

WHO Digital Clearinghouse: Assessment of digital health solutions that issue Digital Documentation of COVID-19 Certificates (DDCC).

1. Introduction

The WHO Digital Clearinghouse is a mechanism to assess digital health solutions using objective, reproducible, and transparent criteria.

The aim is to support governments to invest in an “essential” package of digital solutions, linked to technical assistance and resourcing for common health system requirements. It will also support technologists to design and build digital solutions that leverage appropriate health and data content, to ensure impact and interoperability. The priority is the assessment of digital solutions that deliver digital health interventions at the primary healthcare level in low- and middle-income countries (LMICs).

Digital health solutions submitted will be reviewed using an assessment framework and process described below, and those that meet minimum requirements will be published and curated within the WHO Digital Clearinghouse (see **Annex A**).

2. Background

Public Call: Digital Documentation of COVID-19 Certificates (DDCC).

Product owners that wish to participate in the public call for digital health solutions that issue Digital Documentation of COVID-19 Certificates (DDCC) have been invited to submit an Expression of Interest (EOI) between **14 November 2022 and 2 December 2022**.

A call to submit details in the first stage of the assessment process (Intake stage) was open to EOI respondents between **18 January 2023 and 21 February 2023**. The detailed assessment stage will be open to DDCC solutions that meet the requirements at the intake stage from **10 April 2023 to 7 May 2023**.

Ministries of Health and other stakeholders looking for DDCC solutions appropriate for their specific setting and use case will be able to search the WHO Digital Clearinghouse and access information on published DDCC solutions through an online platform, expected to be live in 2023.

The assessment will cover digital health solutions that issue COVID-19 vaccination status and COVID-19 test results, based on the following specifications published by WHO:

- [Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance, 27 August 2021](#)
- [Digital documentation of COVID-19 certificates: test result: technical specifications and implementation guidance, 31 March 2022](#)

Digital health solutions will be assessed under the following domains:

- **Domain 1:** How well does the solution fulfil a minimum set of functional and non-functional requirements for a DDCC use case?
- **Domain 2:** Does the digital solution meet the requirements for open interoperability standards?
- **Domain 3:** Is the health and data content consistent with WHO data, clinical and public health recommendations for DDCC?
- **Domain 4:** How well does the solution address implementation requirements and constraints of low-resource settings?
- **Domain 5:** To what extent is the solution safe and ready for country use within national digital health ecosystems?

3. Assessment Framework and Review Process

The Assessment Framework is structured under the five domains listed above. Criteria in each domain are further divided into categories and sub-categories shown in **Annex B**.

Each criterion within the Assessment Framework is classified into one of three tiers, depending on the type of supporting evidence or means of verification that will be used to substantiate product owner responses (see Table 1). Some illustrative examples are provided in **Annex C**.

Table 1 Tiers of criteria in assessment framework

Tier	Description
Tier 0	Claims made by the vendor are based on self-attestation without any documentation and have not been verified by the WHO Review panel.
Tier 1	Claims submitted by the vendor have been verified based on visual inspection of submitted documentation. Documentation could include test data, product demo, image of a certificate, screenshots, links to support the relevance of information, trademark documents, licensing, source code documentation, etc.
Tier 2	This applies to claims that are tool-testable only. Claims made by the vendor have been verified based on a review of test results submitted by the vendor. The test results are derived from conformance and verification testing conducted in either a sandbox run by WHO or an external entity.

The full Assessment Framework will be published during Stage 2: Public Call (see below).

4. Review Process and Timeline

Review process	Requirements	Key dates
Expression of interest (EOI)	Product owners invited to submit Expressions of interest to take part in a DDCC public call. Basic information on the vendor and proposed product to be submitted via an online form.	<i>Submissions open:</i> 14 Nov 2022 <i>Deadline:</i> 2 Dec 2022
Public Call	Product owners who have responded to the EOI will be invited to complete the first stage of assessment questions: <ul style="list-style-type: none"> • Full Organisation and product details: Providing details on the organisation and digital health solution. • DDCC Intake Form: Digital health solutions are required to meet a minimum set of criteria to progress to the Detailed Assessment stage. 	<i>Submissions open:</i> 18 Jan 2023 <i>Deadline:</i> 21 February 2023
Intake review	WHO technical team will conduct a review of the intake submissions. DDCC solutions that meet minimum criteria will be invited to progress to the Detailed Assessment stage.	<i>Review to be completed by:</i> 17 Mar 2023
Detailed Assessment Form	For solutions that successfully pass the Intake stage, product owners will be invited to take part in the next stage: <ul style="list-style-type: none"> • Detailed Assessment Form: Depending on the criteria being assessed, product owners will be requested to upload supporting evidence or to submit the product for testing in a sandbox environment (see Annex B). 	<i>Submissions open:</i> 10 Apr 2023 <i>Deadline:</i> 7 May 2023
Detailed review	External reviewers will conduct an assessment and review of all detailed assessment submissions and present preliminary results to a WHO panel for final validation. All solutions that reach this stage will be accepted into the WHO Digital Clearinghouse, alongside a scorecard of results.	<i>Review to be completed by:</i> 18 Jun 2023
Publication of results	The full results will be made available to approved users of the WHO Digital Clearinghouse looking for	<i>Results to be published:</i> by 10 July 2023

	DDCC solutions to meet their specific needs (e.g. Ministries of Health or public health implementers). A summarised version of the results will also be made public.	
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5. Disclaimer

This public call is not a solicitation and replying to it does not guarantee that a vendor will be invited to any solicitation by WHO. No further details of the planned solicitation will be made available to product owners prior to the issuance of solicitation documents.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an Expression of Interest or the completion of the assessments will exclusively be borne by the applicant. The application and selection process set forth in this document will not be subject to claims for financial compensation of any kind whatsoever.

