |
| Diagnostic Imaging Report View |  |

## Assisted Registration

|  |  |
| --- | --- |
| Does the software product conform to the specification for registering a digital health record for an adult or child?  N/A (Go to next question)  YES (please specify below) | |
| **Conformance Requirements** | **Version Number** |
| Assisted Registration |  |

# **Section 3 – Promotion of product**

## My Health Record Register of Conformity

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| --- |
| Would you like your software product to be listed in the Register of Conformity?  YES (please specify below)  N/A (Go to Vendor Deed Poll) |
| I have read and agree with the Vendor [Terms and Conditions on the Register of Conformity](https://www.digitalhealth.gov.au/healthcare-providers/initiatives-and-programs/my-health-record/conformant-clinical-software-products) webpage. |
| The primary and secondary contacts nominated in Section 1.2 consent to their details being made publicly available on the Register of Conformity. |

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| **Part B** |
| **VENDOR DEED POLL** |
| This Deed Poll is made by, <**vendor legal name and ABN/ACN**> (the Vendor), in favour of the System Operator (as defined in the *My Health Records Act 2012* (Cth)).  **Background**   1. The System Operator requiresvendors, whose software is used to connect to the My Health Record system,to implement software products that conform to all applicable My Health Record system Conformance Profiles and the specifications they reference and the Conformance Requirements for My Health Record Connecting Systems (together, the **Specifications**), prior to their software being granted connection to the My Health Record system. The System Operator further requires vendors to maintain compliance with the Specifications while the software connects to the My Health Record system. These Specifications can be found at <https://developer.digitalhealth.gov.au/resources/my-health-record-notice-of-connection-noc-and-conformance-compliance-and-declaration-ccd-testing> 2. The Vendor represents that it has successfully and fully completed testing of conformance for the software product(s) described in this Vendor Declaration Form (the **Software)** without error against the applicable mandatory conformance profile for the functions they are implementing. 3. The Vendor represents that it has completed My Health Record Notice of Connection (**NOC**) testing for the Software.   **Attestation of Software conformance**   1. The Vendor submits this Declaration of Conformance with signed Deed Poll to attest that:    1. the information entered in Part A is true and correct, and the Vendor agrees to be bound by this Part B; and    2. the Software conforms to all mandatory compliance and conformance requirements specified within Section 2 of Part A; and 2. The Vendor acknowledges that giving false or misleading information to a Commonwealth entity is a serious offence under sections 136.1 and 137.1 of the schedule to the *Criminal Code Act 1995* (Cth).   **Delivery, commencement of operation and expiration of this Deed Poll**   1. This Deed Poll commences on the date the Deed Poll is validly executed by the Vendor and continues in operation until the Deed Poll is terminated under clause 13. The Agency may request at any time, and the Vendor agrees to provide, a new Declaration of Conformance with signed Deed Poll.   **Interpretation**   1. For the purposes of this Deed Poll, Business Day means, in relation to the doing of any action in a place, any day other than a Saturday, Sunday or public holiday in the place where the act is to be performed:   **Operative provisions**   1. The Vendor declares that the contents of this Vendor Declaration Form, of which this Deed Poll forms a part, are true and correct and that, in accordance with AS ISO/IEC 17050.1-2005, the Software fully complies with all applicable Specifications. 2. The Vendor warrants and undertakes that:    1. it has successfully completed conformance testing without error against applicable Specifications;    2. as at the date this Deed Poll is given, the Software complies with all applicable Specifications; and    3. at all times during the term of this Deed Poll, the Software will comply with all applicable Specifications. 3. The Vendor acknowledges that the System Operator will conduct quality assurance analysis of the Software’s conformance and compliance with the applicable Specifications from time to time (**Quality Assurance Analysis**) and will comply with clause 9 in respect of any such analysis. For the avoidance of doubt, the Vendor agrees that the System Operator and its representatives are not obligated to treat information provided, obtained or otherwise developed in connection with the Quality Assurance Analysis as confidential. 4. The Vendor must notify the System Operator promptly if there is an error or other issue in the Software that will or has the potential to impact on the operation, security, integrity, clinical safety or reputation of the My Health Record system. 5. The Vendor must promptly notify the System Operator when:    1. there are changes or upgrades to the Software;    2. there is a material change in the Vendor’s legal structure, including if the Vendor is involved in a merger or acquisition;    3. there is a material change in the ownership of intellectual property rights in the Software; or    4. the Vendor’s nominated contact person(s), or their contact details, change. 