

Digital Documentation of COVID-19 Certificates: Test Result

Technical specifications and implementation guidance



**World Health
Organization**

1 **Digital Documentation of COVID-19 Certificates: Test Result: Interim Guidance**

2
3 © World Health Organization 2021

4 Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0
5 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

6 WHO reference number: *Will be available*

7
8 Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes,
9 provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion
10 that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you
11 adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you
12 create a translation of this work, you should add the following disclaimer along with the suggested citation: "This
13 translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or
14 accuracy of this translation. The original English edition shall be the binding and authentic edition".

15
16 Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation
17 rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

18
19 **Suggested citation.** *Will be available*

20
21 **Cataloguing-in-Publication (CIP) data.** CIP data are available at <http://apps.who.int/iris>.

22
23 **Sales, rights and licensing.** To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests
24 for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

25
26 **Third-party materials.** If you wish to reuse material from this work that is attributed to a third party, such as tables,
27 figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain
28 permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned
29 component in the work rests solely with the user.

30
31 **General disclaimers.** The designations employed and the presentation of the material in this publication do not
32 imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country,
33 territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and
34 dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

35
36 The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or
37 recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions
38 excepted; the names of proprietary products are distinguished by initial capital letters.

39
40 All reasonable precautions have been taken by WHO to verify the information contained in this publication. However,
41 the published material is being distributed without warranty of any kind, either expressed or implied. The
42 responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for
43 damages arising from its use.

CONTENTS

44		
45	Acknowledgements	iv
46	Abbreviations	v
47	Glossary	vi
48	Executive Summary	1
49	What is the DDCC:TR?	1
50	Proof Scenarios of the DDCC:TR	3
51	What are the minimum requirements to implement a DDCC:TR?	4
52	1 Introduction	7
53	1.1 Purpose of this document	7
54	1.2 Target audience	8
55	1.3 Scope	8
56	1.3.1 In scope	8
57	1.3.2 Out of scope	8
58	1.4 Assumptions	9
59	1.5 Methods	11
60	1.6 Additional WHO guidance documents	11
61	1.7 Other initiatives	13
62	2 Ethical considerations and data protection principles	14
63	2.1 Ethical considerations for a DDCC:TR	14
64	2.1.1 Key ethical considerations for current proposed uses of DDCC:TR	14
65	2.2 Data protection principles for a DDCC:TR	20
66	2.3 DDCC:TR design criteria	22
67	3 Test Result Certificate Generation	24
68	3.1 Key settings, personas and digital services	24
69	3.2 Certificate Generation workflow	26
70	3.3 Functional requirements for Certificate Generation	27
71	4 Test Result Certificate Verification: Proof of negative SARS-CoV-2 test result or Proof of previous	
72	SARS-CoV-2 infection	30
73	4.1 Proof Scenarios	30
74	4.2 Key settings, personas and digital services	31
75	4.3 Test result certificate verification workflows and use cases	33
76	4.3.1 Test result certificate verification use cases	34

77 4.3.2 Operationalizing the test result certificate verification use cases..... 41

78 4.4 Functional requirements for test result certificate verification..... 41

79 5 DDCC:TR Core Data Set 43

80 5.1 Core data set principles 43

81 5.2 Core data elements..... 45

82 6 PKI for Signing and Verifying a DDCC:TR..... 49

83 6.1 Signing a DDCC:TR..... 50

84 6.2 Verifying a DDCC:TR signature..... 51

85 6.3 Trusting a DDCC:TR signature 52

86 7 National Governance Considerations..... 53

87 8 Implementation Considerations..... 56

88 8.1 Considerations before deploying..... 56

89 8.2 Key factors to consider with solution developers..... 58

90 8.3 Cost category considerations 60

91 8.4 Additional resources to support implementation..... 62

92 References..... 63

93 Annexes..... 66

94 Annex 1: Business process symbols used in workflows 66

95 Annex 2: Guiding principles for mapping the WHO Family of International Classifications (WHO-

96 FIC) and other classifications..... 67

97 Annex 3: What is public key infrastructure (PKI)?..... 70

98 Annex 4: Non-functional requirements..... 74

99 Annex 5: Open Health Information Exchange (OpenHIE)-based architectural blueprint 79

100 Web Annexes.....

101 Web Annex A. DDCC:LR Core data dictionary.....[link to be provided]

102

ACKNOWLEDGEMENTS

103

104

105

The World Health Organization (WHO) is grateful for the contribution that many individuals and organizations have made to the development of this document.

DRAFT

ABBREVIATIONS

1D	one-dimensional
2D	two-dimensional
AEFI	adverse event(s) following immunization
Ag-RDT	Antigen detection rapid diagnostic test
API	application programming interface
COVID-19	Coronavirus disease 2019
DDCC	Digital Documentation of COVID-19 Certificates
DDCC:TR	Digital Documentation of COVID-19 Certificates: Test Result
DDCC:VS	Digital Documentation of COVID-19 Certificates: Vaccination Status
DSC	document signer certificate
EIS	Event Information Site
FHIR	Fast Healthcare Interoperability Resources
HCID	health certificate identifier
HL7	Health Level Seven
HPV	human papillomavirus
ICD	International Classification of Diseases
ICT	information and communications technology
ID	identifier
IHR	International Health Regulations (2005)
IPS	International Patient Summary
ISO	International Organization for Standardization
LIS	Laboratory Information System
NAAT	Nucleic Acid Amplification Test
OpenHIE	Open Health Information Exchange
PHA	public health authority
PHSMs	public health and social measures
PKI	public key infrastructure
QA	quality assurance
SHR	shared health record
SLA	service level agreement
SNOMED CT GPS	Systematized Nomenclature of Medicine Clinical Terms Global Patient Set
WHO-FIC	WHO Family of International Classifications

GLOSSARY

108
109
110
111
112
113
114
115
116
117
118
119
120
121
122
123
124
125
126
127
128
129
130
131
132
133
134
135
136
137
138
139
140
141
142
143
144
145
146
147
148
149
150

Antigen detection rapid diagnostic test (Ag-RDT): directly detects viral protein antigens of SARS-CoV-2, the virus that causes COVID-19, in respiratory samples using a method of lateral flow immunoassay.

Certificate: A document attesting a fact. In the context of the lab result certificate, it attests to the fact that a SARS-CoV-2 diagnostic test has been conducted and the test result has been provided to an individual.

Certificate Authority (CA): Also known as a “certification authority” in the context of a PKI, is an entity or organization that issues digital certificates.

Data controller: The person or entity that, alone or jointly with others, determines the purposes and means of the processing of personal data. A data controller has primary responsibility for the protection of personal data.

Data processing: ‘processing’ means any operation or set of operations performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Data processor: A person or entity that processes personal data on behalf of, or under instruction from, the data controller.

Data subject: The Tested Person or the DDCC:TR Holder if the DDCC:TR Holder represents the Tested Person, such as a minor child, or represents a person who is physically or legally incapable to give consent for the processing of its personal data.

Digital divide: The gap between demographic groups and regions that have access to modern ICT and those that do not or that have restricted access.

Digital Documentation of COVID-19 Certificate(s) (DDCC): A digitally signed HL7 FHIR document that represents the core data set for the relevant COVID-19 certificate.

Digital Documentation of COVID-19 Certificate(s): Test Result (DDCC:TR): A type of DDCC that is used to represent the SARS-CoV-2 diagnostic test result(s) of an individual. Specifically, the DDCC:TR is a digitally signed Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) document containing the data elements included in the DDCC:TR core data set.

DDCC:TR Generation Service: The service that is responsible for generating a digitally signed representation, the DDCC, of the information concerning a test for SARS-CoV-2.

151 **DDCC:TR Registry Service:** The service that can be used to request and receive metadata associated
152 with a DDCC:TR.

153
154 **DDCC:TR Repository Service:** A, potentially federated, service that serves as a repository, or
155 database, of the health content associated to DDCC:TR.

156
157 **Digital Health Solution:** A secure system that is used to capture and/or manage a digital record of
158 the DDCC:TR core data elements, such as a Laboratory Information System (LIS).

159
160 **Digital representation:** A virtual representation of a physical object or system. In this context, the
161 digital representation must be a digitally signed HL7 FHIR document or a digitally signed two-
162 dimensional (2D) barcode (e.g. a QR code).

163
164 **Digital signature:** In the context of this guidance document, it is a hash generated from the HL7
165 FHIR data concerning a test, signed with a private key from a public-private key pair using standard
166 encryption techniques.

167
168 **Digitally signed:** A digital document is digitally signed when plain-text health content is “hashed”
169 with an algorithm, and that hash is encrypted with a private key.

170
171 **Encryption:** A security procedure that translates electronic data in plain text into a cipher code, by
172 means of a cryptographic system, to render it incomprehensible without the aid of the original code
173 or cryptographic system.

174
175 **Health certificate identifier (HCID):** An alphanumeric identifier (ID) for a physical and/or digital
176 health folder which contains one or more test events and associated certificates. Each test event
177 corresponds to a DDCC:TR.

178
179 **Health data:** Personal data related to the physical or mental health of a natural person, including the
180 provision of health services, which reveal information about his or her health status. These include
181 personal data derived from the testing or examination of a body part or bodily substance, including
182 from genetic data and biological samples.

183
184 **Identification document:** A document that attests the identity of or a linkage to someone, for
185 example a passport or a national identity card.

186
187 **Identifier:** A name that labels the identity of an object or individual. For example, it can be a unique
188 alphanumeric string that is associated with an individual, such as a passport number or medical
189 record ID. Other types of identifiers include a document identifier, a facility identifier, and a health
190 worker identifier.

191
192 **Laboratory Information System (LIS):** Sometimes also referred to as a laboratory information
193 management system, is a software system that supports the laboratory activities. Key functionality
194 includes receiving and storing requests for tests and test results. Test results can be made available

195 via paper reports and/or electronic formats, both to human users and to other health information
196 systems (e.g. electronic medical record systems, billing systems, etc.).

197
198 **MAY:** MAY is used to describe technical features and functions that are optional, and it is the
199 implementer's decision on whether to include that feature or function based on the implementation
200 context.^[1]

201
202 **Nucleic Acid Amplification Test (NAAT):** A type of viral diagnostic test for SARS-CoV-2. NAATs
203 detect genetic material (i.e. nucleic acids) with high sensitivity and specificity and are usually the
204 reference method (e.g. gold standard) for SARS-CoV-2 detection. There are multiple NAATs
205 available to detect SARS-CoV-2 that have small variances in performance and larger variances in the
206 ease of use of the test system.

207
208 **One-dimensional (1D) barcode:** A visual black and white pattern using variable-width lines and
209 spaces for encoding information in a machine-readable form. It is also known as a linear code. For
210 this document, it is assumed that the 1D barcode follows one of the international specifications.

211
212 **Paper Test Result Certificate:** A test result certificate that is either handwritten or printed on paper,
213 with a barcode. This barcode can be generated in real time or it can be pre-printed directly onto the
214 certificate or on a barcode sticker.

215
216 **Pass:** A document that gives an individual the authorization to have access to something, such as
217 public spaces, events, and modes of transport.

218
219 **Personal data:** Any information relating to an individual who is or can be identified, directly or
220 indirectly, from that information. Personal data includes biographical data (biodata), such as name,
221 sex, civil status, date and place of birth, country of origin, country of residence, individual registration
222 number, occupation, religion, and ethnicity; biometric data, such as a photograph, fingerprint, facial
223 or iris image; health data; as well as any expression of opinion about the individual, such as
224 assessments of his or her health status and/or specific needs.

225
226 **Public key:** The part of a private–public key pair used for digital encryption that is designed to be
227 freely distributed.

228
229 **Public key infrastructure (PKI):** The policies, roles, software and hardware components and their
230 governance that facilitate digital signing of documents and issuance, distribution, and exchange of
231 keys.

232
233 **Private key:** The part of a private–public key pair used for digital encryption that is kept secret and
234 held by the individual/organization signing a digital document.

235
236 **SHALL:** SHALL is used to describe technical features and functions that are mandatory for this
237 specification.^[2]

238

239 **SHOULD:** SHOULD is used to describe technical features and functions that are recommended, but
240 they are not mandatory. It is the implementer’s decision on whether to include that feature or
241 function based on the implementation context and policies of the implementing Member State.
242 However, the implementer is highly recommended to review the reasons for not following the
243 recommendations before deviating from the technical specifications outlined.^[3]
244

245 **Test Report:** The record, or report, of a SARS-CoV-2 diagnostic test result. A test report contains key
246 demographic information about the tested person, the laboratory or testing centre that conducted
247 the test, the test results, and other details information needed for clinical use. Test reports differ from
248 a “test certificate” in that test reports do not contain means of cryptographically verifying the
249 contents of the report.
250

251 **Test Result Certificate:** A document that, attests to the fact that an individual has been tested for
252 SARS-CoV-2, and attests to the result of that SARS-CoV-2 diagnostic test.
253

254 **Tested Person:** The person who is tested for SARS-CoV-2.
255

256 **Third party use:** Use by a natural or legal person, public authority, agency or body other than the
257 data subject, controller, processor and persons who, under the direct authority of the controller or
258 processor, are authorized to process personal data.
259

260 **Two-dimensional (2D) barcode:** Also called a matrix code. A 2D way to represent information using
261 individual black dots within a square or rectangle. For example, a QR code is a type of 2D barcode. It
262 is similar to a linear (1D) barcode, but it can represent more data per unit area. There are different
263 types defined by open standards.
264

265 **Verifier:** A natural person or legal person, either private or public, formally authorized (under
266 national law, decree, regulation or other official act or order) to verify the SARS-CoV-2 diagnostic
267 test result presented on the DDCC.
268

269 **Verifier Application:** A secure application used to verify the SARS-CoV-2 diagnostic test result
270 presented on the DDCC:TR. A verifier can use the verifier app to scan the barcode and display the
271 data held within the DDCC:TR. The verifier app does not store or transmit any personal data.
272

273 ^[1] This definition is based on the definition [published by the Internet Engineering Task Force \(IETF\)](https://www.ietf.org/rfc/rfc2119.txt)
274 (<https://www.ietf.org/rfc/rfc2119.txt>, accessed 30 June 2021).

275 ^[2] This definition is based on the definition [published by the Internet Engineering Task Force \(IETF\)](https://www.ietf.org/rfc/rfc2119.txt)
276 (<https://www.ietf.org/rfc/rfc2119.txt>, accessed 30 June 2021).

277 ^[3] This definition is based on the definition [published by the Internet Engineering Task Force \(IETF\)](https://www.ietf.org/rfc/rfc2119.txt)
278 (<https://www.ietf.org/rfc/rfc2119.txt>, accessed 30 June 2021).

EXECUTIVE SUMMARY

279

280 In the context of the coronavirus disease (COVID-19) pandemic, the concept of **Digital**
281 **Documentation of COVID-19 Certificates (DDCC)** is proposed as a mechanism by which a person's
282 COVID-19-related health data can be digitally documented via an electronic certificate. A test report
283 that documents a person's SARS-CoV-2 diagnostic test result can be used to generate a certificate
284 that serves as proof of that SARS-CoV-2 diagnostic test result. The resulting artefact of this approach
285 is referred to as the **Digital Documentation of COVID-19 Certificates: Test Result (DDCC:TR)**.

286 The current document is written for the ongoing global pandemic of COVID-19; thus, the approach is
287 architected to respond to the evolving science and to the immediate needs of countries in this
288 rapidly changing context; for this reason, the document is issued as interim guidance.

289 The document is the second part of a series of two guidance documents (see Figure 1) on digital
290 documentation of COVID-19-related data of interest: vaccination status and test result (this
291 document). Technical specifications and implementation guidance regarding certificates for "Proof of
292 Negative SARS-CoV-2 Test Result" and "Proof of Previous SARS-CoV-2 Infection" have been
293 combined into a single DDCC:TR document because both certificates will require some form of
294 testing prior to issuance.

295 *Figure 1 Guidance documents for DDCC*

DDCC: Vaccination Status	DDCC: Test Result	
SARS-CoV-2 Vaccination Status	Proof of Negative SARS-CoV-2 Test Result	Proof of Previous SARS-CoV-2 Infection
Guidance on digitally documenting SARS-CoV-2 vaccination status	Guidance on digitally documenting SARS-CoV-2 diagnostic test results	Guidance on digitally documenting proof of previous SARS-CoV-2 infection

296

297 The World Health Organization (WHO) has developed this guidance and accompanying technical
298 specifications, in collaboration with a multidisciplinary group of partners and experts, to support
299 WHO Member States in adopting interoperable standards for recording SARS-CoV-2 diagnostic test
300 results. The audience of this document are Member States and their implementing partners that
301 want to put in place digitally signed test result certificates.

302 What is the DDCC:TR?

303 A test result certificate attests to the fact that an individual has been tested for SARS-CoV-2 and
304 attests to the result of that SARS-CoV-2 diagnostic test. It includes minimal details about the
305 individual who has been tested, the type of test conducted, the sample collection date and time, the

306 test result, and other data in the core data set (see section 5.2). When required by government
 307 authorities, based on technical and ethical considerations, a test result certificate can be used as
 308 proof of negative SARS-CoV-2 test result or proof of previous SARS-CoV-2 infection¹ (1) for
 309 individualized exemptions from public health and social measures and/or (2) for accessing certain
 310 socioeconomic activities.¹¹ A test result certificate is a health document, and it is not intended for use
 311 as an identity document. It is up to Member States to determine the policies and procedures for
 312 binding a test result certificate to an individual's identity.

313 A "test result certificate" differs from a "test report". "Test reports" contain all relevant medical
 314 information, clinical interpretation of that test, and detailed information for use by authorized health
 315 workers for ongoing clinical care, early detection and containment measures (e.g. contact tracing and
 316 case reporting). Table 1 provides a non-exhaustive list of different uses of a "test report" compared
 317 to a "test result certificate".² A "test report" does not have an expiration date, and it may not
 318 necessarily be verifiable by a third party. A "test result certificate", however, requires the information
 319 contained on a SARS-CoV-2 "test report" to generate a DDCC:TR. The "test result certificate"
 320 describes the SARS-CoV-2 diagnostic test result for a tested person, and it often has a time-bound
 321 period of validity. Furthermore, unlike a "test report", the "test result certificate" is digitally signed
 322 and can be verified in an online, or offline, manner. Table 2 provides additional details related to the
 323 distinction between a "test report" and "test result certificate".

324 *Table 1 Different uses for a "test report" and a "test result certificate"*

Test Report	Test Result Certificate
<p>Test reports are widely known and accepted. There is no additional need to verify these reports as they are already commonly used for clinical care, early detection of cases, and infection containment measures:</p> <ul style="list-style-type: none"> • Clinical care • Contact tracing • Case reporting • Screening 	<p>The use of test result certificates should be determined by Member States, based on their existing legal frameworks, and their risk-based approach to pandemic control and mitigation. They can be used domestically or internationally. Some example scenarios of use include:</p> <ul style="list-style-type: none"> • International travel • Access to socioeconomic activities (e.g. restaurants, sporting events, etc.)

325

326 A DDCC:TR can be purely digital (e.g. stored in a smartphone application or on a cloud-based server)
 327 or it can be a computable representation of a test report rendered as a paper test result certificate

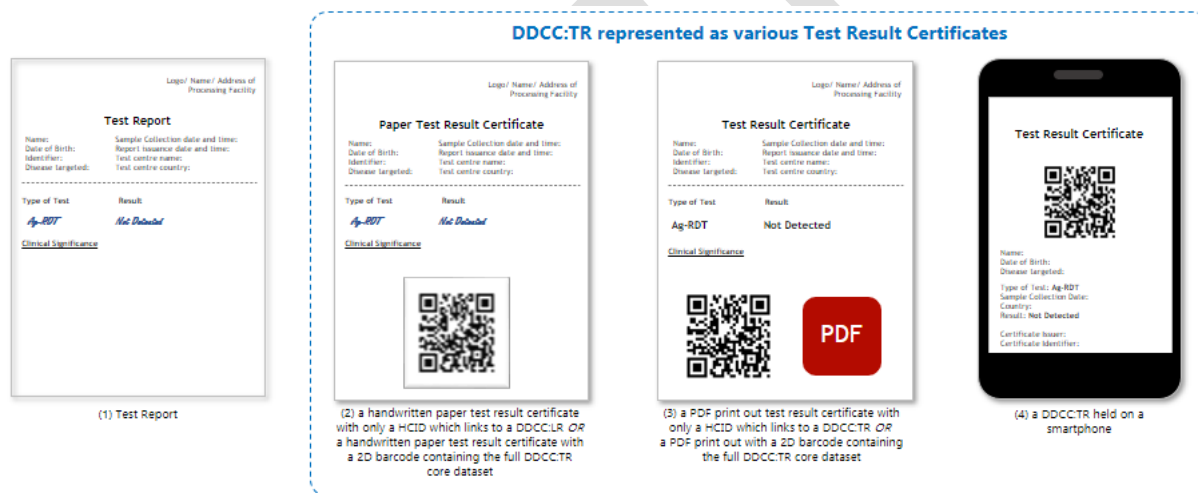
¹ Technical considerations for implementing a risk-based approach to international travel in the context of COVID-19: interim guidance (<https://apps.who.int/iris/handle/10665/342212>)

² Requirements and Scope of Digital Certificates (<https://scienctaskforce.ch/en/policy-brief/requirements-and-scope-of-digital-certificates/>)

328 (see Figure 2). A digital certificate should never require individuals to have access to a smartphone or
329 computer. The link between the paper test result certificate and the digital record can be established
330 using a one-dimensional (1D) or two-dimensional (2D) barcode that is printed on or affixed to the
331 paper. References to a “paper test result” in this document refer to a physical, paper document.

332 **The DDCC:TR is a digitally signed representation of data content that describes a SARS-CoV-2**
333 **diagnostic test result that has been conducted. That data content respects the specified core**
334 **data set and follows the Health Level Seven (HL7) Fast Healthcare Interoperability Resources**
335 **(FHIR) standard. Many representations of test result certificates can then be produced from a**
336 **DDCC:TR.**

337 *Figure 2 Different representations of a test result*



338

339 Proof Scenarios of the DDCC:TR

340 The scope of this document covers two proof scenarios of use for the DDCC:TR:

- 341 1. **Proof of Negative SARS-CoV-2 Test Result:** Test result certificates can be used as
342 documented evidence of a negative test result when SARS-CoV-2 is not detected by a SARS-
343 CoV-2 diagnostic test for viral detection (e.g. a nucleic acid amplification test (NAAT) or an
344 antigen detection rapid diagnostic test (Ag-RDT)).¹
- 345 2. **Proof of Previous SARS-CoV-2 Infection:** Test result certificates can also be used as
346 documented evidence of a previous SARS-CoV-2 infection with a positive result from a SARS-
347 Cov-2 diagnostic test for viral detection (e.g. nucleic acid amplification test (NAAT) or antigen
348 detection rapid diagnostic test (Ag-RDT)).¹ Note that Proof of Previous SARS-CoV-2 Infection
349 does not provide information on infectiousness, transmission risk; or recovery from SARS-
350 CoV-2 infection, as a proof of recovery status requires Proof of Previous SARS-CoV-2
351 Infection and proof that the individual is no longer infectious as per WHO's criteria for
352 releasing COVID-19 patients from isolation.^{1,8,9}

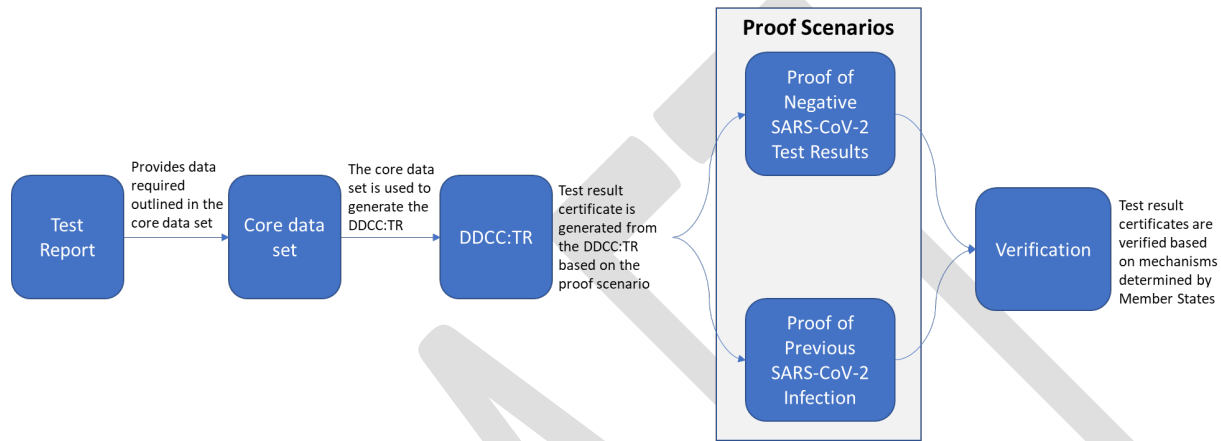
353

354 Member States can use WHO guidance to determine which type of tests are appropriate for each
355 certificate. A risk assessment on the impact of the use of diagnostic testing for the DDCC is
356 recommended. Key considerations for this risk assessment can include considerations related to

357 sensitivity and specificity of SARS-CoV-2 diagnostic tests, access to testing (e.g. does it lead to
358 inequality in society) and the Member State's epidemiological situation.¹

359
360 Figure 3 depicts the overall steps of how a test report is leveraged to create a verifiable test result
361 certificate.