WHO is acting in good faith by issuing this public call, however, this call does not entail any commitment on the part of WHO, either financial or otherwise. WHO reserves the right to send solicitation documents to product owners identified by WHO through means other than the Request for Expression of Interest; reject any or all Expression(s) of Interest, without incurring any obligation to inform the affected applicant(s) of that decision or the grounds thereof; and/or change or cancel the formal solicitation processes at any time, including during the Request for Expression of Interest.

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Annex A WHO Digital Clearinghouse

Challenge

Countries are confronted with an overwhelming availability of technology solutions but lack the information required to make informed decisions to select digital solutions that address their diverse needs while also ensuring the solutions are effective, able to scale, and integrate with existing systems.

Approach

The WHO Clearinghouse focuses on the assessment of digital solutions that deliver digital health interventions at the primary health care level.

The Clearinghouse will provide stakeholders with an essential list of digital solutions, ensuring their digital health interventions comply with WHO digital and data recommendations.

Process

The Clearinghouse supports the assessment of digital solutions using objective, reproducible, testable, and transparent criteria based on an unbiased, impartial, and independent review process.

The Clearinghouse will curate digital health solutions that use open interoperability standards and fulfil functional requirements that are appropriate for the specified public health use case; contain data and health content that is consistent with WHO recommendations; address implementation requirements and constraints of low-resource settings; and are safe and ready for country use within national digital ecosystems.

The Clearinghouse will start with specific health domains and specifications including the Digital Documentation of COVID-19 Certificates (DDCC) followed by routine immunization. For each use case, solutions will demonstrate compliance with the identified specification and interoperability standards. Additionally, solutions will provide evidence of implementation and financial considerations.

Country governments and other stakeholders can expect to begin to see curated solutions available on the platform in mid 2023.

Annex B Assessment Framework

The high-level structure of the assessment framework is provided in Table 1 below. It shows the categories and sub-categories of criteria that solutions will be assessed against, across the 5 domains listed above.

WHO will be seeking feedback from interested product owners to enable the refinement of the assessment framework and review process.

Table 1 Categories and Sub-categories within the draft assessment framework

Category	Sub-category
Product Overview	<ul style="list-style-type: none"> • Basic Information • Design process • Analytics* • Product impact (value proposition)
Privacy and Security	<ul style="list-style-type: none"> • User privacy and security • Data governance and policy • Security – Assessment • Security – Audit trail and logs • Security – Authorisation and Access • Data transmission, Sharing and Release
Oversight and Regulation	<ul style="list-style-type: none"> • Regulatory oversight and compliance • Clinical Risk Categorisation*
Interoperability (Technical, Syntactic, Semantic, Operation and performance, Security and Safety)	<ul style="list-style-type: none"> • Data exchange • Content standards
Health content	<ul style="list-style-type: none"> • Provision of evidence
Technical considerations	<ul style="list-style-type: none"> • Disaster recovery • Reliability • Scalability • Performance • Data retention/ Archiving
Ease of Use	<ul style="list-style-type: none"> • Cultural Appropriateness • Operability in low-resource settings • Usability • Accessibility
Ethical Considerations	<ul style="list-style-type: none"> • Data ownership and empowerment • Consent • Prevention of inequalities • Proportionality, necessity and data minimisation

	<ul style="list-style-type: none"> • Purpose limitation • Transparency
Deployment considerations	<ul style="list-style-type: none"> • Time to deployment • Documentation and Training • Service support/ maintenance availability • Community forums
Sustainability	<ul style="list-style-type: none"> • Organisation details and credibility • Cost considerations

* sub-category contains criteria that are only relevant to specific public health use cases

Annex C Illustrative examples of criteria and means of verification

Illustrative example of criteria	Type of evidence/supporting documentation	Tier
The solution provides optimization for delivery to users with low bandwidth to address issues of limited (or intermittent) Internet connectivity in low digital maturity settings.	Demo	Tier 1
The system supports large numbers of concurrent users performing read and write operations during normal operation.	Self-attestation from product owner	Tier 0
Data concerning system usage is available to system administrators via a dashboard to show current and recent load (last week, last month), and it is possible to export this data.	Test Data	Tier 1
The system can verify and validate the QR Code on a COVID-19 Certificate using digital cryptographic processes in an online mode that includes a status check against the National Registry Service using HL7® FHIR® standard.	Verification test results	Tier 2