



## My Health Record Conformance Vendor Declaration Form Instructions

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### Purpose

This document will aid vendors in completing the My Health Record Conformance Vendor Declaration Form. Submission of the Conformance Vendor Declaration Form is the last step towards having software authorised to connect to the My Health Record system. Refer to the Software vendors guide to My Health Record connection and testing for a summary of the complete process.

### Instructions

Where applicable, please ensure you complete all questions by selecting either Yes and then marking the specific items below the question, No, or N/A if the question does not apply to your software product.

To allow for ease of completion, check boxes and free text fields have been enabled in the form. To select a check box, click on the box and an X will display. If you have incorrectly checked the box, click on it again to remove the X.

When using the form please ensure you identify the appropriate type of request: connecting for the first time, adding a new software product, adding a new function, or changing a function or conformance level. When using these request types, you must specify in the form all the access you currently have, as well as any additional access being applied for.

Please ensure that once you complete the relevant sections you complete the Vendor Deed Poll and email the completed form and relevant documents to: [help@digitalhealth.gov.au](mailto:help@digitalhealth.gov.au)

## Section 1 – Vendor, Contact and Software details

### 1.1 Vendor details

The vendor details captured in this area include the Software Vendor name, general phone number (e.g. organisation's helpline) and address. Use of these items not only identifies you as a candidate for My Health Record access; it will also allow future correspondence to be sent to you. When completing the form please complete all these fields.

## 1.2 Contact details

When completing the form, please ensure you provide details for both the primary and secondary contacts, as well as direct contact numbers for these contacts. It is important that the System Operator can contact you as part of quality assurance or for incident management.

Please advise if you want published contact details to differ from those used by the My Health Record System Operator for incident management.

## 1.3 Software product details

This section of the form requests the following information:

### ***Type of software product***

Software products may be used directly by a healthcare provider as a clinical information system (CIS) or by a contracted service provider (CSP). You may select either a CIS or a CSP or both. For more information on the differences in the NOC (Notice of Connection) tests for a CIS and a CSP, please consult the Software vendor guide to the connection process.

### ***Description of software product***

Please provide a summary of your software product, including information such as the healthcare environment setting where the software will be used. Please limit your response to 60 words.

### ***Types of request***

There are three types of access request in this form. See table below for general examples of these types of access.

Access Type	Definition
New software product	A software product that has never connected to the My Health Record system before.
Add new function or version number	This software product has previously accessed the My Health Record system and is adding a function, such as a new clinical document type or My Health Record view and/or upgrading the version number.
Update to function or conformance level	This software product has previously accessed the My Health Record system and has a relevant My Health Record function that is changing. For example, your software product already produces Discharge Summaries and has previously been approved for a 1A conformance level, and you are upgrading this to conformance level 3A.

### ***List of software components***

Several rows have been provided to allow you to enter all applicable software components, the related version number and the function that component performs. For further details on the types of software component functions please see the table below.

Function	Definition
Manage healthcare identifiers	System functions to manage local copies of an individual's IHI and/or manage local copies of identifiers for healthcare provider individuals and organisations.

Function	Definition
Create clinical documents	System functions to create clinical documents containing personal health information.
Transform to CDA format	System functions to convert clinical documents into CDA (Clinical Document Architecture) format.
Create clinical packages	System functions to create a clinical package out of a clinical document in CDA format and eSignature.
Upload and remove clinical documents in a digital health record.	For system functions to be able to access a digital health record, they must be able to upload and remove clinical documents. Uploading systems must also be able to remove clinical documents.
Gain access and download information in a digital health record.	System functions to gain access to a digital health record and download information.
Render information from a digital health record.	System functions to either display or print information downloaded from a digital health record. Downloaded information may be clinical documents or My Health Record views.
Assist with registration	System functions in the healthcare provider's local system to assist a healthcare provider to register an individual for a digital health record within the My Health Record system.

***Has the software product been issued production access to the Healthcare Identifiers (HI) Service? (Please note this is a prerequisite to My Health Record Production access)***

The Healthcare Identifiers Service (HI Service) is a national system for uniquely identifying healthcare providers and individuals. It is a requirement for connection to the My Health Record system that your software product has approval for connection to the HI Service. If you have not been issued HI production access, this will delay your My Health Record production access. For assistance, please contact [help@digitalhealth.gov.au](mailto:help@digitalhealth.gov.au) to arrange access.

## 1.4 Terminology in clinical documents

***Does the software product include clinical terminology in clinical documents?***

Using clinical terminology within clinical documents ensures that the correct wording is included and displayed. The recommended clinical terminology code sets are Australian Medicines Terminology (AMT) or SNOMED CT® Australian Release (SNOMED CT-AU). If you are using either of these, please select the clinical terminology guide applicable to your software product and enter the version number. If you are using terminology codes other than the above, please use the text field box to describe the clinical terminology you are using.

## 1.5 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 considered when applying for production access to the My Health Record system? (Include exemptions from mandatory requirements here: title, date approved and date of exemption expiry)***

If your organisation has special conditions relating to production access to the My Health Record system, please provide the information in the text field. This information will be assessed on a case-by-case basis. This will add to the time it takes to process your form so please give advanced warning by contacting [help@digitalhealth.gov.au](mailto:help@digitalhealth.gov.au).

## Section 2 – Software compliance and conformance areas

### 2.1 Software compliance – 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?**

The use cases listed in this section come from the technical specifications available from the Australian Digital Health Agency website. We collect this information to ensure that your software product will interact correctly with the My Health Record system. For this item, please specify all the use cases that apply to your software product.