362
363 *Figure 3 Overall DDCC:TR Process*



364
365
366 The level of reliability of the content within a test result certificate should be interpreted by Member
367 States according to the sensitivity and specificity of the specific SARS-CoV-2 diagnostic test used to
368 generate the test report.^{16,17,18,20,21,22,23,36} Furthermore, how these proof scenarios will be
369 implemented, and for what purpose, will depend on the legal frameworks and public health policies
370 determined by the Member State. The use of the HL7 FHIR specification is intended to facilitate the
371 application of different business rules for test result certificates in cross-border use cases. The use
372 cases within the two scenarios will further vary depending on the digital maturity and local context of
373 the country in which a DDCC:TR solution is implemented.

374 What are the minimum requirements to implement a DDCC:TR?

375 DDCC:TR should meet the public health needs of each WHO Member State, as well as the needs of
376 individuals around the world. They should never create inequity due to lack of access to specific
377 software or technologies (e.g. due to a digital divide) or access to diagnostic testing. The
378 recommendations for the implementation of DDCC:TR must therefore be applicable to the widest
379 range of use cases, catering to many different levels of digital maturity within and between
380 implementing countries. The minimum requirements were developed accordingly to allow the
381 greatest possible flexibility for Member States and their implementer(s) to build a solution that is fit
382 for purpose in the context of their overall health information systems.

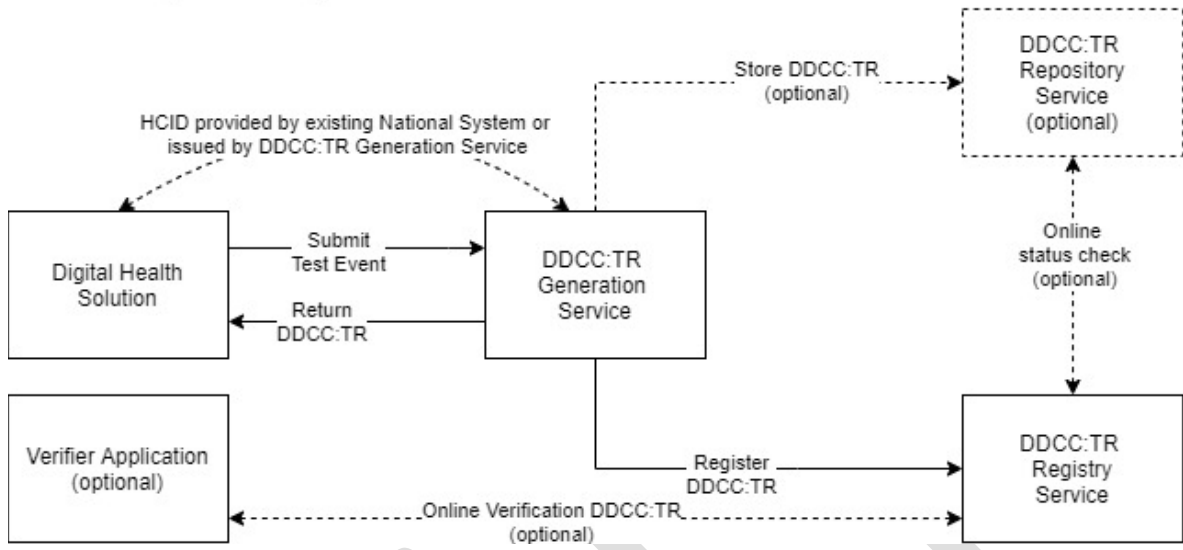
383 The minimum requirements for a DDCC:TR implementation are as follows.

- 384 • The potential benefits, risks and costs of implementing a DDCC:TR solution should be
385 assessed before introducing a DDCC:TR system and its associated infrastructure. This includes

- 386 an impact assessment of the ethical and privacy implications and potential risks that may
387 arise with the implementation of a DDCC:TR.
- 388 • Member States must establish policies for the appropriate use, data protection and
389 governance of the DDCC:TR to reduce the potential harms while achieving the public health
390 benefits involved in deploying such a solution.
 - 391 • An individual who has been tested for SARS-CoV-2 should have access to proof of the test
392 result either in a paper or digital format.
 - 393 • A digitally signed electronic version of the test report data, expressed using the HL7 FHIR
394 specification, must exist as this is the DDCC:TR. As a minimum, both the required data
395 elements in the core data set and metadata should be recorded, as described in section 5.2.
 - 396 • A Public Health Authority (PHA) must operate a DDCC:TR Generation Service to digitally sign
397 an electronic version of the required data elements in the core data set (including metadata),
398 to produce a DDCC:TR. The DDCC:TR Generation Service is responsible for taking test result
399 data, representing it using the HL7 FHIR standard, digitally signing the HL7 FHIR document
400 and updating the DDCC:TR Registry (see below).
 - 401 • Where a paper test result certificate is used, it must be associated with a health certificate
402 identifier (HCID). A DDCC:TR must be associated, as a digital representation, with the paper
403 test result certificate via the HCID. Multiple digital representations of the DDCC:TR (e.g. a 2D
404 barcode) may be associated with paper test result certificate via the HCID. One or more test
405 result certificates may be associated to a single HCID, and each test result certificate may
406 have its own identifier.
 - 407 • For any paper test result certificate, the HCID must appear in a human-readable and a
408 machine-readable format (i.e. alphanumeric characters printed on the paper, as well as
409 rendered within a 1D or 2D barcode).
 - 410 • A DDCC:TR Registry Service must exist and is responsible for storing metadata about the
411 DDCC:TR that is retrievable with the HCID. At a minimum, the DDCC:TR Registry Service
412 stores the core metadata described in section 5.2.
 - 413 • One or more DDCC:TR Repository Service(s) may exist, which can be used to retrieve a
414 DDCC:TR, in which case the location of the DDCC:TR may also be included in the metadata
415 within the DDCC:TR Registry Service.

416 Figure 4 shows the relationships between the digital services. The different services are discussed in
417 more detail in Sections 3 and 4.

418



420

421 These components are minimum requirements; Member States may adopt and develop additional
422 components for their deployed DDCC:TR.

1 INTRODUCTION

423
424
425
426
427
428
429
430
431
432
433
434
435
436
437
438
439
440
441
442
443
444
445
446
447
448

Coronavirus disease (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), was first identified in December 2019 and has spread to become a global pandemic. The pandemic has negatively impacted all societies and economies across the globe. COVID-19 vaccines are being delivered at record speed, but they are currently not equitably distributed globally. As countries reopen their economies, infection control and mitigation measures will still need to be in place due to the continued transmission in all countries. As part of an overall package of interventions, some countries are requiring proof of SARS-CoV-2 diagnostic test results to facilitate the safe and free movement of citizens, including access to socioeconomic activities and public gatherings.

Digital technology can be leveraged to augment paper-based SARS-CoV-2 diagnostic test results, which are easily lost and prone to fraud.^{3,4,5,6} There are a wide range of digital solutions that can be used to digitally document a SARS-CoV-2 diagnostic test results, and choices on design and implementation should be guided by balancing various values and contextual considerations. To ensure respect for human rights and protection of values such as equity and public trust, the technical specifications and implementation guidance outlined in this document have been built on the basis of the ethical considerations and data protection principles described in Chapter 2 of the document.

1.1 Purpose of this document

This document lays out an approach for creating a signed digital version of a SARS-CoV-2 test result certificate based on a core data set of key information to be recorded, and an approach for the digital signature. This certificate of a SARS-CoV-2 diagnostic test result, or “test result certificate”, can be used as proof of negative SARS-CoV-2 test result or proof of previous or history of SARS-CoV-2 infection. The document leverages existing free and open standards, and is driven by the ethics, use cases and requirements for Digital Documentation of COVID-19 Certificates: Test Result (DDCC:TR).

³ Joburg healthcare worker nabbed for allegedly selling fake Covid-19 test certificates (<https://www.news24.com/news24/southafrica/news/joburg-healthcare-worker-nabbed-for-allegedly-selling-fake-covid-19-test-certificates-20210822>)

⁴ Margit, M. Thousands of Israelis Join Telegram Groups Selling Fake COVID Papers - The Media Line (<https://themedialine.org/by-region/thousands-of-israelis-join-telegram-groups-selling-fake-covid-papers/>)

⁵ Deguma MC, Deguma JJ. The possible threat of faking Covid-19 diagnostic tests and vaccination certifications: a call to an immediate action. J Public Health (Oxf). 2021;43(2):e340–1. doi:10.1093/pubmed/fdab054.

⁶ Fake Covid vaccine and test certificate market is growing, researchers say (<https://www.theguardian.com/world/2021/may/16/fake-covid-vaccine-and-test-certificate-market-is-growing-researchers-say>)

449 As Member States are increasingly looking to adopt digital solutions for COVID-19 certificates, this
450 document provides a baseline set of requirements for a DDCC:TR solution that is interoperable with
451 other standards-based solutions. With the baseline requirements met, it is anticipated that Member
452 States will further adapt and extend these specifications to suit their needs, most likely working with
453 a local technology partner of their choice to implement a digital solution.

454 1.2 Target audience

455 The primary target audience of this document are national authorities tasked with creating or
456 overseeing the development of digital certificates for COVID-19. The document may also be useful to
457 government partners such as local businesses, international organizations, non-governmental
458 organizations and trade associations, that may be required to support Member States in developing
459 or deploying a DDCC:TR solution.

460 1.3 Scope

461 1.3.1 In scope

462 This document specifically focuses on how to provide signed digital certificates for SARS-CoV-2
463 diagnostic test results, including:

- 464 → Ethical and legal considerations, and privacy and data protection principles for the design,
465 implementation and use of a DDCC:TR;
- 466 → Proof scenarios and use cases arising from the operation of a DDCC:TR, including the
467 sequence of steps involved in executing the scenarios;
- 468 → A core data set with the data elements that must be included in a DDCC:TR documenting a
469 SARS-CoV-2 diagnostic test result as required by the use cases;
- 470 → A Health Level Seven (HL7) Fast Healthcare Interoperability Resource (FHIR) implementation
471 guide based on the content outlined in this guidance document, to support the adoption of
472 open standards for interoperability; and
- 473 → Approaches for implementing a DDCC:TR, including considerations for setting up a national
474 trust framework to enable digital signing of a test result certificate.

475 1.3.2 Out of scope

476 Aspects that are considered out of the scope of this work are:

- 477 → Policy guidance regarding the use of test result certificates
- 478 → Any guidance regarding interpretation or decision-making of the information provided in a
479 DDCC:TR for any purpose.
- 480 → Digital documentation of COVID-19 vaccination status certificate (which is covered in a
481 separate guidance document)⁷;
- 482 → Digital documentation of COVID-19 certificates for proof of recovery status to exempt
483 individuals from testing or quarantine requirements for travelling internationally because of
484 the uncertainty around any immunity status arising from recovery from previous infection

⁷ Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance, 27 August 2021 (<https://www.who.int/publications/i/item/WHO-2019-nCoV-Digital-certificates-vaccination-2021.1>)

- 485 and the additional data required to provide proof that an individual has met WHO's criteria
486 for releasing COVID-19 patients from isolation;^{1,8,9}
- 487 → Processes for specimen collection, data collection and sample analyzation. WHO guidance on
488 diagnostic testing for SARS-CoV-2 can be found in the separate reference
489 documents;^{16,17,18,20,21,22,23,36}
 - 490 → Processes for generation and verification of test reports (which will be up to the Member
491 States);
 - 492 → Issuance and validation of test result certificates for self-tests, at-home tests and antibody
493 tests;
 - 494 → Verification and associated processes related to identification of a Tested Person and
495 association of a Tested Person's identity to a test result certificate. Processes and
496 mechanisms for Tested Person identification should be based on existing policies and
497 mechanisms of Member States;
 - 498 → Any requirements in regard to quality assurance of laboratories, medical devices and
499 diagnostic tests used to perform the test and provide a test report. These should be guided
500 by existing national and international standards and regulations for diagnostic laboratories,
501 medical devices and tests as defined by the mandated authorities of the Member States.
 - 502 → Considerations for monitoring and evaluation of DDCC:TR roll-out and use;
 - 503 → The choice of algorithm for generating any two-dimensional (2D) barcodes, which is at the
504 discretion of the Member State. A Member State may augment the core data set with
505 additional information to provide a stronger identity binding than is presumed in this
506 document, for use cases that require it under existing Member State policies and regulations.
507 Identity binding would enable utilization of existing 2D barcode algorithms such as those set
508 out by the International Civil Aviation Organization (ICAO) and the European Union. The HL7
509 FHIR implementation guide (at <https://WorldHealthOrganization.github.io/ddcc>) provides an
510 algorithm for generating (2D) barcodes that may be used in the absence of identifying
511 information beyond that found within the core data set; and
 - 512 → Technical functionality to support selective disclosure of information contained in DDCC:TR.

513 1.4 Assumptions

514 The technological specification for a DDCC:TR is intended to be flexible and adaptable for each
515 Member State to meet its diverse public health needs as well as the diverse needs of individuals
516 around the world. It is assumed that there are common requirements across all member states and
517 that a common approach to addressing these could support economies of scale and broad
518 interoperability between solutions.

519
520 The requirements outlined are intended to allow for DDCC:TR solutions to meet the needs of a
521 country's holistic public health preparedness and response plan, while still being usable in other
522 national and local contexts. An overarching assumption is that multiple digital health products and

⁸ Criteria for releasing COVID-19 patients from Isolation (<https://www.who.int/news-room/commentaries/detail/criteria-for-releasing-covid-19-patients-from-isolation>)

⁹ COVID-19 Clinical management: living guidance (<https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1>)

523 solutions will be implemented to operationalize the requirements described in this document. This
524 allows for support of local and sustainable development so that Member States have a broad choice
525 of appropriate solutions without excluding compliant products from any source.

526

527 The following assumptions are made about Member States' responsibilities as foundational aspects
528 of setting up and running a DDCC:TR solution.

- 529 • Member States will be responsible for implementing the policies necessary to support the
530 DDCC:TR workflows, complying with their legal obligations under national and international
531 law, including, in any event, any applicable obligations related to respecting human rights
532 and data protection policies.
- 533 • Member States will adhere to ethical principles and act to prevent new inequities from being
534 created by a DDCC:TR solution.
- 535 • The DDCC:TR is a health document associated with an individual who has proved they are
536 who they claim they are, based on the policies established by the Member State; it is not,
537 itself, an identity card or identification document.
- 538 • It will be up to the Member State to determine the business rules for acceptance of a test
539 result certificate and the certificate validity period for each proof scenario for domestic
540 and/or international use cases.
- 541 • It will be up to the Member State to determine the mechanism for identification of the
542 Tested Person.
- 543 • It will be up to the Member State to determine the format in which to implement the
544 DDCC:TR. To avoid digital exclusion, the recommendations and requirements in the current
545 document are designed to support the use of paper augmented with 1D or 2D barcodes, a
546 smartphone application, or in another format.
- 547 • If a Member State decides to implement the DDCC:TR in a paper format containing a
548 machine-readable barcode (1D or 2D) (i.e. a paper test result certificate), any paper test result
549 certificate issued will need to have a health certificate identifier (HCID) in both a human-
550 readable and machine-readable format to link it to a digital record. The HCID will be used as
551 an index key for the DDCC:TR.
- 552 • Respecting the data protection principles (see section 2.2), Members States will adhere to
553 data protection and privacy laws and regulations established under national law or adopted
554 through bilateral or multilateral agreements.
- 555 • The PHA of a Member State will need to have access to a national public key infrastructure
556 (PKI) for digitally signing the DDCC:TR. This document does not describe the PKI in detail, but
557 key assumptions are that the PHA will need to:
 - 558 o utilize an existing root certificate authority or establish and maintain a root certificate
559 authority that anchors the country's PKI for the purposes of supporting DDCC:TR;
 - 560 o generate and cryptographically sign document signer certificates (DSCs);
 - 561 o authorize document signer private keys to cryptographically sign digital DDCC:TR;
 - 562 o broadly disseminate public keys if there is a desire to allow others to
563 cryptographically validate issued DDCC:TR;
 - 564 o allow for the health content contained within a traditional paper test report to be
565 digitized and verifiable by one or more digital representations, including, as a
566 minimum, a DDCC:TR identified through the HCID; a Member State may choose to
567 also generate and distribute to the DDCC:TR Holder a signed 2D barcode as a digital

- 568 representation, containing, as a minimum, the core data set content (e.g. printed on
569 or attached to the paper record, sent by email, loaded into a smartphone app,
570 downloaded from website);
- 571 o keep the signature-verification processes manageable; the number of private keys
572 used by the PHA to sign DDCC:TR should be no more than a small proportion relative
573 to the number of digital health solutions used to capture health events; and
 - 574 o ensure private keys used to sign DDCC:TR will not be associated with individual
575 health workers.
- 576 • The PHA of a Member State will need to operate a DDCC:TR Generation Service to create
577 DDCC:TR, and a DDCC:TR Registry Service to record their issuance. Optionally, the PHA may
578 also decide to provide a DDCC:TR Repository Service to allow requestors to search for, and
579 retrieve, a DDCC:TR using the HCID (for the purposes of verification).

580 1.5 Methods

581 Since the COVID-19 pandemic began, the number of digital solutions for test result certificate has
582 increased. WHO intends to remain software agnostic, and have conducted consultations with
583 multisectoral experts focused on supporting development of key standards for digital test result
584 certificate, sharing joint learning and supporting development of a governance model with a national
585 trust framework architecture. Furthermore, the WHO has developed this guidance in consultation
586 with Member States and partner organizations to ensure it is implementable in all contexts.

587 1.6 Additional WHO guidance documents

588 Specific guidance on when, where and how DDCC:TR can be used can be found in the following
589 WHO guidance documents:

- 590 → [Policy considerations for implementing a risk-based approach to international travel in the
591 context of COVID-19, 2 July 2021](#)¹⁰ [Technical considerations for implementing a risk-based
592 approach to international travel in the context of COVID-19: interim guidance, 2 July 2021](#)¹
- 593 → [Considerations for implementing and adjusting public health and social measures in the
594 context of COVID-19: interim guidance, 14 June 2021](#)¹¹
- 595 → [Statement on the ninth meeting of the International Health Regulations \(2005\) Emergency
596 Committee regarding the coronavirus disease \(COVID-19\) pandemic](#)¹²

¹⁰ Policy considerations for implementing a risk-based approach to international travel in the context of COVID-19. Geneva: World Health Organization; 2 July 2021 (<https://apps.who.int/iris/handle/10665/342235>, accessed 6 July 2021)

¹¹ Considerations for implementing and adjusting public health and social measures in the context of COVID-19. Geneva: World Health Organization; 14 June 2021 (<https://apps.who.int/iris/handle/10665/341811>, accessed 17 September 2021)

¹² [Statement on the ninth meeting of the International Health Regulations \(2005\) Emergency Committee regarding the coronavirus disease \(COVID-19\) pandemic \(who.int\)](#)

- 597 → [Statement on the eighth meeting of the International Health Regulations \(2005\) Emergency](#)
598 [Committee regarding the coronavirus disease \(COVID-19\) pandemic](#)¹³
599 → [Statement on the seventh meeting of the International Health Regulations \(2005\) Emergency](#)
600 [Committee regarding the coronavirus disease \(COVID-19\) pandemic](#)¹⁴
601 → [Statement on the sixth meeting of the International Health Regulations \(2005\) Emergency](#)
602 [Committee regarding the coronavirus disease \(COVID-19\) pandemic](#)¹⁵
603
604 Specific guidance and recommendations on SARS-CoV-2 diagnostic testing and related strategies
605 can be found in the following WHO guidance documents:
606 → [Diagnostic testing for SARS-CoV-2, 11 September 2020](#)¹⁶
607 → [COVID-19 diagnostic testing in the context of international travel: scientific brief, 16](#)
608 [December 2020](#)¹⁷
609 → [SARS-CoV-2 antigen-detecting rapid diagnostic tests: An implementation guide, 21](#)
610 [December 2020](#)¹⁸
611 → [COVID-19 natural immunity, 10 May 2021](#)¹⁹
612 → [Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities, 25](#)
613 [June 2021](#)²⁰

¹³ Statement on the eighth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic ([https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic))

¹⁴ Statement on the seventh meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic. In: World Health Organization/News [website]; 19 April 2021 ([https://www.who.int/news/item/19-04-2021-statement-on-the-seventh-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/19-04-2021-statement-on-the-seventh-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic), accessed 27 June 2021)

¹⁵ Statement on the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic. In: World Health Organization/News [website]; 15 January 2021 ([https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic), accessed 27 June 2021)

¹⁶ Diagnostic testing for SARS-CoV-2, 11 September 2020 (<https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>)

¹⁷ COVID-19 diagnostic testing in the context of international travel: scientific brief, 16 December 2020 (<https://apps.who.int/iris/handle/10665/337832>)

¹⁸ SARS-CoV-2 antigen-detecting rapid diagnostic tests: An implementation guide, 21 December 2020 (<https://www.who.int/publications/i/item/9789240017740>)

¹⁹ COVID-19 natural immunity, 10 May 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1)

²⁰ Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities: interim guidance. 25 June 2021 (<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>, accessed 8 September 2021).

- 614 → [Antigen-detection in the diagnosis of SARS-CoV-2 infection, 6 October 2021](#)²¹
- 615 → [Assessment tool for laboratories implementing SARS-CoV-](#)
- 616 [2 testing: interim guidance 23 October 2020](#)³⁶
- 617 → [Laboratory biosafety guidance related to COVID-19: interim guidance, 28 January 2021](#)²²
- 618 → [Advice on the use of point-of-care immunodiagnostic tests for COVID-](#)
- 619 [19 scientific brief 8 April 2020](#)²³
- 620

621 1.7 Other initiatives

622 The DDCC:TR core data set guidance laid out in this document may be leveraged to generate

623 artefacts conformant with other initiatives such as the International Civil Aviation Organization (ICAO)

624 guidelines on visible digital seals (“VDS-NC”) for travel-related health proofs²⁴ and the European

625 Union (EU) EU Digital COVID Certificate.²⁵ Additional technical details can be found on the DDCC:TR

626 implementation guide available at: WorldHealthOrganization.github.io/ddcc.

²¹ Antigen-detection in the diagnosis of SARS-CoV-2 infection, 6 October 2021

(<https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>)

²² Laboratory biosafety guidance related to coronavirus disease (COVID-19): Interim guidance, 28 January 2021 (<https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1>)

²³ Advice on the use of point-of-care immunodiagnostic tests for COVID-19 (<https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19>)

²⁴ Guidelines: visible digital seals (“VDS-NC”) for travel-related health proofs. International Civil Aviation Organization (ICAO) Technical Advisory Group (TAG) on the Traveler Identification Group (TRIP); no date (<https://www.icao.int/Security/FAL/TRIP/PublishingImages/Pages/Publications/Guidelines%20-%20VDS%20for%20Travel-Related%20Public%20Health%20Proofs.pdf>, accessed 27 June 2021).

²⁵ EU Digital COVID certificate. In: European Commission [website]; no date (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en, accessed 27 June 2021).

2 ETHICAL CONSIDERATIONS AND DATA PROTECTION PRINCIPLES

As with any digital solution, there are ethical considerations, such as potential impacts on equality and human rights, and data protection principles that need to inform the design of the DDCC:TR technical specifications, as well as provide guidance on how resulting solutions can be ethically implemented.²⁶ The following sections discuss key ethical considerations and data protection principles that Member States are encouraged to – and, where they have legal obligations, must – include in their respective deployments of DDCC:TR. These ethical considerations and data protection principles have also informed the design criteria for a DDCC:TR outlined in the following section.