6. The Vendor must retain copies of test reports that demonstrate conformance and compliance with Specifications for the term of this Deed Poll and for a period of seven years following termination and, without limiting clause 9, must provide a copy of the test report(s) to the System Operator within 14 days on request. 7. The Vendor agrees that the Software will not introduce any virus, disabling or malicious device or code, worm, Trojan, time bomb or other harmful or destructive code (**Harmful Code**) into the My Health Record system. The Vendor must, as soon as it becomes aware that Harmful Code has or might have been introduced into the My Health Record system, immediately notify the System Operator, in which case clause 8 will apply. 8. If:    1. the Vendor notifies the System Operator of an error or other issues in the Software in accordance with clause 4;    2. a Quality Assurance Analysis of the Software in accordance with clause 3 reveals conformance issues with the Software;    3. the Vendor notifies the System Operator that the Software has or may have introduced Harmful Code into the My Health Record system; or    4. the System Operator becomes aware of errors or issues, or potential errors or issues, in the Software, or conformance issues with the Software,   the Vendor must:   * 1. (to the extent the error, issue or introduction of Harmful Code has not been confirmed) promptly confirm whether or not the error, issue or introduction of Harmful Code has occurred and inform the System Operator;   2. provide any further information required by the System Operator;   3. negotiate remediation actions and timeframes to address the error, issue or conformance issue in good faith with the System Operator; and   4. implement at the Vendor’s own cost the agreed remediation actions in the agreed timeframes.   The Vendor acknowledges that if:   * 1. the System Operator and Vendor cannot agree on remediation actions;   2. the Vendor fails to implement the agreed remediation actions in the agreed timeframes; or   3. the System Operator otherwise considers that further action is necessary or desirable, including to ensure the security, integrity or operation of the My Health Record system,   then the System Operator may take any action it considers necessary including, without limitation, preventing the Software from connecting to or accessing the My Health Record system.   1. The System Operator will provide the Vendor with reasonable assistance to assist with resolving problems pertaining to the My Health Record system. 2. From time to time the System Operator or its representatives may conduct, handle or facilitate Quality Assurance Analysis, administrative or statutory reviews, inquiries, investigations, audits or complaints in connection with the My Health Record system (including data related issues). At the System Operator’s request, and on reasonable notice, the Vendor must at its cost provide reasonable assistance in relation to any such activities. This may include, but is not limited to, providing access to material, records, personnel and computer hardware, software and equipment associated with the Software and copies of the Software. 3. The My Health Record system and its functionality will change over time. As such, the Specifications will be updated or replaced from time to time, and the System Operator may withdraw support for previous versions. Although the System Operator will endeavour to consult with affected parties about any such changes, it is impossible to guarantee that the System Operator will consult individually with every participant. The Vendor acknowledges that it may be required to complete internal conformance testing against new/updated Specifications and that failure to do so may result in the Software no longer having a connection or access to the My Health Record system. 4. To the maximum extent permitted by law, the System Operator has no liability to the Vendor, or to any other party claiming via or through the Vendor, in respect of any loss or damage the Vendor might incur or suffer (including, without limitation, as a result of negligence) that is directly or indirectly related to the Software’s connection or access to the My Health Record system which includes, without limitation, any decision of the System Operator to prevent the Software’s connection or access or to include, or not include, the Vendor on the Register of Conformity. 5. The Vendor indemnifies the System Operator and its representatives against all liability, expense, loss, claims, damage or cost reasonably sustained or incurred by the System Operator (or its representatives) in connection with:    1. the Vendor’s breach of one or more terms of this Deed Poll; or    2. any negligent, unlawful or willfully wrong act or omission of the Vendor in connection with this Deed Poll;    3. an allegation that the Software infringes the intellectual property rights or moral rights of the third party; or    4. the Vendor’s breach of one or more terms of this Deed Poll.   The Vendor’s liability under the indemnity in this clause will be reduced proportionately to the extent that any negligent or other tortious act or omission of:   1. the Agency or its representatives; 2. the Commonwealth or its representatives; or 3. another vendor in relation to that vendor’s software system entered on the Register (except where the Vendor has any control over that other vendor or has contributed to that other vendor’s software system entered on the Register), contributed to the relevant liability, expense, loss, damage or cost.   