Web services are used to communicate with the My Health Record System. From the list of My Health Record related web services on the form, please specify all the web services your software product uses.

**Note: Although the PCEHR has been renamed to My Health Record system, existing Web Service names still reference PCEHR rather than My Health Record. The renaming of Web Services will occur over time.**

My Health Record Web Services	My Health Record Use Cases
doesPCEHRExist via B2B – v1.1	UC.CIS.001 – Check if an advertised My Health Record exists
gainPCEHRAccess via B2B – v1.1	UC.CIS.002 – Gain access to a My Health Record
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 My Health Record registration (adult) UC.CIS.502 – Assisted My Health Record registration (child)
CIS to NPP	UC.CIS to NPP.001 – CIS to NPP direct access My Health Record from National Provider using web-browsers

My Health Record Web Services	My Health Record Use Cases
	UC.CIS.toNPP.002 – CIS to NPP direct access My Health Record from National Provider using system browsers
	UC.CIS.toNPP.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

## 2.2 Clinical Documents created by software

### Does the software product generate clinical documents, either directly or via an intermediary system?

Software products may either create clinical documents in Clinical Document Architecture (CDA)® format or request an intermediary system to convert information to CDA® format.

An intermediary system is a software system operated by a healthcare supporting organisation, that provides functions to assist a clinical information system or contracted service provider system to interact with the My Health Record infrastructure. An intermediary system is not a software library or a component of a software product. At present, only Prescription Records and Dispense Records may be generated by an intermediary system.

CDA is an HL7 standard for the creation of electronic clinical documents and is the standard used by the My Health Record system. The conformance level of each type of clinical document indicates the strictness to which it complies with requirements. The combination of the document type and conformance level is represented by the associated template package ID (beginning with '1.2.36.1.2001.1006.1.'). Conformance levels range from the lowest at 1A to the highest at 3B. A current list of template packages can be found within the Digital Health Template package directory at the following link\*:

<https://developer.digitalhealth.gov.au/specifications/clinical-documents/ep-3435-2022>

\* To find the most recent page, please scroll down to the bottom of the screen and locate the appropriate link.

Please complete the template package IDs for the applicable clinical document types and conformance levels that your software product uses. If your software product uses an intermediary system to generate clinical documents in CDA® format, then record only the clinical document type.

**Does the software product conform to the mandatory and relevant conditional requirements listed in the following conformance profiles?**

These profiles contain the requirements to develop functionality for producing My Health Record clinical documents. Please enter a relevant version number against each conformance profile for the clinical document types that your software product produces. If your software product generates clinical documents in CDA® format, then ensure the version number is in alignment with the appropriate template package IDs listed in the Digital Health Template package directory.

### 2.3 CDA® document presentation

***Does the software product conform to the specifications for downloading and rendering CDA® documents?***

CDA® document rendering refers to the display of document titles, time and formatting, banners and colour images within your software product. Please enter the relevant version number against the required conformance profile to show compliance with this item.

### 2.4 My Health Record views

***Does the Software product present My Health Record views?***

A particular My Health Record view displays consolidated information organised in a layout according to the design defined in the requirements. Please select all views used in your software product. Please refer to the My Health Record glossary for the definition of each My Health Record view:

<https://www.myhealthrecord.gov.au/glossary>.

These profiles contain the requirements to develop functionality for displaying My Health Record views. Please enter a relevant version number against each conformance profile for the My Health Record views that your software product displays.

### 2.5 My Health Record Connecting Systems Conformance

***Does the software product conform to the mandatory and relevant conditional requirements for My Health Record Connecting Systems Conformance Profile?***

This requirement document specifies the mandatory and any pertinent conditional requirements for My Health Record Connecting Systems Conformance Profile. Please enter the relevant version number of the My Health Record Connecting Systems Conformance Profile requirements document used in developing your software product.

### 2.6 Assisted Registration

***Does the software product conform to the specification for registering a digital health record for an adult or child?***

These requirements documents specify the necessary functionality to allow the Assisted Registration of an adult or child with the My Health Record system. Please enter the relevant version number of the Assisted Registration requirements document used in developing your software product.

### 2.7 Security Conformance

***Does the software product conform to the relevant conformance requirements within the My Health Record Connecting Systems Security Conformance Profile?***

The requirements document specifies the necessary functionalities required in a software product to conform with the relevant conformance requirements within My Health Record Connecting Systems Security Conformance Profile. It also includes applicable compliance requirements for the software developer organisation/software service provider organisation.

Please enter the relevant version number of the My Health Record Connecting Systems Security Conformance Profile used in developing your software product.

## Section 3 – Promotion of product

### 3.1 My Health Record Register of Conformity

The My Health Record Register of Conformity provides information on software products that meet national My Health Record standards and specifications. Listing on the register will provide positive exposure for your software product in the health industry. You must read and agree to the My Health Record Register of Conformity terms and conditions and acknowledge that your contact details will be displayed on the register. For further information, please visit:

<https://www.digitalhealth.gov.au/healthcare-providers/initiatives-and-programs/my-health-record/conformant-clinical-software-products>

### 3.1 ePIP Register of Conformity

The ePIP Register of Conformity provides information on software products that meet the My Health Record requirements for the Practice Incentives Program eHealth Incentive (ePIP) for general practice. For further information, please visit the ePIP Guidelines on the [Services Australia website](#) and find out about the [ePIP incentive eligibility requirements](#).

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