2.1 Ethical considerations for a DDCC:TR

SARS-CoV-2 diagnostic test results may be documented for individual health purposes such as diagnosis and continuity of care, and for public health uses for infection detection and containment (e.g. surveillance, population screening to detect unknown cases of infection, and contact tracing).²⁰ As proof of a negative SARS-CoV-2 test result, or proof of previous SARS-CoV-2 infection, a DDCC:TR may be issued to individuals based on test results initially recorded for these individual or public health reasons, or they could undergo testing to specifically obtain a DDCC:TR. The functions of a DDCC:TR are distinct from the aforementioned individual or public health purposes because it is a test certificate (as opposed to a test report) issued to individuals that may be used for individualized exemptions from public health and social measures (e.g. post-exposure quarantine), or to facilitate safe free movement or regulation of access to socio-economic activities during the COVID-19 pandemic as required or permitted by legitimate authorities. This section presents the ethical considerations for designing, developing and deploying a DDCC:TR and provides some recommendations for their ethical implementation.

2.1.1 Key ethical considerations for current proposed uses of DDCC:TR

Ethics should be an integral part of the design and deployment of a DDCC:TR solution. Many different considerations will need to be made and weighed against each other. Often, the evidence is uncertain, and there are many different competing ethical perspectives and positions. Evidence alone will not provide the right answer, nor will a simple set of ethical rules. Public health action requires careful judgement and acceptance of responsibility and accountability for the outcomes. Several different ethical considerations should be considered, including the ethical aims of public health action, and procedural values for governing the decision-making process.

²⁶ Committee on Bioethics. Statement on human rights considerations relevant to “vaccine pass” and similar documents. Strasbourg: Council of Europe; 4 May 2021 (<https://rm.coe.int/dh-bio-2021-7-final-statement-vaccines-e/1680a259dd>, accessed 27 June 2021).

661 **2.1.1.1 Ethical Aims**

662 A good starting point is to identify how the use of a DDCC:TR can contribute to important general
663 duties of any government through public health activity in response to the COVID-19 pandemic.

664 Three key ethical aims of public health action are:

665

- 666 1. **PROTECTING AND PROMOTING WELFARE:** to protect and promote the welfare of
667 individuals and communities.
- 668 2. **ENSURING EQUAL TREATMENT:** to ensure equal treatment for all individuals and prevent
669 or mitigate, as far as possible, avoidable and unfair health differences (i.e. health inequities)
670 within the boundaries of the state.
- 671 3. **ENGENDERING PUBLIC TRUST:** to create and maintain trust in public health activities as
672 part of the health system.

673

674 **1. Protecting and Promoting Welfare**

675

676 The primary function of a DDCC:TR is to digitally document, issue and verify proof of SARS-CoV-2
677 diagnostic test result for individuals in a reliable and accurate manner, which can be used exempt
678 holders from certain public health and social measures; or, to facilitate their safe free movement and
679 access to socio-economic activities in lieu of or in addition to a DDCC:VS, as required or permitted by
680 legitimate authorities as part of the overall public health response to the COVID-19 pandemic. Such
681 a function contributes to the achievement of welfare promotion, by increasing opportunities for
682 individuals and communities to pursue their own economic and social goals through greater access
683 to areas of life that would otherwise be curtailed during the pandemic, while at the same time,
684 mitigating risks of disease spread and its negative consequences due to increased movement and
685 congregation during the pandemic.

686

687 **2. Ensuring Equal Treatment**

688

689 Equal treatment requires respecting and protecting all persons equally and acting to ensure, as far as
690 possible, that there is no wrongful or unfair discrimination which may amount to a violation of
691 human rights. In contexts that require or permit the use of a SARS-CoV-2 test result certificate for
692 individualized exemptions from public health and social measures, or individualized access to certain
693 activities and services, a DDCC:TR helps to prevent discrimination against those who have not been
694 vaccinated and are not able to provide a DDCC:VS; and to promote equity through the mitigation of
695 possible disadvantages in opportunities for participation in civil, social, and economic life. For
696 example, DDCC:TR will be especially useful for those who lack access to, or who are not prioritized to,
697 receive a COVID-19 vaccine (e.g. children and young adults); those who are unable to be vaccinated
698 due to medical reasons (e.g. individuals who are at risk of a severe allergic reaction); those who
699 choose not to be vaccinated despite vaccine availability; those who are vaccinated but cannot obtain
700 or provide proof of a valid vaccination status (e.g. individuals who obtain COVID-19 vaccines from
701 illicit sources, recipient country does not recognize or accept the vaccine brand); and, those who are
702 waiting to receive a subsequent dose according to recommended vaccination schedules. Depending
703 on epidemiological and other reasons, a DDCC:TR may also be required as an additional certificate
704 for individuals with a DDCC:VS to ensure safe free movement and gatherings, especially in
705 environments that pose higher risks.

706

707 Like the introduction of DDCC:VS, use of a DDCC:TR as a “health pass” for access to socio-economic
708 activities (e.g. work, domestic and international travel, cultural, entertainment, leisure, conferences,
709 industry trade shows and sporting events) may exacerbate inequalities highlighted by or created by
710 the pandemic, and increase prior disadvantages of particular groups, for the following reasons:

711

712 → Members of certain populations (e.g. refugees, individuals with illegal or insecure residency status,
713 the homeless, and those who live below or at poverty levels) are disproportionately less likely to have
714 opportunities for SARS-CoV-2 testing and certification due to lack of availability, accessibility,
715 affordability (where testing is not free), and other issues.

716

717 → Individuals who rely on DDCC:TR for safe movement may face more burdens than those who have
718 a DDCC:VS. For example, individuals who rely on DDCC:TR as a requirement to perform their work, to
719 travel, or access other socio-economic activities may need to undergo multiple or more frequent
720 testing, which requires time and expense and may place substantial burdens on particular groups. In
721 addition, individuals with a DDCC:TR may be required to comply with additional public health and
722 social measures (e.g. travel quarantine, which incurs additional costs) which do not apply to those
723 with a DDCC:VS. Such measures and their burdens may deter participation in the activities that
724 require a COVID-19 certificate and increase the disadvantages of those without access to
725 vaccinations.

726

727 → A DDCC:TR may increase digital exclusion if individuals lack access to the digital infrastructure or
728 the knowledge and skills to utilize it, or if there is disparity in the establishment or support of the
729 digital infrastructure across, or within, Member States.

730

731 → Individuals with disabilities may face barriers, depending on the administration process and
732 design, in obtaining and using a DDCC:TR.

733

734 An equitable approach to the use of DDCC:TR will ensure that the burdens for individuals who use a
735 DDCC:TR for safe free movement are not disproportionate, and that DDCC:TR and DDCC:VS holders
736 are treated equivalently with respect to exemptions from public health restrictions, unless there are
737 evidence-informed, risk-based reasons to impose differentiated measures. Ensuring an equitable
738 approach also means that those with greater barriers to obtaining and using a DDCC:TR are
739 supported to a greater extent than others.

740

741 **3. Engendering Public Trust**

742

743 Trust is vital to ensure the benefits of DDCC:TR for individuals, communities, and the whole
744 population. For example, the provision of robust data protection measures and the use of procedural
745 considerations, outlined in section 2.2, may contribute to the maintenance of trust in public health
746 systems. This in turn contributes to the delivery of the aim of protecting and promoting welfare. To
747 enhance trust, a DDCC:TR should only be used for its intended purpose, as illegitimate uses (e.g.
748 unjustified exclusion from a socio-economic activity) may result in legitimate uses (e.g. facilitation of
749 safe free movement) being undermined.

750

751 **2.1.1.2 Procedural Values**

752 The pursuit of the ethical aims above can raise additional ethical issues. One way to mitigate ethical
753 issues associated with the pursuit of these ethical aims via deployment of a DDCC:TR is by ensuring
754 that decision-making processes uphold important procedural values. These values, in turn, also
755 contribute to the effective pursuit of the aims. Such values include:

756

757 → **TRANSPARENCY:** providing clear, accurate and publicly accessible information about the basis
758 for the policy and the process by which it is made, from the onset (i.e. notifying the public that such
759 a process is underway). Such a process disciplines decision-making and ensures accountability by
760 providing clear and sound rationale.

761

762 → **INCLUSIVENESS:** providing opportunities for all relevant stakeholders to participate in policy
763 formulation and design. This may be achieved through public consultation or engagement with a
764 wide range of experts, industries, and members of the public to address real and perceived issues.
765 Particularly important stakeholders are those who are likely to be disadvantaged or face distinct or
766 heightened risks with the implementation of DDCC:TR (e.g. individuals who have concerns with
767 SARS-CoV-2 testing due to, for example, the burdens of isolation if one is tested positive for an
768 active infection; individuals with insecure or invalid citizenship or residency status; and individuals
769 who may face barriers in obtaining or using a DDCC:TR).

770

771 → **ACCOUNTABILITY:** providing a clear description for who is responsible for what, and how
772 responsibilities will be regulated and enforced.

773

774 → **RESPONSIVENESS:** providing mechanisms and opportunities to review and revise decisions and
775 policies based on evolving scientific evidence and other relevant data.

776

777 **2.1.1.3 Recommendations**

778 The design, development, and implementation of a DDCC:TR raises many ethical issues and human
779 rights challenges. The following series of recommendations are for the two proof scenarios: Proof of
780 negative SARS-Cov-2 test result and Proof of previous SARS-CoV-2 infection.

781

782 **1. TESTING AND CERTIFICATION SHOULD BE AS ACCURATE AS POSSIBLE:** Use of DDCC:TR to
783 facilitate exemptions from public health and social measures, safe free movement, or access to socio-
784 economic activities is based on the assessment that those with the certificate are at sufficiently low risk
785 of transmitting SARS-CoV-2 to others (proof of negative SARS-CoV-2 test result), and/or at sufficiently
786 low risk of severe disease and death if they contract COVID-19 (proof of previous SARS-CoV-2
787 infection). Therefore, testing and certification should be reliable and accurate to minimize false
788 negatives to mitigate the risk of disease spread or the incidence of severe cases (which would help
789 prevent healthcare resources and systems from being strained), as well as to minimize false positives
790 to prevent the unnecessary imposition of public health and social restrictions on individuals. Member
791 States should conduct the necessary risk assessment to determine what types of SARS-CoV-2
792 diagnostic tests for proof of negative SARS-CoV-2 test result are appropriate and sufficiently accurate
793 and reliable for the different uses of DDCC:TR.^{1,10,17,20,21} It is also for Member States to determine the
794 requirements for proof of a previous SARS-CoV-2 infection to obtain a DDCC:TR, such as the type of

795 test needed and who should carry out the testing, based on relevant scientific information and risk
796 assessment.^{16,17,18,20,21,22,23,36}
797

798 **2. THE SCOPE OF USE OF A DDCC:TR SHOULD BE CLEARLY DEFINED.** A DDCC:TR can be used for
799 a number of purposes. To prevent any potential misuse, any DDCC:TR policy should set out clear and
800 specific policies, and laws if needed, on permitted uses as well as prohibited uses. Use of a DDCC:TR
801 in response to a public health emergency such as the COVID-19 pandemic is only justified when it
802 supports the pursuit of a legitimate aim during the emergency and is provided for by policy,
803 regulations or law; proportionate; of limited duration; based on scientific evidence; and, not imposed
804 in an arbitrary, unreasonable or discriminatory manner.
805

806 **3. DDCC:TR SHOULD NOT BE REQUIRED TO ACCESS ESSENTIAL SERVICES.** COVID-19 certificates
807 should not be a requirement to access goods and services that support the basic necessities of daily
808 life (e.g. health and social services, buying groceries, public transport). Exclusion of those without a
809 COVID-19 certificate from goods and services that meet basic needs would violate human rights. In
810 addition, any public health benefits would likely be outweighed by the harms to individuals and
811 communities. Any potential increased risk that those without a COVID-19 certificate might pose to
812 others through use of such services could be mitigated by compliance with public health and social
813 measures by everyone (e.g. wearing a mask, physical distancing) as well as broader measures such as
814 contact tracing and isolation.
815

816 **4. POTENTIAL BENEFITS, RISKS AND COSTS SHOULD BE ASSESSED BEFORE INTRODUCTION OF
817 A DDCC:TR.** The creation or development of a DDCC:TR should be based on an assessment of the
818 benefits and costs of its uses, and the advantages and disadvantages of the proposed infrastructure,
819 in comparison with other potential or existing ways to record, validate and verify test results and
820 records. A benefits and costs assessment, as a function of stewardship of scarce public health
821 resources, should take short-, medium- and long-term views. A short-term view would consider the
822 utility and opportunity cost of investing in a DDCC:TR infrastructure over other measures for
823 responding to COVID-19 and meeting other public health needs during a public health crisis. A long-
824 term view would consider the potential advantages of a DDCC:TR for strengthening the public health
825 system, such as creating a system for health certification that could be leveraged to ensure safe
826 movement for future epidemics and pandemics. In addition, the ethical issues and risks raised by a
827 DDCC:TR, and the impact of trade-offs between the benefits and burdens accrued to individuals,
828 families, businesses, and other relevant stakeholders should be assessed prior to implementation.
829 Community engagement, particularly with representatives of groups who are likely to face increased
830 disadvantages or risks, should also be conducted.
831

832 **5. OBTAINING AND USING A DDCC:TR SHOULD BE AS INCLUSIVE AND FAIR AS POSSIBLE.**
833 DDCC:TR solutions should be as inclusive as possible and should not create or exacerbate
834 disadvantages. To achieve this, tests should be made generally available, accessible, timely, and
835 affordable and/or free of charge. For the specific activities, venues or services that require a DDCC:VS
836 for access, DDCC:TR can be permitted as an alternative certificate to a DDCC:VS to regulate safe free

837 movement.²⁷ It is necessary to provide cost-effective DDCC:TR solutions, including paper-based
838 certificates, for individuals and groups with existing disadvantages, such as those without digital
839 skills, those with disability barriers, those living in areas with poorer digital connectivity, and those
840 who are undocumented migrants. Any additional public health and social measures imposed on
841 individuals with a DDCC:TR that are not required for those with a DDCC:VS should be based on clear
842 scientific evidence that the additional measures are necessary and proportionate and do not
843 constitute violation of human rights.

844
845 **6. ALL COMMUNICATION SHOULD BE CLEAR AND TRANSPARENT.** Relevant information
846 pertaining to the implementation of a DDCC:TR should be communicated in a transparent and
847 accessible manner (including in language that is comprehensible to affected parties), which would
848 help contribute to the promotion of public trust and acceptance of DDCC:TR. This communication
849 includes how DDCC:TR would work to benefit individuals, public health and society at large; the
850 threshold or criteria for why DDCC:TR is used in certain contexts and not others, and when its use
851 may be removed; the policies and mechanisms in place to limit access to and use of a DDCC:TR by
852 third parties; and whether DDCC:TR data are linked to other types of data and the purposes of any
853 data linkage. Relevant information would also include specific requirements of the testing process
854 (e.g. recognized tests and providers, number of tests), costs, the duration of validity of the certificate,
855 the locations or activities for which a DDCC:TR is used, the restrictions that would be removed or
856 remain for a DDCC:TR holder in a given context, and the implications of testing positive for active
857 infection and required or recommended actions (e.g. the need to self-isolate and physically distance
858 from others).

859
860 **7. THE DDCC:TR SHOULD BE CONSTANTLY MONITORED FOR IMPACT AND ADJUSTED AS**
861 **NECESSARY.** Post implementation, it is important to monitor and evaluate the effects of DDCC:TR
862 regularly in terms of positive and negative outcomes (e.g. impact on public health, equity, and
863 human rights) and to consider potential interventions to mitigate negative outcomes. Such
864 monitoring and evaluation should also review uses that do not fit neatly into legitimate and
865 illegitimate use categories set by policies, to consider whether these uses should be continued,
866 modified, or stopped. Adequate resources should be provided to support monitoring and evaluation
867 activities, and the information should be made publicly available to promote transparency and trust.

868
869 **8. THERE SHOULD BE ETHICAL SAFEGUARDS WHEN DDCC:TR DATA IS USED FOR SCIENTIFIC**
870 **PURPOSES.** Use of DDCC:TR data for scientific purposes (e.g. research) is ethically justifiable when
871 they provide information and evidence to support public health responses to the pandemic, and
872 when ethical safeguards are in place to protect public and individual interests and promote public
873 trust. In this regard, appropriate ethics oversight and governance of such data uses (including for

²⁷ Scottish Human Rights Commission. COVID-19 status certificates: human rights considerations. April 2021 (https://www.scottishhumanrights.com/media/2176/21_04_28_-_covid-certificates-and-human-rights-vfinal.pdf, accessed 30 August 2021)

874 non-research activities such as surveillance²⁸) should be implemented. Data subjects and other
875 members of the public should also be informed of the nature and occurrences of these activities in
876 advance, and any options they may have for controlling or limiting DDCC:TR data for these uses.
877 DDCC:TR data are sensitive and should, in general, be anonymized (or pseudonymized, or de-
878 identified) for scientific purposes, to minimize risks to the data subjects. Where DDCC:TR data need
879 to be retained in an identifiable form for these purposes, consideration should be given to whether
880 consent is required or should be waived based on satisfaction of appropriate ethical criteria (e.g.
881 minimal risk, impracticability of obtaining consent, no adverse effects on the rights and welfare of the
882 data subjects and serving a public health good).
883

884 2.2 Data protection principles for a DDCC:TR

885 The previous section highlights the importance of data protection to the fostering of public trust in
886 the implementation of DDCC:TR. This section presents specific and fundamental data protection
887 principles for the deployment of a DDCC:TR as a response to the COVID-19 pandemic. The principles
888 are designed to provide guidance to the national authorities tasked with creating or overseeing the
889 development of the DDCC:TR. The objectives are to encourage Member States to adopt or adapt
890 their national laws and regulations, as necessary, respect personal data protection principles, and
891 ensure respect for the human rights and fundamental freedoms of individuals, in particular the right
892 to privacy, to build trust in the implementation of the DDCC:TR.

893 The data protection principles are as follows.

894 1. LAWFUL BASIS, LEGITIMATE USE AND FAIR PROCESSING

895 The personal data collected in the interest of the application of the DDCC:TR should be processed in
896 a fair and non-discriminatory manner, based on the consent of the data subject, the necessity to
897 protect the vital interests of the data subject or of another data subject, or explicitly justified by
898 legitimate public health objectives.

899 The processing of personal data in the interest of the application of the DDCC:TR should have a
900 lawful basis. It should comply with applicable laws, including broader human rights standards and
901 data privacy and data protection laws, as well as respecting the highest standards of confidentiality,
902 and moral and ethical conduct.

903 Personal data collected for the application of the DDCC:TR should only be accessed, analysed, or
904 otherwise used while respecting the legitimate interests of the data subjects concerned. Specifically,
905 to ensure that data use is fair, data should not be used in a way that violates human rights or in any
906 other ways that are likely to cause unjustified or adverse effects on any individual(s) or group(s) of
907 individuals.

908 Any retention of personal data processed in the interest of the application of the DDCC:TR should
909 have a legitimate and fair basis. Before any data are retained, the potential risks, harms and benefits

²⁸ Guidelines on ethical issues in public health surveillance. Geneva: World Health Organization, 2017
(<https://www.who.int/publications/i/item/who-guidelines-on-ethical-issues-in-public-health-surveillance>,
accessed 15 Sept 2021)

910 should be considered. Personal data should be permanently deleted after the time needed to fulfil
911 their purpose unless their extended retention is justified for specified purposes.

912 **2. TRANSPARENCY**

913 The processing of personal data in the interest of the application of the DDCC:TR should be carried
914 out to be transparent to the data subjects. Data subjects should be provided with easily accessible,
915 concise, comprehensible and reader-friendly information in clear and unambiguous language
916 regarding: the purpose of the data processing; the type of data processed; how data will be retained,
917 stored and shared, or made otherwise accessible; who will be the recipients of the data and how long
918 the data will be retained. Information should also be provided to data subjects on applicable data
919 retention schedules, and on how to exercise their data subject rights. A list of entities authorized to
920 process personal data in the interest of the application of the DDCC:TR should be made public.

921 **3. PURPOSE LIMITATION AND SPECIFICATION**

922 Personal data collected in the interest of the DDCC:TR should not be processed in ways that are
923 incompatible with specified legitimate purposes. The use of this data for any other purpose,
924 including the sale and use of personal data for commercial purposes, should be prohibited, except
925 with the explicit, unambiguous and freely given prior consent of the data subject.

926 The purposes for which personal data are processed in the interest of the application of the DDCC:TR
927 should be specified no later than at the time of data collection. The subsequent use of the personal
928 data should be limited to the fulfilment of those specified purposes.

929 Transfer of personal data processed in the interest of the application of the DDCC:TR to a third party,
930 or allowing access by a third party, should only be permitted if the principles underlying the lawful
931 basis, as referred to above, are met; and the third party affords appropriate protection that is equal
932 to or higher than those protections provided by the data controller, for the personal data.

933 Personal data processed in the interest of the application of the DDCC:TR should be relevant to the
934 purposes for which they are to be used and, to the extent necessary for those purposes, be accurate,
935 complete, and kept up to date.

936 **4. PROPORTIONALITY, NECESSITY AND DATA MINIMIZATION**

937 The processing of personal data should be relevant (have a rational link to specified purposes),
938 adequate (sufficient to properly fulfil the specified purposes) and limited to what is required to fulfil
939 the specified purposes. The processing of personal data should not be excessive for the purposes for
940 which those personal data are collected. Data collected and retained on the DDCC:TR should be as
941 limited as possible, respecting proportionality and necessity. Data access, analysis or other use
942 should be kept to the minimum necessary to fulfil their purpose. The amount of data, including their
943 granularity, should be limited to the minimum necessary. Selective disclosure mechanisms should be
944 used to support proportionate data access.

945 Data use should be monitored to ensure that it does not exceed the legitimate use. Personal data
946 retained in the interest of the application of the DDCC:TR should only be retained and stored for the
947 time that is necessary for specified purposes. Personal data accessed at the point of verification of
948 the DDCC:TR should not be retained and stored in a repository, database or otherwise.

949 **5. CONFIDENTIALITY AND SECURITY**

950 Personal data processed in the interest of the application of the DDCC:TR should be kept confidential
951 and not disclosed to unauthorized parties; personal data should only be accessible to the data
952 subject or to other explicitly authorized parties.

953 With regard to the nature and sensitivity of the personal data processed in the interest of the
954 application of the DDCC:TR, appropriate organizational, physical and technical security measures
955 should be implemented for both electronic and paper-based data to protect the security and
956 integrity of personal data. This protection includes measures to protect against personal-data breach,
957 and measures to ensure the continued availability of that personal data for the purposes for which it
958 is processed; this applies regardless of whether the data are stored on devices, applications, servers
959 or networks, or if they are sent through services involved in collection, transmission, processing,
960 retention or storage.

961 Taking into account the available technology and cost of implementation, robust technical and
962 organizational safeguards and procedures (e.g. efficient monitoring of data access, data breach
963 notification procedures) should be implemented to ensure proper data management throughout the
964 data life cycle. Such measures are to prevent any accidental loss, destruction, damage, unauthorized
965 use, falsification, tampering, fraud, forgery, unauthorized disclosure or breach of personal data.

966 In case of a security breach leading to the accidental or unlawful destruction, loss, alteration,
967 unauthorized disclosure of or access to personal data transmitted, stored or otherwise processed,
968 DDCC:TR Holders should be notified in an appropriate and timely manner. DDCC:TR Holders should
969 be notified of: any data breach; the nature of the data breach, which may affect their rights as data
970 subjects; and recommendations to mitigate potential adverse effects.

971 **6. DATA SUBJECT RIGHTS, COMPLAINT AND LEGAL REDRESS**

972 DDCC:TR Holders, if they have provided sufficient evidence of being the DDCC:TR Holder, should be
973 able to exercise data subject rights. These data subject rights include the right of access, correction,
974 deletion, objection and restriction of personal data, subject to conditions regulated by national law,
975 decree, regulation or other official act or order. Data subjects have the right to seek redress by a
976 complaint procedure if they suffer harm or loss as a result of misused DDCC:TR data or incorrect or
977 incomplete data. Data subjects should be provided with easily accessible, concise, comprehensible
978 and reader-friendly information about how they might exercise their data subject rights and how to
979 seek legal redress, including how they can exercise any rights in the case of alleged fraud.