The System Operator holds the benefit of this indemnity on trust for its representatives and may enforce this indemnity on behalf of its representatives.   1. The Vendor may terminate this Deed Poll by giving the System Operator at least seven days written notice, in which case the System Operator may take any action it considers necessary or desirable including, without limitation, preventing the Software’s connection or access to the My Health Record system and removing the Software from the Register of Conformity. 2. This Deed Poll will terminate immediately upon cancellation of the Software’s connection or access to the My Health Record system. 3. Clauses 3 (but only for a period of seven years following termination), 6, 10 (but only for a period of seven years following termination), 11, 12, 13, 16 and 17, and any definitions or other provisions necessary to give effect to these clauses, will survive termination of this Deed Poll. 4. Nothing in this Deed Poll limits or restricts any function, power, right or entitlement of the System Operator under the *My Health Records Act 2012* (Cth) or My Health Records Rule.   **Disputes**   1. The Vendor will not commence court proceedings relating to any dispute arising from this Deed Poll except when the Vendor seeks urgent relief from a court or when dispute resolution has failed under clause 19. 2. The Vendor agrees to negotiate in good faith to settle any dispute with the Agency in connection with this Deed Poll and, if the dispute cannot be settled by negotiation (including negotiation between senior management of the Vendor and the System Operator) then, within 30 days of the dispute being notified to senior management, the Vendor may agree to use an alternative dispute resolution process to attempt to resolve the dispute. 3. The Vendor must at all times during the dispute continue to fulfil its obligations under this Deed Poll. The Vendor acknowledges that the System Operator may, during the course of the dispute, take any action it considers necessary including, without limitation, temporarily suspending or removing the applicable Software from the Register of Conformance.   **Notices**   1. A notice under this Deed Poll must be in writing, in English and signed by a person duly authorised by the sender. A notice or other communication is properly given or served if the Vendor: 2. delivers it by hand; 3. posts it; or 4. transmits it by electronic mail,   to the System Operator’s address for notices specified below:  Australian Digital Health Agency  Level 25, 175 Liverpool Street  Sydney NSW 2000  [myhealthrecord.operations@digitalhealth.gov.au](mailto:myhealthrecord.operations@digitalhealth.gov.au)  CC: General Counsel [legal@digitalhealth.gov.au](mailto:legal@digitalhealth.gov.au)  *The Vendor acknowledges that the Agency may provide notices relevant to this Deed Poll to the address set out in Part A.*   1. A notice given in accordance with clause 21 takes effect when taken to be received (or at a later time specified in it), and is taken to be received: 2. if delivered by hand, when the entity who sent the notice holds a receipt for it, signed by a person employed by the intended recipient at the physical address for receipt of notices; 3. if sent by post from and to an address within Australia and correctly addressed, after seven Business Days; 4. if sent by post from or to an address outside Australia and correctly addressed, after twenty Business Days; 5. if sent by electronic mail, only in the event that the recipient acknowledges receipt by any means in person, by phone or by a message which has been generated by the intended recipient and not purely by a machine; and 6. if the delivery receipt, or transmission of the notice is not on a Business Day or is after 5.00pm on a Business Day, at 9.00am on the next Business Day. 7. This Deed Poll is governed by, and will be construed according to, the laws in force in the state of New South Wales.   Executed as a deed poll.   |  | | --- | | **SIGNED** **SEALED AND DELIVERED** for and on behalf of:  Vendor legal name:  ABN/ACN:  in accordance with the requirements of section 127 of the Corporations Act 2001 on:  **Date:**  **by:**    [OPTION 1: *For deeds being signed under hand and witnessed with wet signatures*, otherwise *DELETE THIS OPTION 1 AND USE OPTION 2*]  in the presence of:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed name of witness Signature of witness  [OPTION 2: *For any deeds being signed and witnessed electronically by video link,* *include this statement, otherwise DELETE THIS OPTION 2 AND USE OPTION 1*] By signing below the witness attests or confirms that [this document] or [a copy of this document] was signed in counterpart and witnessed over audio visual link in accordance with section 14G of the *Electronic Transactions Act 2000* (NSW):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of witnessing the signatory’s signature Date of this attestation or confirmation  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Printed name of witness Signature of witness | |

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**Australian Digital Health Agency** ABN 84 425 496 912, Level 25, 175 Liverpool Street, Sydney, NSW 2000 [digitalhealth.gov.au](http://www.digitalhealth.gov.au/)

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