980 **7. INDEPENDENT OVERSIGHT AND ACCOUNTABILITY**

981 An independent public authority should be responsible for monitoring whether any data controller
982 and data processor involved in the processing of personal data in the interest of the DDCC:TR adhere
983 to the principles and may recommend revoking the authorization to collect or otherwise process
984 DDCC:TR data. Such a public authority should have access to all information necessary to fulfil its
985 task. Adequate policies and mechanisms should be in place to ensure adherence to these principles.

986 **2.3 DDCC:TR design criteria**

987 Due to the ethical considerations and data protection principles outlined above, the following design
988 criteria were determined to inform the requirements for implementing a DDCC:TR as part of a holistic
989 package of interventions to address the COVID-19 pandemic.

- 990 1. Implementation of the DDCC:TR should not increase health inequities or increase the digital
991 divide.
- 992 2. Everyone who has a valid negative SARS-CoV-2 test result for active infection or valid proof
993 of previous SARS-CoV-2 infection, within the window period recognized by relevant
994 competent authorities, has the right to obtain and hold a DDCC:TR where it is a prerequisite
995 for access to socio-economic activities.
- 996 3. The DDCC:TR needs to be in a format that can be accessible to all (e.g. in paper and digital
997 formats). Any solution should also work in online and offline environments across multiple
998 platforms – paper and digital.
- 999 4. Individuals should not be treated differently or given different levels of trust due to the
1000 format of the DDCC:TR they are using (e.g. there should be no discrimination based on
1001 whether someone is presenting a DDCC:TR on a smartphone or a paper card).
- 1002 5. Any solution should not be at an additional cost to the person who has taken the relevant
1003 diagnostic test(s) to evidence their SARS-CoV-2 diagnostic test result (negative SARS-CoV-2
1004 infection or proof of previous SARS-CoV-2 infection within a valid time period).
- 1005 6. The interoperability specifications used in DDCC:TR solutions should utilize open standards
1006 to ensure equitable access to a range of non-proprietary digital tools.
- 1007 7. The infrastructure that the DDCC:TR solution is built on should ensure that individuals and
1008 Member States are not locked into a commitment with only one vendor.
- 1009 8. Any solution should be as environmentally friendly as possible. The most environmentally
1010 sustainable options should be pursued to reduce any additional undue harm to the
1011 environment.
- 1012 9. Any solution should be designed to augment and work within the context of existing health
1013 information systems, as appropriate.
- 1014 10. Any solution should not share or store more data than is needed to successfully execute its
1015 tasks. The DDCC:TR should contain only the minimum data necessary to achieve the
1016 facilitation of safe movement and access to socioeconomic activities, and privacy-protecting
1017 features should be built into the system and be respected accordingly
- 1018 11. Anti-fraud mechanisms should be built into any approach.
- 1019 12. Digital technology should not be the only mechanism available for verification. There should
1020 always be possible ways to revert to a paper-only manual verification of test result
1021 certificates. For example, a paper representation may be printed from the DDCC:TR and
1022 combined with an identity verification as outlined within the policy set by the public health
1023 authority.

1024
1025 It is important to note that despite the technological design criteria outlined here, it will be essential
1026 for Member States to ensure that the legal and policy frameworks are in place to support responsible
1027 use of the DDCC:TR as defined by the Member State.

3 TEST RESULT CERTIFICATE GENERATION

1028
1029
1030
1031
1032
1033
1034
1035
1036
1037
1038
1039
1040
1041

1042

1043
1044
1045
1046
1047
1048
1049
1050
1051

This section broadly describes the use cases and actors involved in generating a test result certificate. In the context of COVID-19, a DDCC:TR can be employed to generate test result certificate for either proof of a negative SARS-CoV-2 test result or proof of previous SARS-CoV-2 infection.

Processes for specimen collection, data collection, sample analysis and the generation of test reports (if required) will be defined by Member States and are outside the scope of this document. These activities will serve as pre-conditions for test result certificate generation. Furthermore, Member States will need to define how a certificate will be generated, issued and adapted to their own contexts and levels of digital maturity, in compliance with their legal and policy frameworks.

Note that a test report and a test result certificate (DDCC:TR) serve different purposes (Table 2):

Table 2 Differences between a test report and a test result certificate

	Test Report	Test Result Certificate
Features	<ul style="list-style-type: none"> → Contains all relevant medical information → Encodes detailed information for use by authorized health professionals → Has no expiration date → Test report(s) in combination with clinical symptoms can aid diagnosis or evaluation of disease status → May not be verified by a third party 	<ul style="list-style-type: none"> → Requires information contained on a test report to generate a DDCC:TR → Provides a claim about the SARS-CoV-2 diagnostic test result of a tested person → Contains the minimum information necessary for verifying the validity of the claim → Has a time-bound validity period → Is digitally signed and can be verified in an offline or online manner
Possible Uses	<ul style="list-style-type: none"> → For individual health purposes and clinical care → For early detection and containment measures (e.g. contact tracing, case reporting, surveillance, screening) → Depending on Member State policies, used to inform vaccination requirements 	<ul style="list-style-type: none"> → For individualized exemptions from public health and social measures (e.g. post exposure quarantine) → To facilitate safe and free movement and access to socioeconomic activities (e.g. national and/or international travel, participation in public gatherings)

3.1 Key settings, personas and digital services

Certificate generation is expected to involve the following settings:

1. **Certificate generation site:** where the certificate is generated. This site may be the same as where pre-conditions for the certificate generation process take place (i.e. where the testing takes place), but it does not have to be. The site would operate under the auspices of the Public Health Authority (PHA). This could be a lab or other type of facility, as determined by the Member State.
2. **Certificate issuance site:** where the certificate is issued to the DDCC:TR Holder. This may be the same as the certificate generation site or could be an online website and/or application.

1052
 1053
 1054
 1055
 1056
 1057

The key personas, or relevant stakeholders, involved in the provision of a DDCC:TR are outlined in Table 3. These key personas are anticipated to interact with the digital services outlined in Table 4 in ways supportive of the workflow’s successful execution.

Table 3 Key personas for Certificate Generation

Role	Description
Tested Person	The person who is tested.
DDCC:TR Holder	The person who has the Tested Person’s test result certificate. The person is usually the Tested Person but does not have to be. For example, a caregiver may hold the DDCC:TR for a child or other dependant.
Data Entry Personnel	The person who enters the information about the Tested Person (as outlined in the core data set) that was manually recorded at a sample collection site into a digital system. If a Digital Health Solution, such as a laboratory information system (LIS) is in place, lab technicians can also be considered Data Entry Personnel as they would be able to digitally document a lab result through the LIS right away.
Public Health Authority (PHA)	An entity or organization under whose auspices the test is performed and the DDCC:TR is issued.

1058
 1059

Table 4 Digital services for Certificate Generation

Digital service	Description
Digital Health Solution	<p>A secure system that is used to record and/or manage a digital record of the DDCC:TR core data elements (e.g. Laboratory Information System, Laboratory Management Information System).</p> <p>The Digital Health Solution is responsible for distribution the DDCC:TR and any associated representations (such as a QR code) to the DDCC:TR Holder, based on the PHA policy.</p>
DDCC:TR Generation Service	<p>The service that is responsible for taking data about a SARS-CoV-2 diagnostic test result, converting that data to use the HL7 FHIR standard, signing that HL7 FHIR document and returning it to the Digital Health Solution. The signed HL7 FHIR document is the DDCC:TR.</p> <p>This service also registers this signed document in a location available to the DDCC:TR Registry Service and (optionally) persisting the signed HL7 FHIR document to the DDCC:TR Repository Service and potentially generates extra representations, such as QR code representations.</p>
DDCC:TR Registry Service	The service that persists a record of the DDCC:TR certificate metadata and (optionally) the location of the DDCC:TR Repository Service endpoint, which can be leveraged for online verification.
DDCC:TR Repository Service	The DDCC:TR Repository Service is an optional digital service that has a repository, or database, of all the DDCC:TR. It is able to return a copy of the DDCC:TR (the signed HL7 FHIR document) and potentially the barcode representation (e.g. a QR code) of the signed HL7 FHIR document.

3.2 Certificate Generation workflow

1061

1062

The process for Certificate Generation is summarized in Figure 5. It is assumed that for a certificate to be generated, the following activities have already taken place as per the norms and processes of the Member State:

1063

1064

1065

1066

1067

1068

1069

1070

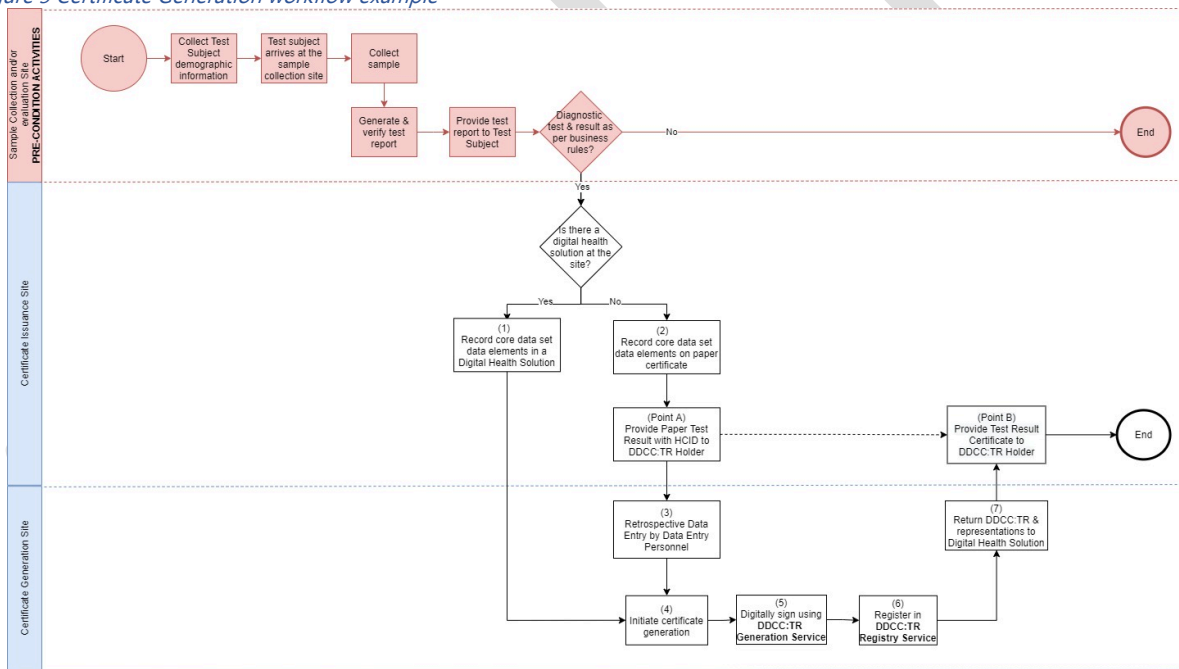
1071

1072

1073

1. An individual has arrived at the sample collection site to be tested for SARS-CoV-2.
2. Demographic data has been captured in accordance with Member State policies.
3. The specimen has been collected and analysed.
4. A test report has been generated and verified by authorized personnel.
5. A test report is provided to the Tested Person.
6. The test type and corresponding result meet the business rules to generate a DDCC:TR, as determined by the Member State.

Figure 5 Certificate Generation workflow example



1074

1075

1076

The workflow’s actors and settings may be described as follows:

1077

1078

1079

1080

1081

1082

1083

1084

1085

1086

1. The Certificate Issuance Site SHALL have a local Digital Health Solution. The Data Entry Personnel records details of the test event, which SHALL be recorded based on the DDCC:TR core data.
2. If a Digital Health Solution is not available at the Certificate Issuance Site, the test result certificate is intended to be captured initially in a paper format, data elements of the DDCC:TR core data set content SHALL be entered onto the paper test result certificate. The paper test result certificate SHALL have an HCID in a human readable format and a 1D or 2D barcode format. The HCID SHALL be used to establish a globally unique identifier (ID) for the DDCC:TR or to reference the ID of a previously established DDCC:TR. The paper test result certificate SHALL be provided to the DDCC:TR Holder at Point A.

- 1087 3. If a Digital Health Solution is not available at the Certificate Issuance Site, retrospective data
1088 entry of DDCC:TR core data set content SHALL occur at the Certificate Generation Site.
- 1089 4. The DDCC:TR core data set content is submitted to the DDCC:TR Generation Service and the
1090 certificate generation process is initiated.
- 1091 5. The DDCC:TR Generation Service SHALL generate a digitally signed HL7 FHIR document
1092 using a private key.
- 1093 6. The signed HL7 FHIR document SHALL be registered in the DDCC:TR Registry Service.
- 1094 7. A digitally signed HL7 FHIR test result certificate (DDCC:TR) SHALL be generated, and a
1095 signed 2D barcode representation of the DDCC:TR MAY be generated by the DDCC:TR
1096 Generation Service and returned to the Digital Health Solution. The resulting artefact SHALL
1097 be provided to the DDCC:TR Holder (who MAY be the Tested Person) as per existing Member
1098 State norms and practices, in a digital format at Point B.

1099 If a Digital Health Solution does not exist at the Certificate Issuance Site, details of the test event
1100 SHALL be recorded and persisted in a paper test result record, according to the required DDCC:TR
1101 core data set. Details of the test event can then be electronically recorded into a Digital Health
1102 Solution available at Certificate Generation Site, by Data Entry Personnel and resulting test result
1103 certificate and/or its representations may be provided to the DDCC:TR Holder at Point B.

1104 3.3 Functional requirements for Certificate Generation

1105
1106 To sign a digital document, PKI technology is required. Each Member State would be responsible for
1107 managing its own PKI through its PHA or another national delegated authority. PKI is described in
1108 further detail in Chapter 6 and Annex 4. This document assumes that a PKI has already been
1109 deployed or is available within a country to support the DDCC:TR workflows described in this section.
1110 This PKI supports the sharing of public keys that correspond to the private keys that have been used
1111 to cryptographically sign DDCC:TR and may support the sharing of public keys from trusted
1112 international PHAs so that signed DDCC:TR representations issued by these parties may be
1113 cryptographically verified.

1114
1115 High-level functional requirements for the activities described in Fig. 5 are presented in Table 5 as
1116 suggested features that any digital solution used to support DDCC:TR generation should have. These
1117 are written as guidance requirements only to be used as a starting point for Member States or other
1118 interested parties that need to develop their own specifications for a digital solution for DDCC:TR to
1119 take and adapt.

1120
1121 Non-functional requirements are included in Annex 4.

Table 5 Functional requirements for the Certificate Generation

Requirement ID	Functional requirement
DDCC.FXNREQ.001	It SHALL be possible to issue a new paper test result certificate to the Tested Person, or DDCC:TR Holder, for the purpose of recording the test event.
DDCC.FXNREQ.002	A PHA SHALL put in place a process to replace or reissue lost or damaged paper test result certificate with the necessary supporting technology.
DDCC.FXNREQ.003	It SHALL be possible to associate a globally unique HCID to a Tested Person under which test result certificates are registered.
DDCC.FXNREQ.004	It SHALL be possible to enter or attach the HCID as a 1D or 2D barcode to any paper test result certificate issued to the Tested Person (or DDCC:TR Holder).
DDCC.FXNREQ.005	It SHALL be possible to manually record the core data set content on a paper test result certificate issued to the Tested Person (or the DDCC:TR card holder).
DDCC.FXNREQ.006	It SHALL be possible to manually sign the paper test result certificate and include the official stamp of the administering centre as a non-digital means of certifying that the content has been recorded by an approved authority.
DDCC.FXNREQ.007	It SHALL be possible to retrieve information about the lab test event of the Tested Person from the content in the DDCC:TR or one of its representations.
DDCC.FXNREQ.008	All data concerning the test result SHALL be handled in a secure manner to respect confidentiality of the Tested Person's health data.
DDCC.FXNREQ.009	Digital technology SHALL NOT be needed for any aspect of paper test result certificate issuance – the process SHALL function in an entirely offline and non-electronic manner.
DDCC.FXNREQ.010	Paper test result certificate and the validation markings they bear SHALL be designed to combat fraud and misuse.
DDCC.FXNREQ.011	If a Digital Health Solution to capture and manage SARS-CoV-2 diagnostic test result and related content is available, then it MAY be responsible for outputting the test data using the HL7 FHIR standard.
DDCC.FXNREQ.012	If a Digital Health Solution to capture and manage SARS-CoV-2 diagnostic test result and related content is available, is part of the national PKI trust framework, and is authorized by the PHA to sign test result content as a DDCC:TR then it SHALL register the DDCC:TR through the DDCC:TR Registry Service.
DDCC.FXNREQ.013	If an online or connected public health DDCC:TR Generation Service is available at the time of recording SARS-CoV-2 test results, then it SHALL be possible to register the test report as soon as possible after the result is available.
DDCC.FXNREQ.014	The DDCC:TR Generation Service involved in the test result SHALL ensure encryption of data, in transit and at rest, to provide end-to-end security of personal data.
DDCC.FXNREQ.015	The DDCC:TR Generation Service MAY be the agent responsible for issuing the HCID, provided that the HCID can be associated at the time of test event in a timely manner. If the DDCC:TR Generation Service is responsible for issuing HCIDs, it SHALL only issue unique HCIDs. The same HCID should never be reused.
DDCC.FXNREQ.016	If pre-generated HCIDs are used, the generation of the HCIDs, along with any supporting technology to ensure HCIDs will not be duplicated within or across certificate generation sites, SHALL be managed by PHA policy.
DDCC.FXNREQ.017	It SHALL be possible for the DDCC:TR Generation Service to accept data transferred from an authorized, connected LIS where such a system exists.
DDCC.FXNREQ.018	It SHALL be possible for the DDCC:TR Generation Service to represent test result data using the HL7 FHIR format.
DDCC.FXNREQ.019	It SHALL be possible for the DDCC:TR Generation Service to digitally sign the HL7 FHIR document representation of the test result data
DDCC.FXNREQ.020	It MAY be possible for the DDCC:TR Generation Service to generate a machine-readable 2D barcode (e.g. a QR code) that, in addition to the HCID, contains further useful technical information, such as a web end point for validating the HCID, or a public key.

DDCC.FXNREQ.021

It **MAY** be possible for the DDCC:TR Generation Service to generate a 2D QR code that includes the unencrypted minimum core data set content (in HL7 FHIR standard) of the test result, thus providing a machine-readable version of the test result certificate.

DDCC.FXNREQ.022

The DDCC:TR Generation Service **SHALL** create an association between an HCID, the test result data associated with it in a DDCC:TR, any QR code generated from the data, and the private key used to sign the data.

1123

DRAFT

4 TEST RESULT CERTIFICATE VERIFICATION: PROOF OF NEGATIVE SARS-CoV-2 TEST RESULT OR PROOF OF PREVIOUS SARS-CoV-2 INFECTION

This section describes the use cases and actors involved in using a DDCC:TR for proof of negative SARS-CoV-2 test result or proof of previous SARS-CoV-2 infection, as well as functional requirements for a digital solution. Certificate verification relies on the PHA having access to a trusted means of digitally signing an HL7 FHIR document, which represents the core data set content for the DDCC:TR. It will be up to Member States to define the purposes for which this scenario is applied and adapted to their own contexts and levels of digital maturity, in compliance with their legal and policy frameworks.

4.1 Proof Scenarios

In the context of certificate verification, the DDCC:TR can be leveraged in one of two ways, as: (1) proof of a negative SARS-CoV-2 test result or (2) proof of previous SARS-CoV-2 infection. It will be up to the Member State to determine the business rules for acceptance of a test result certificate and the validity period for each proof scenario for domestic and/or international use cases.

Table 6 provides illustrative business rule structures to support each type of proof. These business rules will need to be established and clearly communicated by Member States based on their local policies and agreements made with other Member States. The Event Information Site (EIS) is maintained by the WHO Secretariat to be used by National IHR Focal Points. EIS contains timely information related to testing regime from different countries.

Table 6 Example of business rule decisions to support each type of proof scenario

Type of Proof	Test Type*	Test Result	Validity Period**
Proof of Previous SARS-CoV-2 Infection	[Determined by the Member State]	Detected	Sample date more than [number of days] ago and less than [number of days] ago
Proof of Negative SARS-CoV-2 Test Result	[Determined by the Member State]	Not Detected	Sample time less than [number of hours] ago

*The accepted types of SARS-CoV-2 diagnostic tests will need to be determined by the Member State for each proof scenario.

**The time periods to be defined by the Member State have been denoted in square brackets [time period].

Business rules for proof of previous SARS-CoV-2 infection will reflect each Member State's risk-based approach.^{1,8} As the available science evolves, and as the application of risk-based approaches may evolve, it is expected that WHO's guidance related to these business rules would also evolve.

4.2 Key settings, personas and digital services

As with the DDCC:VS Proof of Vaccination, the DDCC:TR includes a verification site, where it is necessary for people to provide their SARS-CoV-2 diagnostic test result. This could include a variety of places (e.g. restaurants, airports, movie theatres); but how, when, where, and by whom the DDCC:TR can be verified should be defined and regularly updated by the Member State. The relevant policies, including data protection policies, should be put in place accordingly.

The key personas, or relevant stakeholders, involved in the provision of a DDCC:TR are outlined in Table 7. These key personas are anticipated to interact with digital services (Table 8). Not all of these digital services will have a user interface that the key personas directly interact with, but they are still critical building blocks of a DDCC:TR system architecture.

Table 7 Key personas for test result certificate verification

Role	Description
DDCC:TR Holder	DDCC:TR Holder is the person who wants to assert a claim related to a SARS-CoV-2 diagnostic test result. This person could be the same person as the Tested Person or, for example, could be a caregiver who may hold the DDCC:TR for a child or other dependant.
Verifier	The person or entity that wants to verify the diagnostic test result claim (i.e. verify the test result shown on a DDCC:TR for proof of a negative SARS-CoV-2 test result or proof of previous SARS-CoV-2 infection using a predefined set of acceptance criteria or business rules).
National Public Health Authority (PHA)	The entity under whose auspices SARS-CoV-2 diagnostic test is performed and DDCC:TR is issued. The PHA is also responsible for the DDCC:TR Generation Service and the DDCC:TR Registry Service.

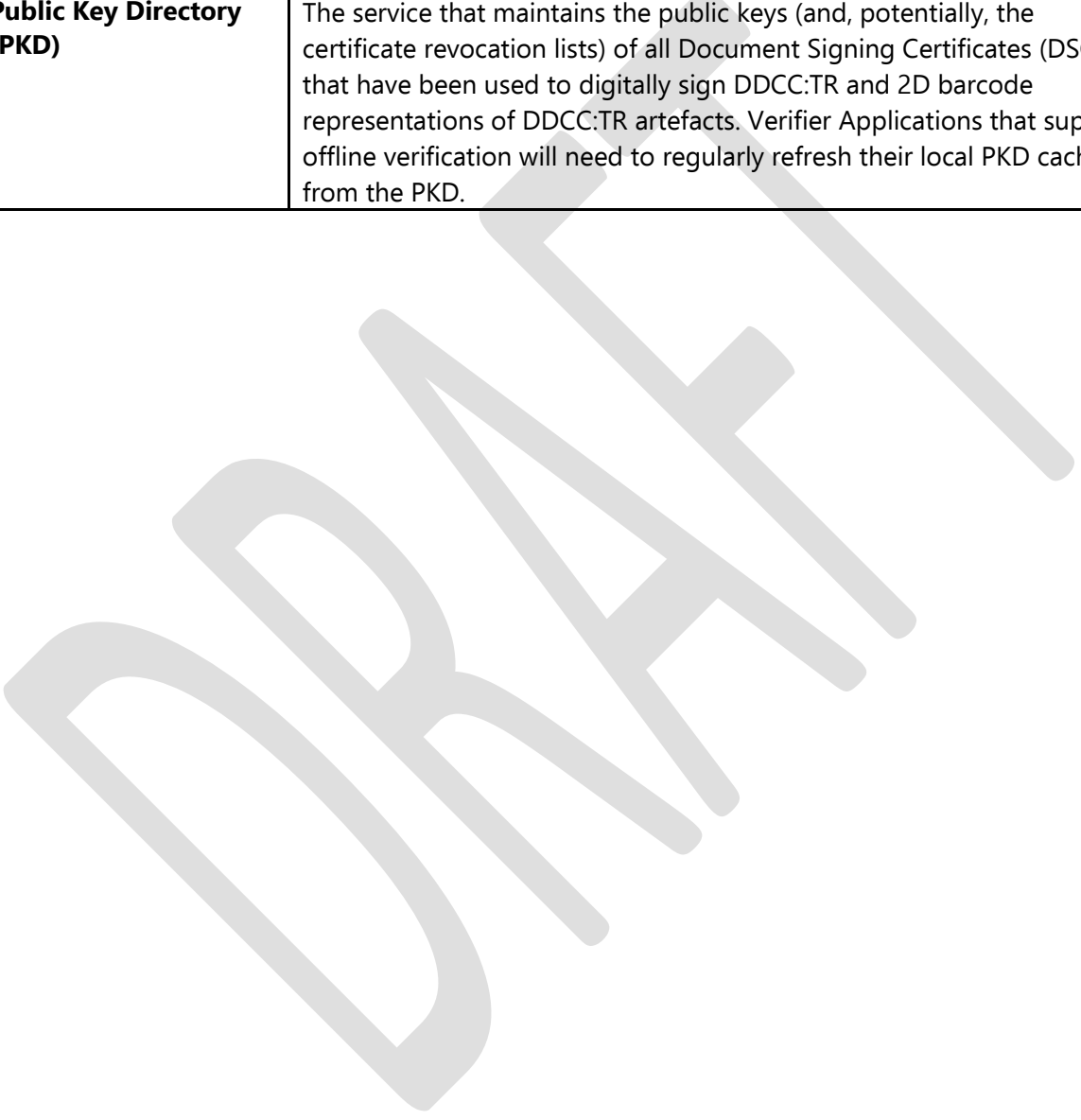
Table 8 Digital services for test result certificate verification

Digital service	Description
Health Certificate Identifier (HCID)	<p>A unique identifier for DDCC:TR. The HCID may be provided by an existing national system or alternatively, it could also be issued directly by the DDCC:TR Generation Service which will then encode the ID in the DDCC:TR. It appears on paper test result certificate in both a human readable format and as a 1D or 2D barcode. It is part of the DDCC:TR core data set.</p> <p>An index that associates the HCID with metadata about the DDCC:TR is stored in the DDCC:TR Registry Service.</p>
Verifier Application	A digital solution that can inspect and cryptographically verify the validity of the DDCC:TR. This can be an application on a mobile phone or otherwise, and it can operate online or offline.
DDCC:TR Registry Service	The service that persists a record of the DDCC:TR certificate metadata and (optionally) the location of the DDCC:TR Repository Service endpoint which can be leveraged for online verification.

	The DDCC:TR Registry Service can be utilized to determine whether a DDCC:TR has been revoked, for example, due to revocation of a key within the PKI or issues within the supply chain.
DDCC:TR Repository Service	The optional service that may be leveraged to look up DDCC:TR and/or return one or more representations of the DDCC:TR based on the DDCC:TR HCID. The DDCC:TR Repository Service may be implemented as a single centralized database or as a federation of databases.
Public Key Directory (PKD)	The service that maintains the public keys (and, potentially, the certificate revocation lists) of all Document Signing Certificates (DSCs) that have been used to digitally sign DDCC:TR and 2D barcode representations of DDCC:TR artefacts. Verifier Applications that support offline verification will need to regularly refresh their local PKD cache from the PKD.

1170

1171



4.3 Test result certificate verification workflows and use cases

The process for Certificate Verification is summarized in Figure 6. It is assumed that for a test result certificate and/or its representations to be verified, the following activities have already taken place as per the norms and processes of the Member State:

1. A signed HL7 FHIR document, DDCC:TR, has been generated by the DDCC:TR Generation Service and registered within the DDCC:TR Registry Service. Optionally, DDCC:TR may be persisted to a DDCC:TR Repository Service.
2. The Verifier's application has, as part of a regular update procedure, downloaded and cached the public keys of all verifiable DDCC:TR 2D barcodes from a Public Key Directory (PKD) service as well as, optionally, a set of Certificate Revocation Lists (CRL) that denote public keys that have been revoked.
3. The DDCC:TR Holder is presenting a digitally signed DDCC:TR or its representation(s) that was signed by a DSC for which the Verifier's application has a cached copy of the relevant public key.
4. The Holder's 2D barcode is encoded using a method and format that is understandable by the Verifier's application and can navigate to the national PHA's trusted online verification service (for online verification).

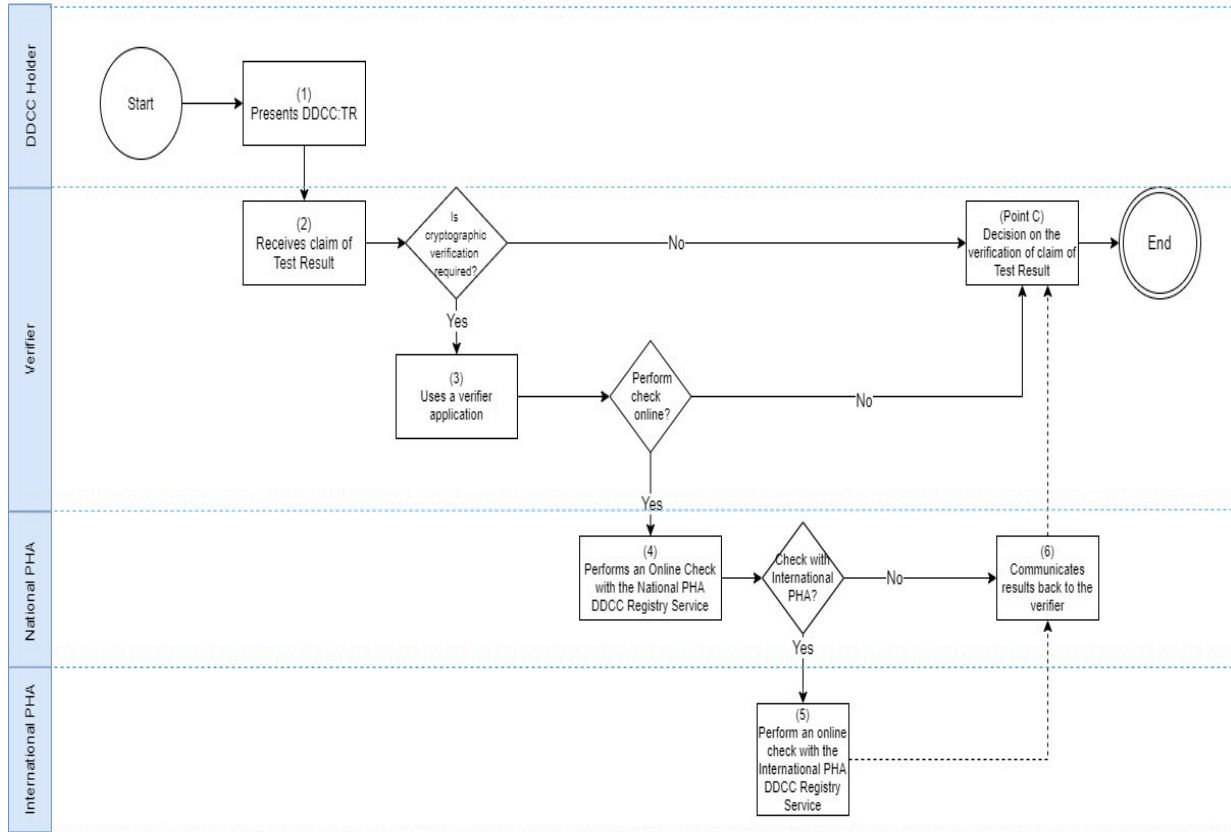
The workflow's actors and settings, and its related high levels requirements, may be described as follows.

1. A DDCC:TR Holder presents a DDCC:TR to a Verifier in support of a claim of a SARS-CoV-2 diagnostic test result.
2. To verify the SARS-CoV-2 diagnostic test result claim of a verifiable DDCC:TR Holder, there are four separate pathways (Manual Verification, Offline Cryptographic Verification, Online Status Check [for national DDCC:TR], and Online Status Check [for international DDCC:TR]) that a Verifier could take to check the SARS-CoV-2 diagnostic test result claim at Point C, elaborated as test result certificate verification use cases in Table 9. A Verifier may visually verify a DDCC:TR, or scan a machine-readable version of the DDCC:TR's HCID and use that when accessing a verification service or verify using a digitally signed, machine readable representation of the core data set content (e.g. as a 2D barcode).

Note that, regardless of the use case, a DDCC:TR Generation Service is required as a precondition to support registration of DDCC:TR within the DDCC:TR Registry Service, which is required, as part of the Certificate Generation Workflow (see section 3.2).

The DDCC:TR Repository Service is optional depending on which use case is being implemented. To support online verification, both the DDCC:TR Registry Service and DDCC:TR Repository Service are required.

Figure 6
Test Result Certificate Verification



1209 DDCC:TR: Digital Documentation of COVID-19 Certificates: Test Result; PHA: public health authority.

1210
1211 The business process symbols used in the workflows are explained in Annex 2.

1212

1213 **4.3.1 Test result certificate verification use cases**

1214 Navigating through the workflow diagram shown in Figure 6, there are four possible verification
1215 pathways (illustrated separately in Fig. 7, Fig. 8, Fig. 9 and Fig. 10). These pathways are the use cases
1216 for test result certificate verification listed in Table 9. The required digital services for each use case
1217 are also outlined in Table 9.

1218
1219

Table 9 Test result certificate verification use cases

Use case ID	UC001	UC002	UC003	UC004
Use case name	Manual Verification	Offline Cryptographic Verification	Online Status Check (National DDCC:TR)	Online Status Check (International DDCC:TR)
Figure	Figure 7	Figure 8	Figure 9	Figure 10
Use case description	A Verifier verifies a DDCC:TR based on its human-readable content using purely visual means, based on their subjective judgement. This type of check is common, currently well accepted, is quick and easy to do, and requires no digital technology.	A Verifier verifies a DDCC:TR using digital cryptographic processes in an offline mode	This pathway is used when the DDCC:TR is being verified in the same jurisdiction as it was issued. A Verifier verifies a DDCC:TR using digital cryptographic processes in an online mode that includes a status check against the PHA's DDCC:TR Registry Service and optionally the DDCC:TR Repository.	This pathway is used when the DDCC:TR is being verified in a foreign jurisdiction to where it was issued. A Verifier verifies an internationally issued DDCC:TR using digital cryptographic processes in an online mode that includes a status check against the National PHA's DDCC:TR Registry Service, which in turn accesses an International PHA's DDCC:TR Registry and DDCC:TR Repository, if such services exist and such access is authorized by the issuing PHA. It is assumed in this workflow that a Verifier does not directly access an International PHA's DDCC:TR Registry or Repository Service.
Connectivity required	Offline	Offline	Online	Online
Level of verification	Verification is visually performed by the Verifier. As judgement can be subjective, it relies on policies to protect against discrimination and detect fraud.	<ul style="list-style-type: none"> <input type="checkbox"/> Can confirm that the HCID barcode on the printed test result is valid and has not been altered. <input type="checkbox"/> Can confirm whether the DDCC:TR has been issued by an authorized PHA. <input type="checkbox"/> Can confirm that the hash of any signed 2D barcodes matches the health content represented therein. 	<ul style="list-style-type: none"> <input type="checkbox"/> Can confirm that the HCID barcode on the paper card is valid and has not been altered. <input type="checkbox"/> Can confirm whether the DDCC:TR has been issued by an authorized PHA. <input type="checkbox"/> If authorized to do so, can confirm that the content on a DDCC:TR paper card matches the DDCC:TR digital content. <input type="checkbox"/> Can confirm that the hash of any signed 2D barcodes matches the health content represented therein. <input type="checkbox"/> Can check whether signed 2D barcodes containing DDCC:TR content have been revoked or updated. 	<ul style="list-style-type: none"> <input type="checkbox"/> Can confirm that the HCID barcode on the paper card is valid and has not been altered. <input type="checkbox"/> Can confirm whether the DDCC:TR has been issued by an authorized PHA. <input type="checkbox"/> If authorized to do so, can confirm that the content on a DDCC:TR paper card matches the DDCC:TR digital content. <input type="checkbox"/> Can confirm that the hash of any signed 2D barcodes matches the health content represented therein. <input type="checkbox"/> Can check whether signed 2D barcodes containing DDCC:TR content have been revoked or updated.

Verify whether the DDCC:TR has been revoked?	Not possible	Possible if a cache of revoked certificates is maintained by the Verifier	Possible	Possible
DDCC:TR Registry Service	Not required	Required	Required	Required
DDCC:TR Repository Service	Not required	Optional	Required	Required

1221
1222
1223
1224

DDCC:TR, Digital Documentation of COVID-19 Certificates: Test Result; HCID, health certificate identifier; ID, identifier; PHA, public health authority.

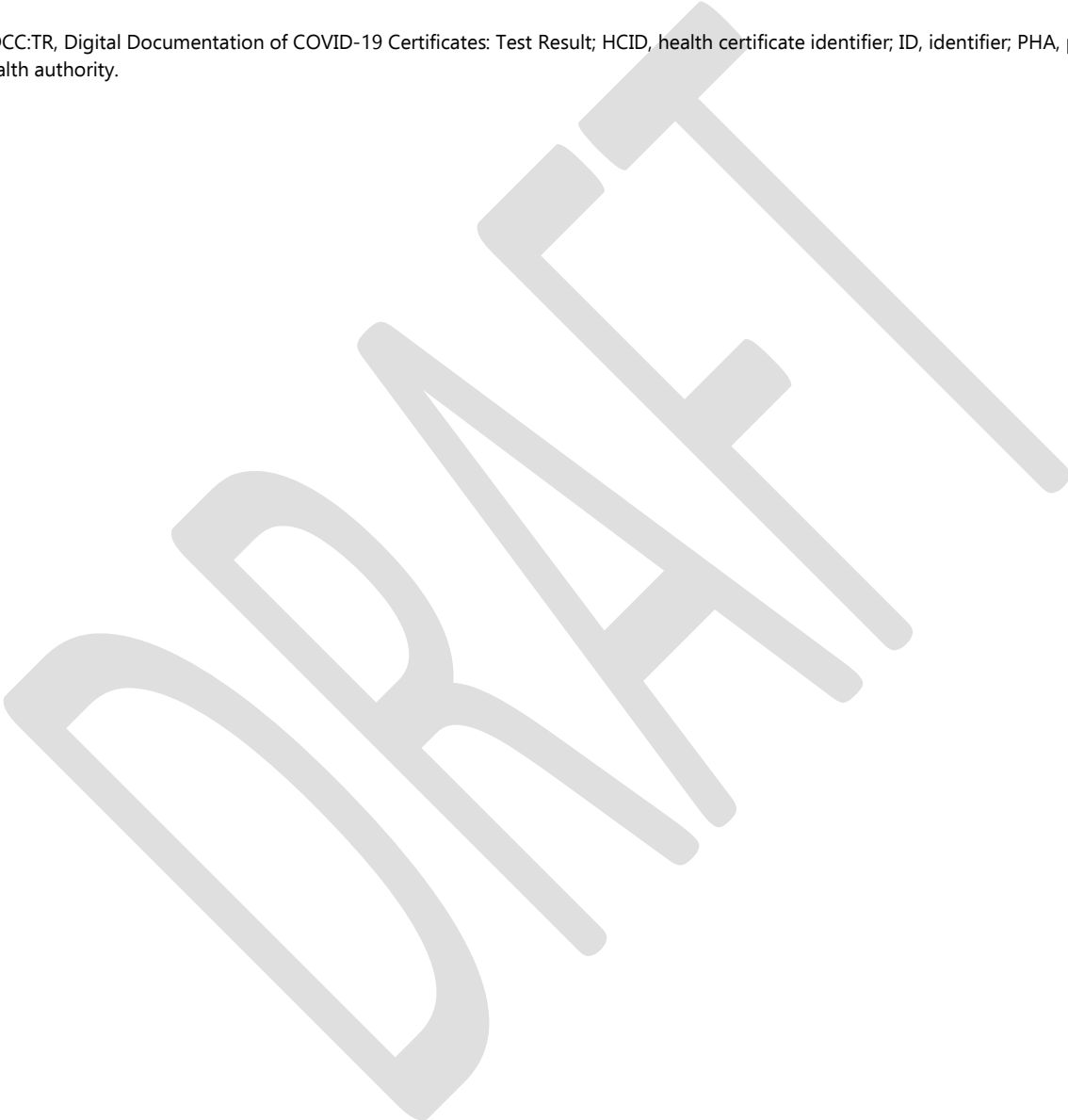
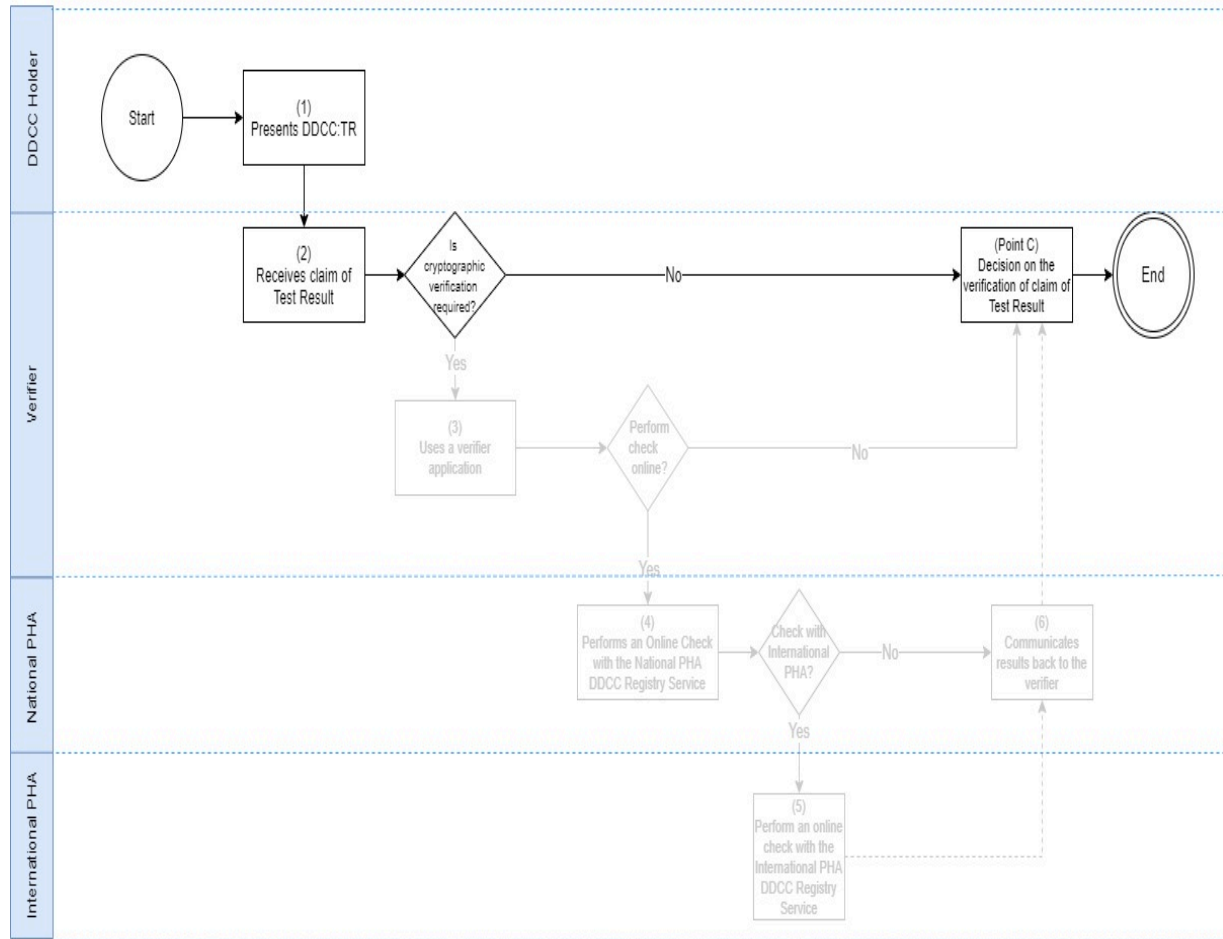


Figure 7
Test Result Certificate Verification: Manual Verification Use Case

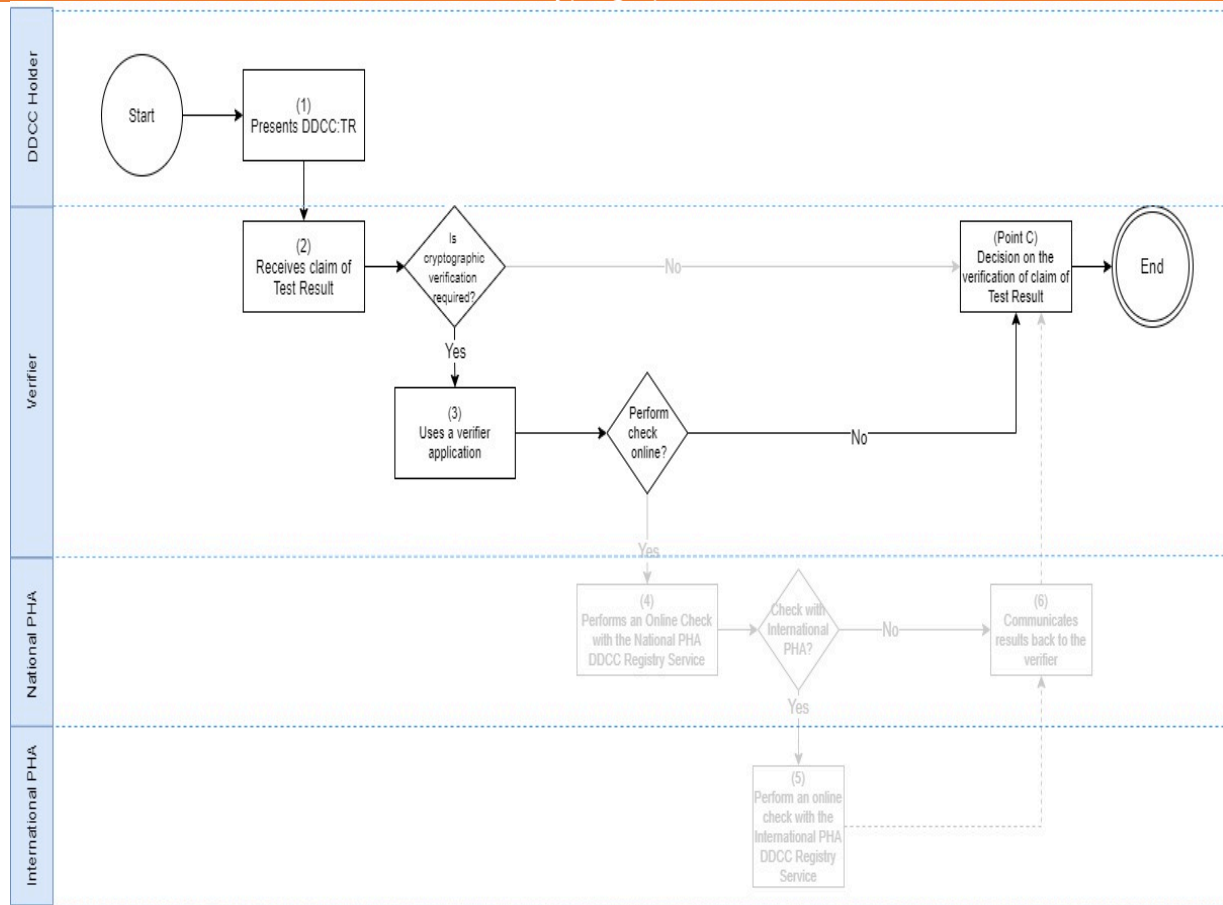


DDCC:TR: Digital Documentation of COVID-19 Certificates: Test Result; PHA: public health authority.

The business process symbols used in the workflows are explained in Annex 2.

1225

Figure 8
 Test Result Certificate Verification: Offline Cryptographic Verification Use Case

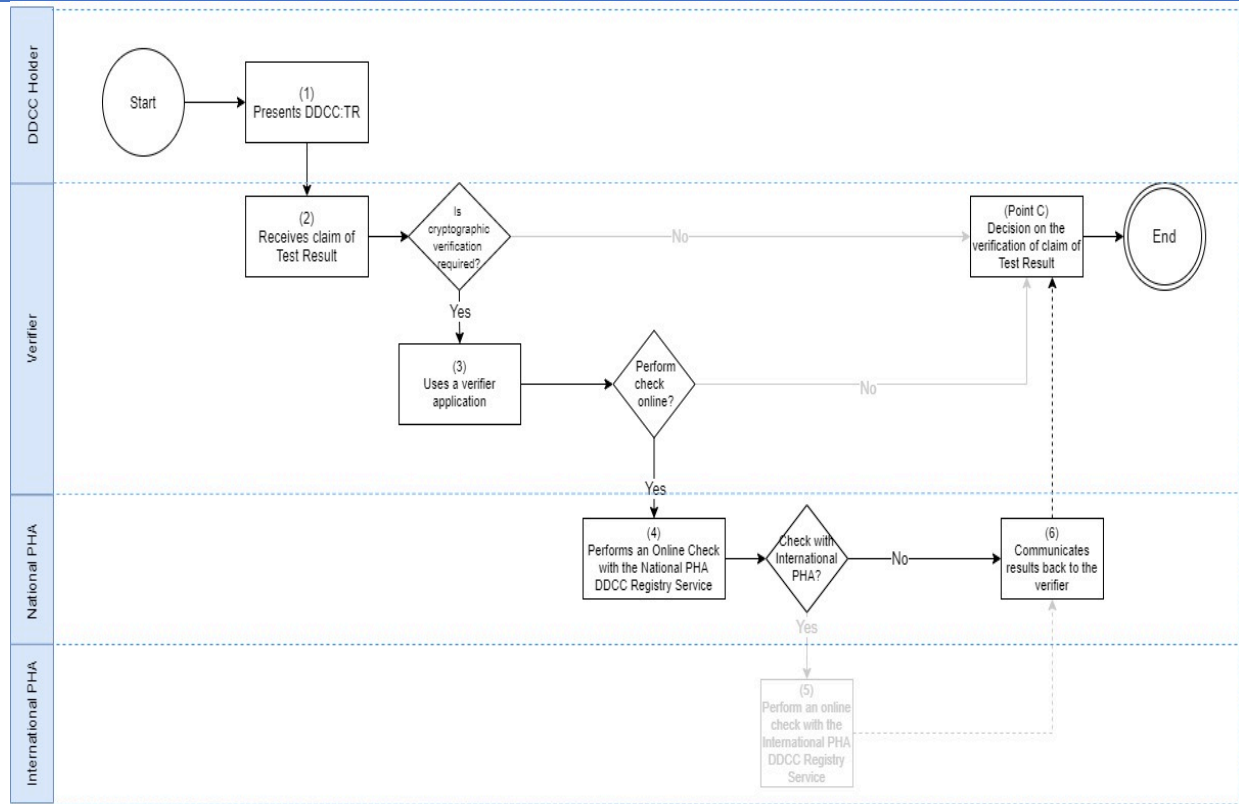


DDCC:TR: Digital Documentation of COVID-19 Certificates: Test Result; PHA: public health authority.

The business process symbols used in the workflows are explained in Annex 2.

1226

Figure 9
 Test Result Certificate Verification: Online Status Check (National DDCC:TR) Use Case

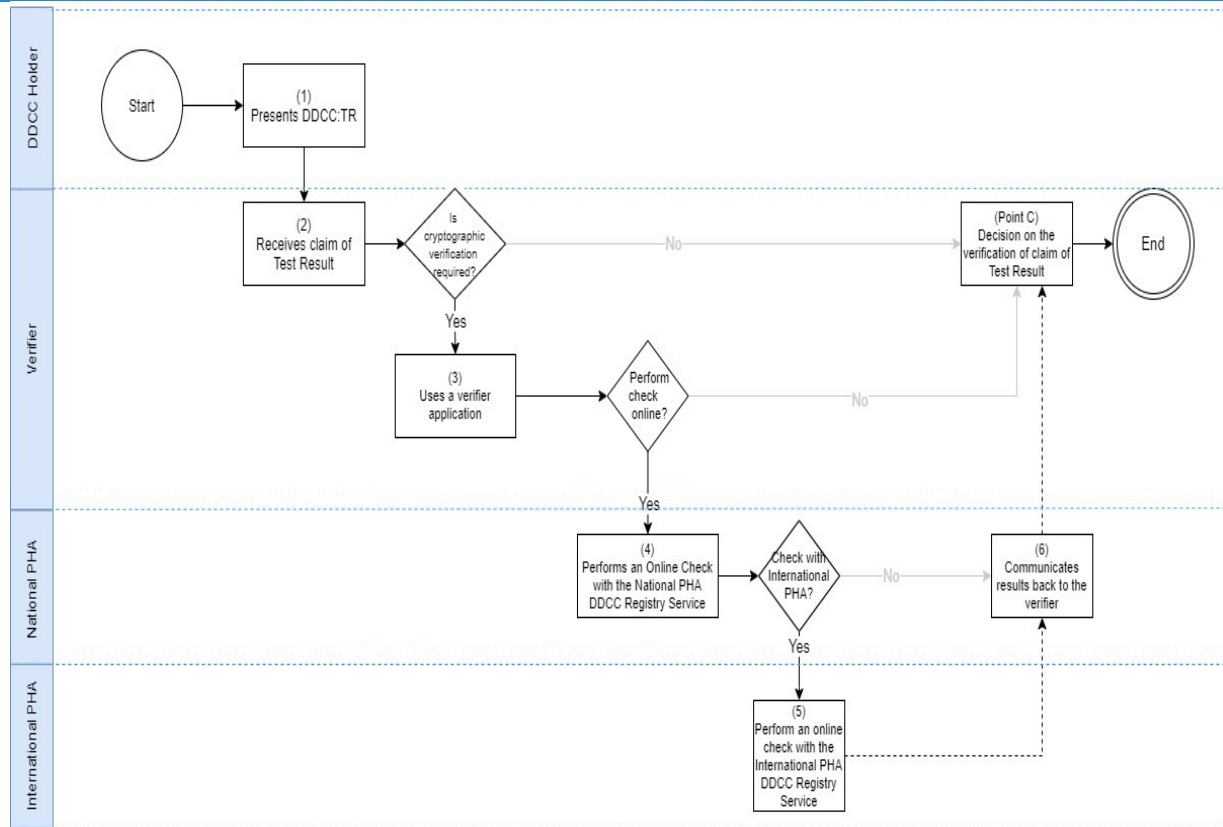


DDCC:TR: Digital Documentation of COVID-19 Certificates: Test Result; PHA: public health authority.

The business process symbols used in the workflows are explained in Annex 2.

1227

Figure 10
 Test Result Certificate Verification: Online Status Check (International DDCC:TR) Use Case



DDCC:TR: Digital Documentation of COVID-19 Certificates: Test Result; PHA: public health authority.

The business process symbols used in the workflows are explained in Annex 2.

1228

1229 4.3.2 Operationalizing the test result certificate verification use cases
 1230 The HL7 FHIR implementation guide includes implementable specifications for the test result
 1231 certificate verification use cases described in this document, (available at
 1232 WorldHealthOrganization.github.io/ddcc [Note: The HL7 FHIR implementation guide has yet to be
 1233 updated to reflect additional DDCC:TR content.]). The HL7 FHIR implementation guide for DDCC:TR
 1234 will contain a standards-compliant specification that explicitly encodes computer-interoperable logic,
 1235 including data models, terminologies, and logic expressions, in a computable language sufficient for
 1236 implementation of test result certificate verification use cases.

1237 4.4 Functional requirements for test result certificate verification

1238 High-level functional requirements for the activities described in Fig. 6 are presented in Table 10 as
 1239 suggested features that any digital solutions that would facilitate DDCC:TR verification may have.
 1240 These are written as guidance requirements only to be used as a starting point for Member States or
 1241 other interested parties that need to develop their own specifications for a digital solution for
 1242 DDCC:TR to take and adapt.

1243
 1244 Non-functional requirements are included in Annex 4.

1245
 1246 *Table 10 Test Result Certificate Verification Functional Requirements*

Requirement ID	Functional requirement	UC001 Manual	UC002 Offline	UC003 Online
DDCC.FXNREQ.023	Paper test result certificate and the validation markings they bear SHOULD be designed to combat fraud and misuse. Any process that generates paper test result certificate SHOULD include elements on the card that support the Verifier in visually checking that the card is genuine (e.g. water marks, holographic seals etc.) without the use of any digital technology.	x	x	x
DDCC.FXNREQ.024	If a paper test result document bearing a 1D or 2D barcode is presented to a Verifier, then it SHALL be possible for the Verifier to scan the code and, as a minimum, read the HCID encoded in the barcode, to visually compare it with the HCID written on the paper test result certificate, if present.		x	x
DDCC.FXNREQ.025	If a paper test result certificate or computable test report document bears a QR code and that barcode includes a digital signature, then it MAY be possible for the Verifier to check the signature, using information downloaded from a PKD, to ensure it is genuine.			x
DDCC.FXNREQ.026	It MAY be possible to log all offline verification operations so that, at a later stage when an online connection is available, verification decisions can be reviewed and reconfirmed against data provided by the online DDCC:TR Registry Service. For example, this may be done to confirm that a certificate that was checked offline in the morning using public key and revocation data downloaded from the DDCC:TR Registry Service the day before has not been added to a public key revocation list issued that same day. However, personal data accessed at the point of verification of the DDCC:TR should not be retained and stored in a repository, database or otherwise.		x	
DDCC.FXNREQ.027	It SHALL always be possible to perform some form of offline verification of paper test result certificate; any solution should be designed so that a loss of connectivity to online components of the solution cannot force the verification work to stop.		x	x

DDCC.FXNREQ.028	If, at the time of verification, a Verifier has connectivity to a DDCC:TR Registry Service managed by a PHA, then it SHALL be possible to query whether the HCID present in the barcode (and the public key, if also present) of the paper test result certificate are currently valid.			x
DDCC.FXNREQ.029	When making the verification check, any solution SHALL send only the minimum information required for the verification to complete. The minimum information comprises the metadata (see section 5.2) and signature of the DDCC:TR.			x
DDCC.FXNREQ.030	When receiving a request for validation, a PHA SHALL consult its DDCC:TR Registry Service and respond with a status to indicate that the signing key has not been revoked, that the key was issued by a certified authority, and that the DDCC has not otherwise been revoked.			x
DDCC.FXNREQ.031	A PHA servicing a validation request of a test result certificate via an HCID MAY respond with basic details of the test result certificate holder (name, date of birth, sex, etc.), in accordance with PHA policies, so that the Verifier can confirm that the paper test result certificate corresponds to the DDCC:TR Holder who has presented himself or herself for validation.			x
DDCC.FXNREQ.032	A PHA SHALL maintain a PKI to underpin the signing and verification process. Lists of valid public keys and revocation lists will be held in such a system and MAY be linked to the DDCC:TR Generation Service to associate public keys with HCsIDs.			x
DDCC.FXNREQ.033	A PHA MAY log the requests it receives for verification (even if rendered anonymous), so that it has a searchable history for the purposes of audit and fighting fraud, provided that such logging respects data protection principles.			x
DDCC.FXNREQ.034	A PHA SHALL be able to return a verification status, as defined by the implementer, to a requestor, based on the information provided.			x
DDCC.FXNREQ.035	A PHA MAY be able to service individual verification requests (i.e. details relating to one test result certificate) or requests sent in bulk (details of multiple certificates sent in one request).			x
DDCC.FXNREQ.036	When receiving a request for validation, a PHA MAY respond with the last test result certificate or provide history of test result certificates, in accordance with Member State policies.			x
DDCC.FXNREQ.037	A PHA SHOULD be able to validate that the requestor making a verification request is an authorized agent, but MAY also allow anonymous verification requests.			x
DDCC.FXNREQ.038	The certificate authority (or authorities) in each country SHALL maintain records of the DSCs issued for the purpose of signing test result certificates and expose any service(s) that allow a public key to be looked up and checked against its records to check for validity.			x
DDCC.FXNREQ.039	Any communication between a Verifier and a DDCC:TR Registry Service or other data service managed by a PHA SHALL be secured to prevent interference with the data in transit and at rest.			x
DDCC.FXNREQ.040	SMS-based verification of alphanumeric HCsIDs MAY be provided by a PHA as a means of sending a verification request or receiving a response with a status code.			x

1247

1248

5 DDCC:TR CORE DATA SET

1249

1250 The DDCC:TR core data set includes data elements about the tested person and SARS-CoV-2
1251 diagnostic test result and related information that are required to support proof of negative SARS-
1252 CoV-2 test result or proof of previous SARS-CoV-2 infection. Stakeholders and systems may use the
1253 DDCC:TR core data set as defined or they may continue to use their existing terminology with a map
1254 to the DDCC:TR core data set, so long as it contains the required data elements in the DDCC:TR core
1255 data set. The recommended core data set is intended to include the critical data required for
1256 interoperability, specific to the scenarios of use defined and driven by the public health need. A
1257 comprehensive data dictionary in spreadsheet format can be found in Web Annex A.

5.1 Core data set principles

1259 To develop the core data set, existing digital certificates, and guidelines such as International Civil
1260 Aviation Organization (ICAO) guidelines on visible digital seals (“VDS-NC”) for travel-related health
1261 proofs, the European Union (EU) EU Digital COVID Certificate International Civil Aviation
1262 Organization (ICAO), US-based Vaccine Certificate Initiative (VCI) specification, the ISO mdoc
1263 specification, and the ASEAN lab result are considered.

1264

1265 The following key principles were used to guide the formulation of the core data set.

- 1266 • Data Minimization: Aligned with the principle of data privacy protection, only the minimum
1267 set of data elements necessary for documenting a SARS-CoV-2 diagnostic test result for the
1268 purposes of a DDCC:TR should be included. Each data elements must have a purpose in
1269 accordance with the predefined use cases. This is especially important for personal data.
- 1270 • Open Standards: Aligned with the principle of open access, proprietary terminology code
1271 systems or proprietary standards cannot be recommended to Member States
- 1272 • Implementable on Digital and Paper: Aligned with the principle of equity, data requirements
1273 should not increase inequities or put individuals at risk. Additionally, data input requirements
1274 should be feasible on paper but take advantage of the benefits of digital technology.
- 1275 • To underscore the importance of the ability to implement, the data content model for the
1276 DDCC:TR core data set has been developed as an HL7 FHIR implementation guide. The DDCC
1277 test result implementation guide is based on the widely adopted HL7 FHIR International
1278 Patient Summary (IPS) health data content model.²⁹

1279

1280 Logical Observation Identifiers Names and Codes (LOINC) and International Classification of Diseases
1281 (ICD) are the preferred data standards for DDCC:TR. To support broadly deployed legacy systems, the
1282 DDCC:TR normative core data set includes 1:1 equivalent mappings to SNOMED codes that may be
1283 leveraged, in some cases, as allowed alternatives.

1284

²⁹ International Patient Summary Implementation Guide: 1.0.0 – Continuous Integration Build [website].
Health Level Seven International – Patient Care Work Group; 2021 (<https://build.fhir.org/ig/HL7/fhir-ips>,
accessed 27 June 2021).

1285 LOINC is identified as a universal code system for laboratory tests, health measurements and
1286 observations.³⁰ LOINC:

- 1287 • is a rich catalogue of measurements, including laboratory tests, clinical measures and
1288 anthropometric measures;
- 1289 • enables the exchange and aggregation of clinical results for care delivery, outcomes
1290 management and research by providing a set of universal codes and structured names;
- 1291 • enables comparability and analysis of consolidated laboratory result data;
- 1292 • accelerates secondary use of clinical results for other purposes such as public health
1293 reporting, quality measurements and other types of analyses.

1294

1295 The 11th revision of ICD (ICD-11), which comes into effect for recording and reporting in January
1296 2022, is recommended as the most suitable and future-proof value set for use in the DDCC:TR data
1297 dictionary.³¹ ICD-11 is:

- 1298 • a global public good that is completely free and available for all to use in its entirety; no
1299 payment will be required to access any additional parts of the code system;
- 1300 • kept clinically updated through an open, public and transparent maintenance process;
- 1301 • able to provide comprehensive content coverage and the granularity required for data fields
1302 in individual-level systems, including the DDCC:TR;
- 1303 • easy to integrate into software systems via a public API for use in all settings, without
1304 additional tooling; this is due to ICD-11's digital and multilingual structure; and
- 1305 • human-readable and machine-readable.

1306

1307 For countries with legacy ICD systems (e.g. the 10th revision of ICD, ICD-10), WHO will provide ICD-
1308 10 based value sets for use in the DDCC:TR data dictionary, as well as mappings to other freely
1309 available classifications and terminologies (e.g. Anatomical Therapeutic Chemical (ATC), SNOMED CT
1310 GPS³², etc.). For guiding principles of the WHO Family of International Classifications (WHO-FIC) and
1311 other classifications, as well as terminology mapping in the context of the WHO DDCC:TR, see Annex
1312 3.

³⁰ <https://loinc.org/>

³¹ ICD-11: International Classification of Diseases 11th Revision. In: World Health Organization International Classification of Diseases [website]. Geneva: World Health Organization; 2021 (<https://icd.who.int/en>, accessed 27 June 2021).

³² Global Patient Set. In: SNOMED International [website]. London: SNOMED International; 2021 (<https://www.snomed.org/snomed-international/learn-more/global-patient-set>, accessed 27 June 2021).

1313
1314
1315
1316
1317
1318
1319
1320
1321
1322

1323
1324
1325
1326
1327
1328
1329

5.2 Core data elements

The three key sections of the core data set are:

1. The header
2. Data elements for the lab test result
3. Test result certificate metadata

The **header section** data elements include the Tested Person’s ID information. The header section is intended to capture information about the tested individual to allow for information on the test result certificate be linked to a specific person.

Table 11 Header section of the DDCC:TR with preferred code system

Data element label	Description	Data type	Preferred code system	Requirement status for Proof of Negative Test Result	Requirement status for Proof of Previous SARS-CoV-2 Infection
Name	The full name of the tested person	String	Not applicable	Required	Required
Date of Birth	The tested person's date of birth (DOB) if known. If unknown, use assigned DOB for administrative purposes.	Date	Complete date, following ISO 8601 (YYYYMMDD or YYYY-MM-DD)	Required	Required
Unique Identifier	Unique identifier for the tested person, according to the policies applicable to each country. There can be more than one unique identifier used to link records (e.g. national ID, health ID, medical record ID).	ID	Not applicable	Optional	Optional

ISO: International Organization for Standardization, ID: identifier

The **data elements for each SARS-CoV-2 test event** section outlines the data that need to have been collected for each SARS-CoV-2 test event.

Table 12 Data for each SARS-CoV-2 test event, with preferred code system

Data element label	Description	Data type	Preferred code system	Requirement status for Proof of Negative Test Result	Requirement status for Proof of Previous SARS-CoV-2 Infection
Agent targeted	Name of the agent being tested for (such as SARS-CoV-2).	Coding ¹	ICD-11	Required	Required
Type of test	Name of the type of test that was conducted e.g. NAAT.	Coding	LOINC	Required	Required
Test brand	The brand or trade name used to refer to the test conducted.	Coding	As defined by Member State	Optional	Optional
Test manufacturer	Name of the manufacturer of the test conducted.	Coding	As defined by Member State	Optional	Optional
Specimen Sample Origin	The type of sample that was taken e.g. Nasopharyngeal swab or Saliva specimen.	Coding	ICD-11	Optional	Optional
Date and time of sample collection	Date and time when sample was collected.	DateTime	Time zone designator following ISO 8601 (YYYY-MM-DDThh:mm+/-HH:MM) e.g. 2021-11-01T12:30-2:00	Required	Required
Date and time of report issuance	Date and time when the test report was generated.	DateTime	Time zone designator following ISO 8601 (YYYY-MM-DDThh:mm+/-HH:MM) e.g. 2021-11-01T12:30-2:00	Optional	Optional
Test result	Detected or Not detected presence of SARS-CoV-2 infection	Coding	ICD-11	Required	Required
Test centre or facility name	A codable name or identifier of the facility responsible for conducting the test	Coding	As defined by Member State	Optional	Optional

Test centre country	The country in which the individual has been tested	Coding	ISO 3166-1 alpha-3 (or numeric)	Required	Required
----------------------------	---	--------	---------------------------------	----------	----------

1331

1332

ICD-11: International Classification of Diseases 11th Revision; ID: identifier; ISO: International Organization for Standardization, LOINC: Logical Observation Identifiers Names and Codes

1333

1334

1335

1 Coding data elements are multiple choice and the input options, or values, are data elements taken from a set of predefined options (e.g. type of test, test brand)

1336

1337

The **test result certificate metadata** contains data elements that are not typically visible to the user, but that are required to be linked to the certificate itself. It is anticipated that additional metadata elements will be added by Member States at the time of certificate generation to support specific use case implementations.

1338

1339

1340

1341

Table 13 Test Result certificate metadata

Data element label	Description	Data type	Preferred code system	Requirement status for Proof of Negative Test Result	Requirement status for Proof of Previous SARS-CoV-2 Infection
Certificate issuer	The authority or authorized organization that issued the test result certificate.	String	Not applicable	Required	Required
Health Certificate Identifier (HCID)	Unique identifier used to associate the test results represented in paper test result certificates to their digital representation(s).	ID	Not applicable	Required	Required
Certificate schema version	Version of the core data set and HL7 FHIR Implementation Guide that the certificate is using.	String	Not applicable	Required	Required
Certificate valid from	Date and time at which the test result certificate became valid. No health or clinical inferences should be made from this date	DateTime	Time zone designator following ISO 8601 (YYYY-MM-DDThh:mm+/-HH:MM) e.g. 2021-11-01T12:30-2:00	Optional	Optional

1342

ID: identifier; UTC: Coordinated Universal Time, ISO: International Organization for Standardization

1343

1344 It should be noted that a Member State may choose to add its own data fields to this model. The Member State may additionally choose to
1345 have one core data set for both scenarios or have two separate data sets (as mentioned above). The proposed specification is intended to
1346 provide a basis for generating interoperable certificates that can serve the purposes of identifying persons who have a proof of previous
1347 SARS-CoV-2 infection or who have recently tested negative for SARS-CoV-2 infection.

DRAFT

6 PKI FOR SIGNING AND VERIFYING A DDCC:TR

1348

1349

1350

1351

1352

1353

1354

1355

1356

1357

1358

1359

1360

1361

1362

1363

1364

1365

1366

1367

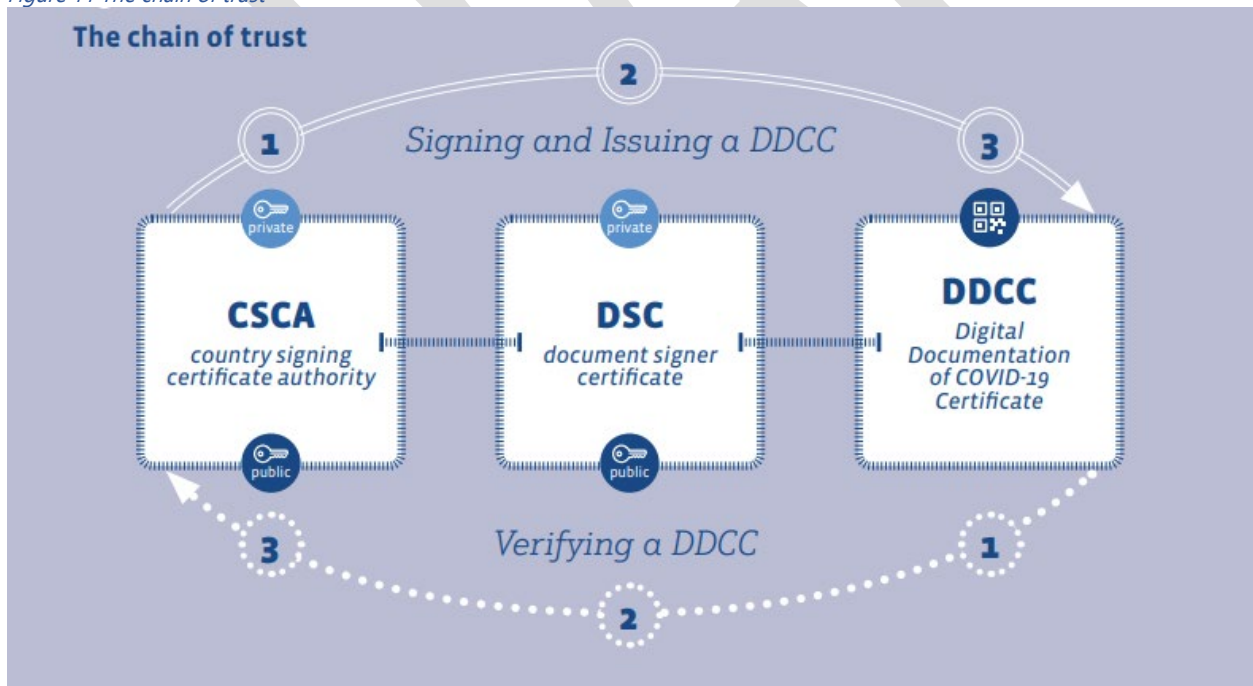
1368

The scenarios presented in earlier chapters, and the data associated with them, suggest the need for a digital ecosystem within a country for the issuance, updating and verification of the DDCC:TR. This ecosystem would comprise a suite of digital tools for the management of DDCC:TR data and the processes and governance rules for using these systems. It could be as simple as a server for storing and managing the data or as extensive as an entire health information exchange infrastructure.

In Annex 5, considerations for such a national architecture of digital components are presented as a generic design for a set of interconnected components that would facilitate the successful operation of a national DDCC:TR system. Member States are at different levels of digital health maturity and investment and have different local contexts. The architecture is presented as general guidance with the expectation that this guidance will be adapted and tailored to suit the specific real-world needs of each Member State.

To sign a digital document, PKI technology is required. PKI uses private and public key pairs to operationalize digital signing and cryptographic verification. Content that is signed by a private key can be verified by the corresponding public key of the key pair. This sign-verify mechanism is leveraged to establish the trust framework (chain of trust; see Fig. 11). There are many different mechanisms/technologies to implement this approach. PKI is described in further detail in Annex 3.

Figure 11 The chain of trust



1369

1370

1371

1372

CA, certificate authority; DDCC, Digital Documentation of COVID-19 Certificate; DSC, document signer certificate.

1373 Member States will need to establish or utilize a domestic PKI that can be leveraged to issue and to
1374 verify DDCC:TR. An existing PKI framework may be used, provided it meets the requirements outlined
1375 in this document. This document assumes that a PKI has already been deployed or is available within
1376 a country to support the DDCC:TR workflows described in Chapter 3 and Chapter 4. The PKI can be
1377 maintained and managed by another government entity (e.g. ministry of ICT, ministry of interior,
1378 ministry of foreign affairs) or by a contractor that the PHA has selected. Regardless, PHAs will have
1379 the signing authority. The two key steps for establishing a PKI framework are:

- 1380
- 1381 1. The PHA will need to generate at least one document signer certificate (DSC) – a private–
1382 public key pair that can be used by the trusted agents of the PHA to sign the DDCC:TR.
- 1383 2. The Member State will need to establish a mechanism to assert that a DSC from a PHA has
1384 been authorized to sign health documents. Two approaches are outlined in Chapter 7.
- 1385

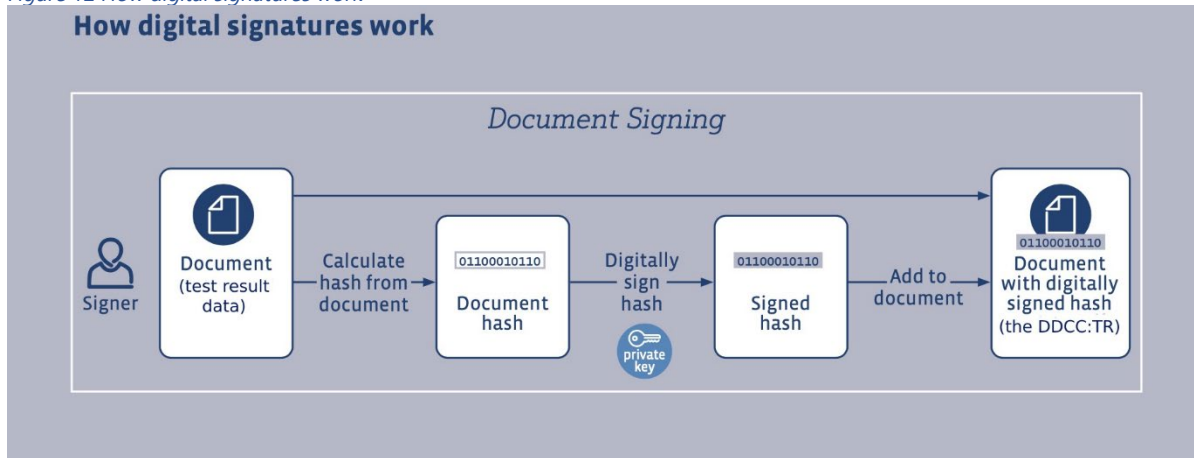
1386 There are many ways in which a PKI can be implemented. An example implementation of digital
1387 signing is provided in the [implementation guide](https://github.com/WorldHealthOrganization/ddcc) available at
1388 <https://github.com/WorldHealthOrganization/ddcc>. The precise algorithms used for the
1389 implementation – for example for hashing and for signature generation – are at the discretion of the
1390 Member State.

1391 6.1 Signing a DDCC:TR

1392 The process of signing a DDCC:TR is shown in the top row of Figure 11 and involves three steps.

- 1393 1. The PHA generates a private and public key pair that serve as the “root certificate”. The
1394 private key is kept highly secure (never revealed to another party, maintained in a
1395 disconnected location, stored on media that is itself password-protected, etc.); the public key
1396 will be widely disseminated.
- 1397 2. The PHA generates one or more DSC key pairs. DSC private keys are kept highly secure, and
1398 public keys are widely disseminated. The DSC key pair is digitally signed by the root
1399 certificate’s private key.
- 1400 3. A DDCC:TR is digitally signed using the DSC’s private key. A 2D-barcode representation (e.g.
1401 QR code) of the signed content can be generated if required. The process of signing is
1402 illustrated in Figure 12 and works as follows.
 - 1403 a. A human-readable plain text description of the test result data is transformed into a
1404 non-human-readable “document hash” using a hashing algorithm, which is a
1405 mathematical function that performs a one-way transformation of data of any size to
1406 data of a fixed size in a manner that is impossible to unambiguously reverse.
 - 1407 b. The DSC’s private key is used to sign the hash in a process in which the digital
1408 information of the private key further transforms the digital hash to produce a
1409 “signed hash”.
 - 1410 c. This signed hash now effectively contains information about the private key and the
1411 data contained on the DDCC:TR in a non-human-readable and cryptographically
1412 secure format.
 - 1413

1414 Figure 12 How digital signatures work



1415
1416

6.2 Verifying a DDCC:TR signature

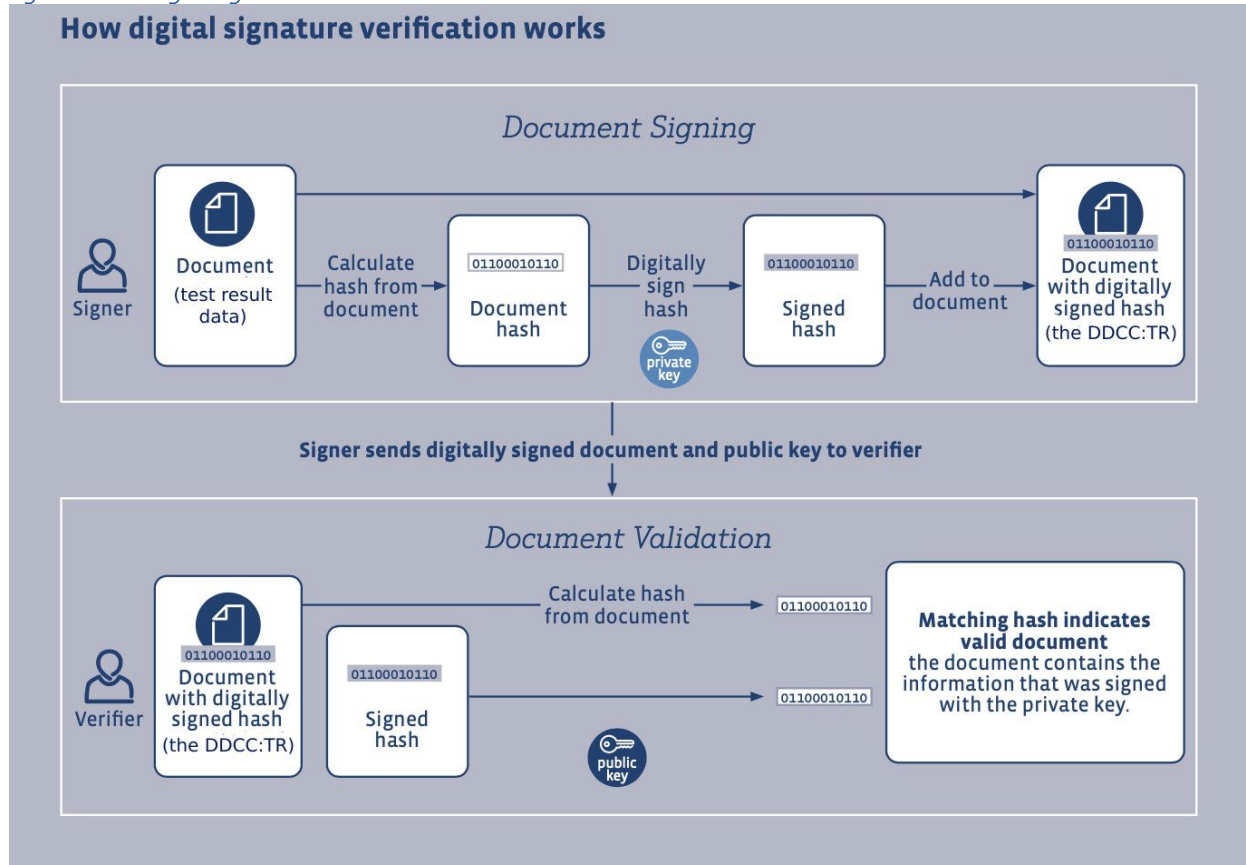
1417

1418 The verification process, shown in in the bottom row of Fig. 11 and further detailed in Figure 13,
1419 reverses the signing process to verify content in the signed DDCC:TR.

- 1420 1. A Verifier calculates its own hash (i.e. "calculated hash") from the information in the DDCC:TR
1421 using the same hashing algorithm as was used by the document signer.
- 1422 2. The DDCC:TR's signed hash is read by a digital solution.
- 1423 3. The document signer's public key is used to cryptographically transform the signed hash
1424 back to the document hash. The Verifier can compare the document hash from step 2 to its
1425 own calculated hash from step 1. If they match, the Verifier is confident that:
 - 1426 a. only someone with access to the DSC's private key could have signed the document,
1427 because the public key was able to decrypt the document hash; and
 - 1428 b. the data that was signed is the same as the data read from the DDCC:TR, because the
1429 calculated hash matches the document hash.
- 1430 4. The PHA's root certificate public key is used to cryptographically verify that the document
1431 signer's signature was issued under the responsibility of the PHA.

1432

Figure 13 How digital signature verification works



1433

1434

6.3 Trusting a DDCC:TR signature

1435

1436

1437

1438

1439

1440

1441

1442

1443

1444

1445

1446

1447

1448

1449

1450

1451

1452

The cryptographic strength of private–public key pairs is based on the mathematics of asymmetric cryptography, a process involving “one-way” mathematical functions, which are operations that are easy to compute in one direction but extremely hard to reverse. They provide a high level of security provided the private key is not compromised and remains available only to the entity performing the signing. Operationally, private keys are kept highly secure and public keys are broadly shared. Provided that a private key is not compromised and unintentionally revealed to another party, content that is “signed” by (i.e. encoded with) a private key may be readily verified by (i.e. decrypted by) anyone who has the corresponding public key. Anyone using the public key associated with the private key can be confident that:

1. material they decrypt with a public key can only have been signed by the holder of the corresponding private key; and
2. the holder of the private key cannot deny that they signed the material.

PKI is the mechanism whereby the public key is circulated to all that need it and the receiver is assured that the public key comes from a trusted source. Furthermore, a PKI also includes means for revoking keys, so that if a private key is compromised, the public keys can be flagged as no longer valid.

7 NATIONAL GOVERNANCE CONSIDERATIONS

1453
1454
1455
1456
1457
1458
1459
1460
1461
1462
1463
1464
1465
1466
1467
1468
1469
1470
1471
1472
1473
1474
1475
1476
1477
1478
1479
1480
1481
1482
1483
1484
1485
1486

Governance in the health sector is “a wide range of steering and rule-making related functions carried out by governments/decisions makers as they seek to achieve national health policy objectives that are conducive to universal health coverage”.³³ A national framework to govern the complex and dynamic health policy for implementing DDCC:TR should be tailored to meet the Member State’s needs, which vary. This section provides an overview of some key governance considerations for Member States implementing DDCC:TR solutions. However, it will be the responsibility of the Member State to determine the most appropriate governance mechanisms for its context.

Fundamentally, trust in the system should derive from the security-by-design of a PKI and the governance rules put in place by the Member State to operate it. The test result certificate verification requires governance to be established at two levels: (1) the PHA, and (2) the Member State. At PHA level, at least one DSC needs to be utilized to sign the DDCC:TR. At Member State level, an authorized DSC sharing mechanism needs to be established to indicate which DSCs are currently permitted to sign the DDCC:TR. There two recommended approaches are:

- 1. Root certificate authority:** The Member State establishes a root certificate authority which holds a root certificate for the DDCC:TR. The private key of the Root Certificate managed by the Member State, may be used by the Member State to sign a PHA’s DSC which has been authorized for use. The public key of the root certificate can be used to validate that the DSC is authorized. Note that the term root does not imply hierarchy or that the root certificate authority is at the top of that hierarchy. However, it is used to denote that a root certificate authority may be trusted directly.³⁴
- 2. Master list:** The Member State establishes a mechanism to manage and distribute, as appropriate, a master list of DSCs that have been authorized for PHAs to use to sign DDCC:TR.

Member States can leverage an existing PKI or create a new one specifically for DDCC:TR. Regardless, depending on how a Member State’s health systems are organized, there are several PKI options that the national-level ministry of health could consider, depending on the governance context in the Member State.

³³ Health system governance. In: World Health Organization/Health topics [website]. Geneva: World Health Organization; no date (https://www.who.int/health-topics/health-systems-governance#tab=tab_1, accessed 27 June 2021).

³⁴ Adams C, Farrell S, Kause T, Mononen T. Internet X.509 Public Key Infrastructure Certificate Management Protocol (CMP), section 3.1.1.2 Certification Authority. Reston (VA) and Geneva: The Internet Society Network Working Group; 2005 (<https://datatracker.ietf.org/doc/html/rfc4210#section-3.1.1.2>, accessed 27 June 2021).

1487 To ensure that national governing bodies can establish mutual trust with other Member States
1488 through bilateral or multilateral agreements, governance mechanisms should be in place for the
1489 digital signing infrastructure based on each Member State’s governance context. In addition to the
1490 authorized DSC sharing mechanism, the following components should be addressed with clear
1491 policies in place for each Member State.

- 1492
- 1493 • **Issuing DDCC:TR:** There should be clear and transparent processes in place for issuing
1494 DDCC:TR to establish trust in the system. Transparently acknowledging which entities are
1495 eligible to issue a DDCC:TR reduces the potential for fraudulent issuance of DDCC:TR and
1496 provides accountable entities when possible fraud has occurred. Member States need to
1497 define the accreditation processes and provide parameters for identification of reliable tests
1498 and testing centres. It will be up to the PHA to determine which laboratories and testing
1499 centres are authorized to participate in generation and issuance of DDCC:TR.^{35,36}
 - 1500 • **Verifying DDCC:TR:** Member States need to define the requirements for what it means to
1501 have a “valid” DDCC:TR. Furthermore, Member States will need to decide whether the
1502 DDCC:TR can be verified by anyone with the means to verify a DDCC:TR; alternatively, they
1503 may decide on a list of trusted Verifiers, in which case only trusted Verifiers would be able to
1504 verify a DDCC:TR. The appropriate privacy mechanisms should be built into the
1505 implementation based on this decision.
 - 1506 • **Revocation of DDCC:TR:** There should be clear and transparent processes for revocation of
1507 a DDCC:TR in case fraud has occurred, incorrect information needs to be rectified, or issues
1508 have been discovered at a lab and test results need to be recalled. These revocation
1509 processes should also include standard operating procedures for:
 - 1510 o **Informing individuals:** Individuals will need to be informed if their DDCC:TR has
1511 been revoked and for what reason. Enforcing revocation without clearly
1512 communicated justification may lead to erosion of trust in governing bodies.
 - 1513 o **Informing Verifiers:** Verifiers will need to be informed if DDCC:TR have been
1514 revoked in order to be able to continuously trust that DDCC:TR issued by a specific
1515 entity are still valid. For example, if there are reports of counterfeit DDCC:TR, Verifiers
1516 should be informed about the possibility of encountering counterfeit DDCC:TR. This
1517 allows for continued trust in the system.
 - 1518 o **Remedy provision:** If a DDCC:TR is revoked, Member States should apply measures
1519 to rectify the situation, for example by providing the option of a new test to be
1520 conducted, if advisable. Alternatively, there might be processes to obtain a new,
1521 verifiable DDCC:TR.
 - 1522 • **Data management and privacy protection:** Member States are responsible for data
1523 timeliness and completeness, and for the accuracy of DDCC:TR issued by their PHAs. Personal

³⁵ Laboratory assessment tool for laboratories implementing SARS-CoV-2 testing
(<https://www.who.int/publications/i/item/laboratory-assessment-tool-for-laboratories-implementing-covid-19-virus-testing>)

³⁶ Assessment tool for laboratories implementing SARS-CoV-2 testing: Interim Guidance: User Guide.
(<https://www.who.int/publications/i/item/assessment-tool-for-laboratories-implementing-covid-19-virus-testing>, accessed 22 October 2021).

1524
1525
1526

data about individuals with DDCC:TR from other countries need to be processed according to a set of principles and processes agreed upon by Member States, to establish trust between Member States.

DRAFT

8 IMPLEMENTATION CONSIDERATIONS

Since COVID-19 was declared a Public Health Emergency of International Concern under the IHR in January 2020, there has been a clear and urgent need for all Member States to effectively address the COVID-19 pandemic. In the digital age, there has also been immediate acknowledgement that digital health solutions can effectively and immediately be leveraged to support the public health response to the pandemic. Some key implementation considerations need to be taken into account before deploying a digital health solution.

8.1 Considerations before deploying

Using the framework of essential components of a digital health implementation presented in the *WHO/ITU's National eHealth Strategy Toolkit*³⁷ and the guidance provided in the *Digital implementation investment guide (DIIG)*³⁸, the following considerations and key questions should be examined prior to deployment of a DDCC:TR solution.

Strategy and investment

- What are the potential benefits, risks, and costs of implementing a DDCC:TR solution? These should be assessed before introducing a DDCC:TR system and its associated infrastructure. An impact assessment should include ethical and privacy implications and potential risks that may arise with the implementation of DDCC:TR.
- What is the potential impact on individuals, families, businesses, health workers, and other relevant stakeholders?
- What is the potential impact on public health and on the economy?
- What is the additional value added beyond using the paper system only?

Infrastructure

- How can existing digital health investments be leveraged? Due to the need for pandemic response, existing digital health investments should be leveraged as much as possible.
- Is high-volume printing capacity for paper forms available domestically?
- Consider the coverage of mobile phone adoption before pursuing a mobile-only solution. Is there broad mobile phone adoption and high coverage of mobile phone networks outside the major urban areas? Among those with mobile phones, is there broad adoption of smart phones?
- Is a PKI in place that can also be leveraged to support digitally signing DDCC:TR digital documents?

³⁷ National eHealth Strategy Toolkit: overview. Geneva: World Health Organization and International Telecommunication Union; 2012 (<https://www.who.int/ehealth/publications/overview.pdf>, accessed 28 June 2021).

³⁸ Digital implementation investment guide (DIIG): integrating digital interventions into health programmes. Geneva: World Health Organization; 15 September 2020 (<https://www.who.int/publications/i/item/9789240010567>, accessed 28 June 2021).

- 1561 • Where sample collection is done at a site different from the lab, supply chain challenges will
1562 need to be addressed regarding the transport of specimens from the point of collection to
1563 the lab and regarding the issuing of paper documents to DDCC:TR holders.
1564

1565 **Legislation, Policy and compliance**

- 1566 • Are policies for appropriate use and data protection in place to address the ethical
1567 considerations and data protection principles of DDCC:TR?
1568 • How will it be assured that individuals are not treated differently, or given different levels of
1569 trust, due to the format of the DDCC:TR they are using (e.g. smartphone application or paper
1570 certificate)?
1571 • What technical and organizational safeguards exist to ensure proper data management
1572 throughout the data lifecycle? Will additional processes (e.g. monitoring of data access, data
1573 breach notification) need to be implemented?
1574 • What review processes are needed for any newly developed policies or procedures?
1575

1576 **Leadership and governance**

- 1577 • Is there an existing department within the ministry of health that will be accountable for this
1578 work? There needs to be a clear accountable entity, whether it is a single department or a
1579 formalized cross-cutting group or committee, that is responsible for operationalizing
1580 DDCC:TR.
1581 • Is there a clear governance mechanism and are standard operating procedures in place to
1582 support the use and maintenance of the DDCC:TR?
1583 • What agency will be responsible for independent oversight for use of the DDCC:TR, and what
1584 level of authority will it be given? How will the impact of DDCC:TR use on public health, the
1585 economy, the environment, and individuals be assessed? Are mechanisms in place to course
1586 correct as needed?
1587 • What agreements or formal collaborations will need to be established in a memorandum of
1588 understanding?
1589 • Will there need to be agreements established bilaterally, multilaterally or at a regional level
1590 to establish trusted recognition between DDCC:TR of different provenance? Are bilateral or
1591 regional agreements in place that can be leveraged?
1592

1593 **Workforce**

- 1594 • Is the value added by the digital representation clearly communicated? Personnel may face
1595 the additional burden of operating a dual system of paper-based and digital solutions.
1596 • Are change management processes and support in place when implementing a DDCC:TR?
1597 • Is there a ready domestic supply of digitally competent health workers? If not, what level of
1598 effort and resources would be needed to conduct training and other capacity building
1599 measures?
1600 • Are there health informatics programmes at national level or in the private sector, provided
1601 through institutions such universities and learning platforms that can support health workers
1602 who are taking up new digital health solutions?
1603 • Given the frequently changing context of the COVID-19 pandemic, how will continuous
1604 training and update of health workers, health facility managers, and public health officials
1605 take place to ensure continued relevance of the DDCC:TR?

1606
1607
1608
1609
1610
1611
1612
1613
1614
1615
1616
1617
1618
1619
1620
1621
1622
1623
1624
1625
1626
1627
1628
1629
1630
1631
1632
1633
1634
1635
1636
1637
1638
1639

Services and applications

- Do point-of-service applications exist that are used for other workflows not related to test, but which could be leveraged to collect the DDCC:TR core data set and associate these data with an HCID? Examples may include existing LIS or HMIS solutions that can be readily extended to support new workflows.
- Are there existing products in the marketplace that would fit your needs and adhere to international specifications and guidance?
- Are there different types of software models, including: custom-developed software, commercial off-the-shelf (COTS) software, free packaged software, open-source software, and software as a service (SaaS)? The benefits and risks of these different software models should be considered.
- If deciding to use open-source products, is there a responsive established user community that will provide support and help add features at no cost?
- Which services and applications would be the most environmentally sustainable?

Standards and interoperability

- Is there an existing interoperability framework to guide how a DDCC:TR can interoperate with other existing solutions? Are there solutions in the marketplace that have operationalized standards for interoperability?
- Is conformance-testing capacity available domestically to test whether DDCC:TR solutions adhere to national (and/or international) specifications?
- Are there reusable components, such as terminology services, that could be incorporated? An example of how to leverage the OpenHIE framework is given in Annex 6.

Health content

- What is the process to account for the constantly changing context of COVID-19? As the evidence base increases and relevant clinical and/or public health guidelines are updated, there may be new health content requirements. Implementation of the DDCC:TR should change in accordance with the changing health context and remain evidence based.
- If the lab is to be generating the DDCC:TR, core data set elements captured at the time of the sample collection will need to be conveyed to the lab along with the specimen using either an electronic or paper-based means.

8.2 Key factors to consider with solution developers

If a PHA that is responsible for the delivery of a digital solution does not have the appropriate technology skills in-house, then it may want to look for one or more partners to provide that service. The choice of a digital partner will ideally be subject to a competitive process: multiple potential suppliers will be considered to identify partners that represent the best fit for the work at the optimal price, with consideration of the total cost of ownership, timeline and sustainability of the solution. The approach to inviting tenders for the work, assessing tenders, awarding a contract, and then working with a partner should consider the following high-level key factors.

- 1649 • The terms of reference for the work that needs to be performed should be clearly expressed
1650 and at a level of detail that allows solution developers to respond with a high degree of
1651 confidence in their bids.
- 1652 • An early decision is needed as to whether work will be performed under a fixed price or a
1653 time-and-materials arrangement (or a mixture of the two in which, for example, a core
1654 product is delivered but additional work paid on a pro-rata basis).
- 1655 • The timeline for work should be realistically set. The realization of a digital solution is a
1656 technology project, and projects are subject to the triple constraints of scope, cost and time,
1657 with the quality of the work affected by all three. The engaging authority should have a
1658 realistic understanding of the likely effort of the project and the effects on scope and cost if
1659 the timeline is set to be too short. A phased approach to deliver a minimum viable product
1660 first and iterate further enhancements is often recommended.
- 1661 • A decision is needed as to whether a single supplier (with sub-contractors) or a consortium
1662 of suppliers is permitted. Working with a consortium brings the advantage that multiple
1663 best-in-class vendors can collaborate, but also involves the complication of extra
1664 communication and coordination between these actors.
- 1665 • The metrics for success of the work should be defined early so that the goals and outcomes
1666 of the project are clear to all involved. Ideally, these metrics should be measurable key
1667 performance indicators (speed of operation, compliance with regulations, etc.). Contracts
1668 (and payment schedules) can be tied to performance indicators to incentivize vendors and
1669 keep the focus clearly on the desired outcome.
- 1670 • Suppliers should demonstrate solid expertise in the area of work for which they are being
1671 engaged; they should have a portfolio of previous experience and be able to provide
1672 references. A demonstration of relevant previous work can be requested to gain confidence
1673 in the vendor's expertise.
- 1674 • Suppliers should also demonstrate a solid track record of project management for delivering
1675 digital solutions. This will include establishing a clear communication plan so that the
1676 regularity of and format for reporting on project progress is understood and the procedure
1677 for escalation of problems is agreed.
- 1678 • The working hours, location and corporate culture (including working language) of any
1679 supplier should be considered to ensure that teams will work together well and that the risk
1680 of miscommunication is reduced.
- 1681 • As noted at the start of the chapter, if the strategy is to build a digital solution as part of a
1682 longer-term investment in public health technology that will outlive the COVID-19 pandemic,
1683 then the choice of a supplier that can potentially become a long-term partner in that journey
1684 is advisable.
- 1685 • It should be clear where the intellectual property for any work delivered by the digital
1686 supplier will reside, particularly if the supplier is creating new assets. The same applies to the
1687 purchase and use of any software licenses needed to execute the project and the operation
1688 of the product created.

1689
1690 A successful partnership with a digital solution developer rests on clear, binding contracts, a shared
1691 understanding of the goals and desired outcomes of the work, and a working relationship that aligns
1692 all parties behind these goals.

1693
1694
1695
1696
1697
1698

8.3 Cost category considerations

Specific cost categories and related cost drivers will affect the budget of the DDCC:TR work. However, how they will be incurred will depend on the Member State’s implementation strategy. Table 14 provides a non-exhaustive list of possible cost drivers for implementing a DDCC:TR solution.

Table 14 Illustrative costs for a DDCC:TR

Cost category	Key cost drivers and considerations
Ongoing/all phases	
Governance	<ul style="list-style-type: none"> • Coordination of personnel to develop and maintain relevant partnerships • Conducting an impact assessment and developing new policies, processes and standard operating procedures for ongoing monitoring of use and impact • Independent oversight and monitoring
Management and staffing	<ul style="list-style-type: none"> • Personnel to oversee the overall programme until planned end (if there is one), including project management – and vendor management, if applicable • System set-up and end-user support • Monitoring feedback and taking corrective action • Handling complaints and exercising data subject rights, including legal redress
Development and setup	
Technology adaptation	<ul style="list-style-type: none"> • Building completely new COVID-19 systems or leveraging existing software systems (e.g. adapting LIS) • Subscriptions, licensing fees and implementation costs associated with the software model • Custom configurations or any enhancements, if needed, or any custom-developed software • Translations and localizations, if needed
Deployment	
Equipment and hardware	<ul style="list-style-type: none"> • Data storage (e.g. costs for storage in the cloud, or on local servers or individual devices) • Devices (e.g. printers and scanners) needed at the certificate collection site
Testing	<ul style="list-style-type: none"> • Quality assurance, end-user testing and testing of conformity with standards and interoperability with other systems (if part of the design); ensure costs are allocated for collecting end-user feedback and updating the digital system according to feedback received
Training	<ul style="list-style-type: none"> • Training technicians, health facility managers and data entry personnel, which may involve travel or other logistical costs • Training materials for verifiers of DDCC:TR
Roll-out	<ul style="list-style-type: none"> • Transport of any necessary hardware, software or materials (including printed paper result) to the certificate generation or certificate-issuance sites

	<ul style="list-style-type: none"> • Increased technical support required during the roll-out phase
Outreach and raising awareness	<ul style="list-style-type: none"> • Communications on when, where and how people can obtain a DDCC:TR • Communication of what DDCC:TR can and cannot be used for • Battling “infodemics” (too much information, misinformation and disinformation) associated with DDCC:TR • Meeting accessibility requirements of individuals and reaching groups with disadvantages, such as individuals with digital skill barriers or disability barriers
Integration and interoperability	
Establishing trust frameworks	<ul style="list-style-type: none"> • Adapting content, depending on acceptance agreements between Member States • Coordination for establishing agreements between Member States
Interoperability with other systems	<ul style="list-style-type: none"> • Undertaking mapping exercises and adopting standards agreed upon through the establishment of trust frameworks • Any licensing fees associated with use of standards (note that the standards proposed by WHO in this guidance document have no licensing fees)
Scale	
Printing	<ul style="list-style-type: none"> • With the Paper Test Result: printing, which will increase as more people are tested and, subsequently, more people receive a paper test result certificate. If handwritten rapid test results need to be leveraged (e.g. at the entrance to sporting facilities or movie theatre), is there the ability to do high volume pre-printing of barcoded HCIDs on paper test result forms?
Human resources	<ul style="list-style-type: none"> • As people are tested: the additional personnel to support use of the systems, including training, management, etc.
IT licensing	<ul style="list-style-type: none"> • Depending on the licensing model associated with any digital solution, the additional licences that may need to be purchased as the number of operators or amount of data increases, or additional IT infrastructure is needed
IT scalability	<ul style="list-style-type: none"> • As data volume and number of system users grows, the scaling up of the capacity of the digital solution to provide the necessary storage and processing power
Sustained operations	
Refresher training	<ul style="list-style-type: none"> • Consistent training of new staff when staff leave, and refresher training for existing staff – with content updates made as the context changes
Adaptive management	<ul style="list-style-type: none"> • Monitoring and evaluation of DDCC:TR implementation practices and processes, with application of learnings
Communication	<ul style="list-style-type: none"> • Continued messaging, with consideration of accessibility needs • Continued help desk or customer service technology support for users of the DDCC:TR
Technology maintenance	<ul style="list-style-type: none"> • Fixing bugs, adding features, maintaining customizations, releasing updates, and hardware maintenance and replacement

1700 8.4 Additional resources to support implementation

1701 Additional resources that can be leveraged to support the implementation of DDCC:TR include
1702 examples of implementations already deployed, additional technical specifications for specific use
1703 cases, and general guidance on implementing digital health solutions. Note that the following is a
1704 non-exhaustive list of examples.

1705

1706 **WHO Interoperability Standard for DDCC:TR**

- 1707 • [DDCC:TR HL7 Implementation Guide](#)
- 1708 • DDCC:TR Core Data Dictionary (Link to be added)

1709

1710 **Example specification that can be used to guide implementation:**

- 1711 • [EU Digital COVID Certificate](#)²⁵
- 1712 • [ICAO Guidelines: visible digital seals \(“VDS-NC”\) for travel-related health proofs](#)²⁴

1713

1714 **General implementation WHO guidance for digital health solutions:**

- 1715 • [Digital implementation investment guide \(DIIG\): integrating digital interventions into health](#)
1716 [programmes](#)³⁸ *Error! Bookmark not defined.*– provides a generic systematic process for
1717 countries to develop a costed implementation plan for digital health, which can be leveraged
1718 to specifically guide implementation of the DDCC:TR.

1719

1720

REFERENCES

1. Technical considerations for implementing a risk-based approach to international travel in the context of COVID-19: interim guidance : annex to: Policy considerations for implementing a risk-based approach to international travel in the context of COVID-19. Geneva: World Health Organization; 2 July 2021 (<https://apps.who.int/iris/handle/10665/342212>, accessed 6 July 2021).
2. Requirements and Scope of Digital Certificates (<https://scienctaskforce.ch/en/policy-brief/requirements-and-scope-of-digital-certificates/>)
3. Joburg healthcare worker nabbed for allegedly selling fake Covid-19 test certificates (<https://www.news24.com/news24/southafrica/news/joburg-healthcare-worker-nabbed-for-allegedly-selling-fake-covid-19-test-certificates-20210822>)
4. Margit, M. Thousands of Israelis Join Telegram Groups Selling Fake COVID Papers - The Media Line (<https://themedialine.org/by-region/thousands-of-israelis-join-telegram-groups-selling-fake-covid-papers/>)
5. Deguma MC, Deguma JJ. The possible threat of faking Covid-19 diagnostic tests and vaccination certifications: a call to an immediate action. J Public Health (Oxf). 2021;43(2):e340–1. doi:10.1093/pubmed/fdab054.
6. Fake Covid vaccine and test certificate market is growing, researchers say (<https://www.theguardian.com/world/2021/may/16/fake-covid-vaccine-and-test-certificate-market-is-growing-researchers-say>)
7. Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance, 27 August 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Digital_certificates-vaccination-2021.1)
8. Criteria for releasing COVID-19 patients from Isolation (<https://www.who.int/news-room/commentaries/detail/criteria-for-releasing-covid-19-patients-from-isolation>)
9. COVID-19 Clinical management: living guidance (<https://www.who.int/publications/i/item/WHO-2019-nCoV-clinical-2021-1>)
10. Policy considerations for implementing a risk-based approach to international travel in the context of COVID-19. Geneva: World Health Organization; 2 July 2021 (<https://apps.who.int/iris/handle/10665/342235>, accessed 6 July 2021)
11. Considerations for implementing and adjusting public health and social measures in the context of COVID-19. Geneva: World Health Organization; 14 June 2021 (<https://apps.who.int/iris/handle/10665/341811>, accessed 17 September 2021)
12. Statement on the ninth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic ([https://www.who.int/news/item/26-10-2021-statement-on-the-ninth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/26-10-2021-statement-on-the-ninth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic))
13. Statement on the eighth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic ([https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-07-2021-statement-on-the-eighth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic))

14. Statement on the seventh meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic. In: World Health Organization/News [website]; 19 April 2021 ([https://www.who.int/news/item/19-04-2021-statement-on-the-seventh-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/19-04-2021-statement-on-the-seventh-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic), accessed 27 June 2021).
15. Statement on the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic. In: World Health Organization/News [website]; 15 January 2021 ([https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic), accessed 27 June 2021).
16. Diagnostic testing for SARS-CoV-2, 11 September 2020 (<https://www.who.int/publications/i/item/diagnostic-testing-for-sars-cov-2>)
17. COVID-19 diagnostic testing in the context of international travel: scientific brief, 16 December 2020 (<https://apps.who.int/iris/handle/10665/337832>)
18. SARS-CoV-2 antigen-detecting rapid diagnostic tests: An implementation guide, 21 December 2020 (<https://www.who.int/publications/i/item/9789240017740>)
19. COVID-19 natural immunity, 10 May 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Natural_immunity-2021.1)
20. Recommendations for national SARS-CoV-2 testing strategies and diagnostic capacities: interim guidance. 25 June 2021 (<https://www.who.int/publications/i/item/WHO-2019-nCoV-lab-testing-2021.1-eng>, accessed 8 September 2021).
21. Antigen-detection in the diagnosis of SARS-CoV-2 infection, 6 October 2021 (<https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays>)
22. Laboratory biosafety guidance related to coronavirus disease (COVID-19): Interim guidance, 28 January 2021 (<https://www.who.int/publications/i/item/WHO-WPE-GIH-2021.1>)
23. Advice on the use of point-of-care immunodiagnostic tests for COVID-19 (<https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19>)
24. Guidelines: visible digital seals (“VDS-NC”) for travel-related health proofs. International Civil Aviation Organization (ICAO) Technical Advisory Group (TAG) on the Traveler Identification Group (TRIP); no date (<https://www.icao.int/Security/FAL/TRIP/PublishingImages/Pages/Publications/Guidelines%20-%20VDS%20for%20Travel-Related%20Public%20Health%20Proofs.pdf>, accessed 27 June 2021).
25. EU Digital COVID certificate. In: European Commission [website]; no date (https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en, accessed 27 June 2021).
26. Committee on Bioethics. Statement on human rights considerations relevant to “vaccine pass” and similar documents. Strasbourg: Council of Europe; 4 May 2021 (<https://rm.coe.int/dh-bio-2021-7-final-statement-vaccines-e/1680a259dd>, accessed 27 June 2021).
27. Scottish Human Rights Commission. COVID-19 status certificates: human rights considerations. April 2021 (https://www.scottishhumanrights.com/media/2176/21_04_28_covid-certificates-and-human-rights-vfinal.pdf, accessed 30 August 2021)

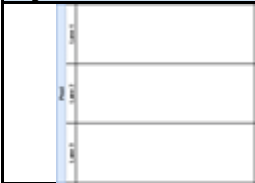
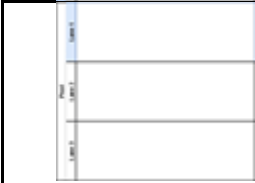






28. Guidelines on ethical issues in public health surveillance. Geneva: World Health Organization, 2017 (<https://www.who.int/publications/i/item/who-guidelines-on-ethical-issues-in-public-health-surveillance>, accessed 15 Sept 2021)
29. International Patient Summary Implementation Guide: 1.0.0 – Continuous Integration Build [website]. Health Level Seven International – Patient Care Work Group; 2021 (<https://build.fhir.org/ig/HL7/fhir-ips>, accessed 27 June 2021).
30. <https://loinc.org/>
31. ICD-11: International Classification of Diseases 11th Revision. In: World Health Organization International Classification of Diseases [website]. Geneva: World Health Organization; 2021 (<https://icd.who.int/en>, accessed 27 June 2021).
32. Global Patient Set. In: SNOMED International [website]. London: SNOMED International; 2021 (<https://www.snomed.org/snomed-international/learn-more/global-patient-set>, accessed 27 June 2021).
33. Health system governance. In: World Health Organization/Health topics [website]. Geneva: World Health Organization; no date (https://www.who.int/health-topics/health-systems-governance#tab=tab_1, accessed 27 June 2021).
34. Adams C, Farrell S, Kaue T, Mononen T. Internet X.509 Public Key Infrastructure Certificate Management Protocol (CMP), section 3.1.1.2 Certification Authority. Reston (VA) and Geneva: The Internet Society Network Working Group; 2005 (<https://datatracker.ietf.org/doc/html/rfc4210#section-3.1.1.2>, accessed 27 June 2021).
35. Laboratory assessment tool for laboratories implementing SARS-CoV-2 testing: Tool (<https://www.who.int/publications/i/item/laboratory-assessment-tool-for-laboratories-implementing-covid-19-virus-testing>)
36. Assessment tool for laboratories implementing SARS-CoV-2 testing: Interim Guidance: User Guide. (<https://www.who.int/publications/i/item/assessment-tool-for-laboratories-implementing-covid-19-virus-testing>, accessed 22 October 2021).
37. National eHealth Strategy Toolkit: overview. Geneva: World Health Organization and International Telecommunication Union; 2012 (<https://www.who.int/ehealth/publications/overview.pdf>, accessed 28 June 2021).
38. Digital implementation investment guide (DIIG): integrating digital interventions into health programmes. Geneva: World Health Organization; 15 September 2020 (<https://www.who.int/publications/i/item/9789240010567>, accessed 28 June 2021).

ANNEXES

Annex 1: Business process symbols used in workflows

Table A1.1 provides an overview of the standardized notation for business process mapping that is used to depict the Continuity of Care use cases and Proof of Vaccination use cases.

Table A1.1 Business process symbols used in workflows

Symbol	Symbol name	Description
	Pool	A pool consists of multiple “swim lanes” that depict all the individuals or types of users that are involved in carrying out the business process or workflow.
	Swim lane	Each persona is assigned to a swim lane, a designated area for noting the activities performed or expected by that specific actor.
	Start event or trigger event	The start event notes the beginning of the process.
	End event	The end event notes the end of a business process.
	Activity, process, step or task	Each activity notes the successive actions performed by the actor for that swim lane.
	Sequence flow	This denotes the flow direction from one process to the next.
	Message flow	This denotes the flow of data or information from one process to another.
	Gateway	This symbol is used to depict a fork, or decision point, in the workflow, which may be a simple binary (e.g. yes/no) filter with two corresponding output arrows, or a different set of outputs.

Annex 2: Guiding principles for mapping the WHO Family of International Classifications (WHO-FIC) and other classifications

Mapping from classifications and terminologies used in existing systems to the International Classification of Diseases, 11th revision (ICD-11), and other WHO-FIC classifications should follow the principles listed below.³⁹

1. Establish use case(s) prior to developing the map – this involves identifying and formulating the purpose(s) for which the map will be used and describing the different types of users and how they will process data using the map.
2. Clearly define the purpose, scope and directionality of the map.
3. Maps should be unidirectional and single purpose. Separate unidirectional maps should be used in place of bidirectional maps (to support both a forward and a backward map table). Such unidirectional maps can support data continuity for epidemiological and longitudinal studies. Maps should not be reversed.
4. Develop clear and transparent documentation that is freely available to all and that describes the purpose, scope, limitations and methodology of the map.
5. Ideally, the producers of both terminologies in any map should participate in the mapping effort to ensure that the result accurately reflects the meaning and usage of their terminologies. As a minimum, both terminology producers should participate in defining the basic purpose and parameters of the mapping task, reviewing and verifying the map, developing the plan for testing and validation, and devising a cost-effective strategy for building, maintaining and enhancing the map over time.
6. Map developers should agree on the competencies, knowledge and skills required of team members at the onset of the project. Ideally, target users of the map should also participate in its design and testing to ensure that it is fit for its intended purpose.
7. Establish quality assurance (QA) and usage validation protocols at the beginning of the project and apply them throughout the mapping process. QA and usage validation involve ensuring the reproducibility, traceability, usability and comparability of the maps.

Factors that may be involved in QA include quality-assurance rules, testing (test protocols, pilot testing) and quality metrics (such as computational metrics or precisely defined cardinality, equivalence and conditionality). Clear documentation of the QA process and validation procedures is an important component of this step in the mapping process. If it is feasible to conduct a pilot test, doing so will improve the QA and validation process. Mapping is an iterative process that will improve over time as it is used in real settings.

Usage validation of maps is an independent process involving users of the maps (not developers of the maps) in order to determine whether the maps are fit for purpose (e.g. whether end users

³⁹ Further mapping guidance details are provided in the forthcoming white paper on WHO-FIC classifications and terminology mapping produced in collaboration with the WHO-FIC Network, available at www.who.int/classifications.

45 reach the correct code in the target terminology when using manual and automated maps, etc.).
46 Key principles for usage validation of maps include:

- 47 a. Use a “gold standard” (i.e. a statement in the original source data – e.g. a diagnosis as
48 written in the medical record) as the reference point.
 - 49 b. Compare the original source data with the end results of the following two processes.
 - 50 i. Coding of original source data with a source terminology – map code(s) of source
51 terminology to code(s) of target terminology; and
 - 52 ii. Coding of original source data with target terminology.
 - 53 c. Use a statistically significant sample size that is representative of the target terminology
54 and its prototypical use case settings.
 - 55 d. When performing usage validation of automated maps, always include human (i.e.
56 manual) validation.
- 57 8. Dissemination: Upon publication and release, include information about release mechanisms,
58 release cycle, versioning, source/target, and licence agreement requirements, and provide a
59 feedback mechanism for users. Dissemination of maps should also include documentation as
60 stated above, describing the purpose, scope, limitations and methodology used to create the
61 maps.
- 62 9. Maintenance: Establish an ongoing maintenance mechanism, release cycle, types and drivers of
63 changes, and versioning of maps. The maintenance phase should include an outline of the
64 overall life-cycle plan for the map, conflict resolution mechanism, continuous improvement
65 process, and decision process around when an update is required. Whenever maps are updated,
66 the cycle of QA and validation must be repeated.
- 67 10. When map specialists are conducting mapping manually, it is recommended to provide the
68 necessary tools and documentation to drive consistency. Such items include: the tooling
69 environment (workflow details and resources related to both source and target schemes); source
70 and target browsers, if available; technical specifications (use case, scope, definitions); editorial
71 mapping principles or rules to ensure consistency of the maps, particularly where human
72 judgement is required; and implementation guidance. Additionally, it is best practice to provide
73 an environment that supports dual independent authoring of maps, as this is thought to reduce
74 bias among human map specialists. Development of a consensus management process to aid in
75 the resolution of discrepancies and complex issues is also beneficial.
- 76 11. In computational mapping, it is advisable to include resources to ensure consistency when
77 building a map using a computational approach, including a description of the tooling
78 environment, when human intervention would occur, documentation (e.g. the rules used in
79 computerized algorithms), and implementation guidance. It is also advisable to always compute
80 the accuracy and error rate of maps. It is important to manually verify and validate the computer-
81 generated mapping lists. Such manual checking is necessary in the QA process, as maps that are
82 generated automatically often contain errors. Such manually verified maps can also assist in the
83 training of the machine-learning model when maps for different sections of terminologies are
84 being generated sequentially.

- 85 12. The level of equivalence between source and target entities – such as equivalent, broader,
86 narrower – should be specified.
- 87 13. If the mapping uses cardinality as a metric, then it must be clearly defined in terms of what is
88 being linked between source and target, how the cardinalities are counted, and the direction of
89 the map. The cardinality of a map (one-to-one, one-to-many, many-to-one, and many-to-many),
90 without a clear definition, however, has a very weak semantic definition, being nothing more
91 than the numbers of source entities and target entities that are linked in the map.
- 92 14. Maps should be machine-readable to optimize their utility.
- 93 When creating maps using ICD-11, map into the foundation component first, then generate maps to
94 mortality and morbidity statistics through linearization aggregation.

Annex 3: What is public key infrastructure (PKI)?

The solution discussed in this document involves applying digital signatures to information to provide a guarantee that the information has been validated by an accredited authority. The proposed method is to employ a digital certificate using a private–public key pair, a common mathematical approach for encryption and digital trust. The processes, systems, software and rules around the management of these certificates form a PKI – essentially all the components that need to be in place for a trusted solution to work.

Why is a PKI needed?

Various individuals and organizations, when presented with a test result certificate, will need to be able to verify that the certificate has come from an approved authority, and that what the document purports to be is indeed true.

For paper-based records, verification has been achieved historically by means of signatures and unique seals (e.g. stamps, holographic images, special paper), but these can be copied or forged. The electronic equivalent, making use of technology, is a digital certificate. At its simplest, the electronic equivalent can be a pair of keys: a private key and a public key. Either key can be used to digitally encrypt information in such a way that it can only be decrypted by its twin key. The private key is kept secret and protected, as the name suggests, but the public key is widely disseminated.

What is a PKI?

A system is needed to distribute public keys and to reassure the recipient that the public key has come from an accredited source (i.e. the certificate authority). This is one job of a PKI, which is a mechanism for disseminating the public keys and for following up with any revocation notices if a public key is found to be compromised. Revocation may happen, for example, if the private key is obtained by an unintended party.

In essence, the PKI binds a certificate to the identity of a particular individual or organization so that a recipient can trust that the public key provided does reliably resolve back to the individual or organization in question.

How is a PKI used?

This property of the pair of keys for encryption or decryption (based on a one-way mathematical operation involving the factorization of large numbers) has many useful applications. Examples are:

Example 1: If I want to send a confidential message to a friend, then I can encrypt the message with my friend’s public key and send it out confident that only the person with the private key (my friend) will be able to read it.

Example 2: Likewise, if I want to send a message to my same friend and give that friend confidence that it could only have come from me, I can encrypt the message with my private key, and my friend can then decrypt it with my public key, knowing that only someone with the private key (i.e. me) could have written it.

138 This second scenario is of interest for signing DCC:TR data. It can be guaranteed that data has been
139 approved and signed by a trusted authority if certificates are signed using private keys held by that
140 authority and the person checking is in possession of the public key.

141

142 The keys are long alphanumeric sequences (see Fig. A4.1). There are various software tools for
143 generating public–private key pairs.

144

145 *Figure A3.1 An example key*

146 ----- BEGIN SSH2 PUBLIC KEY -----

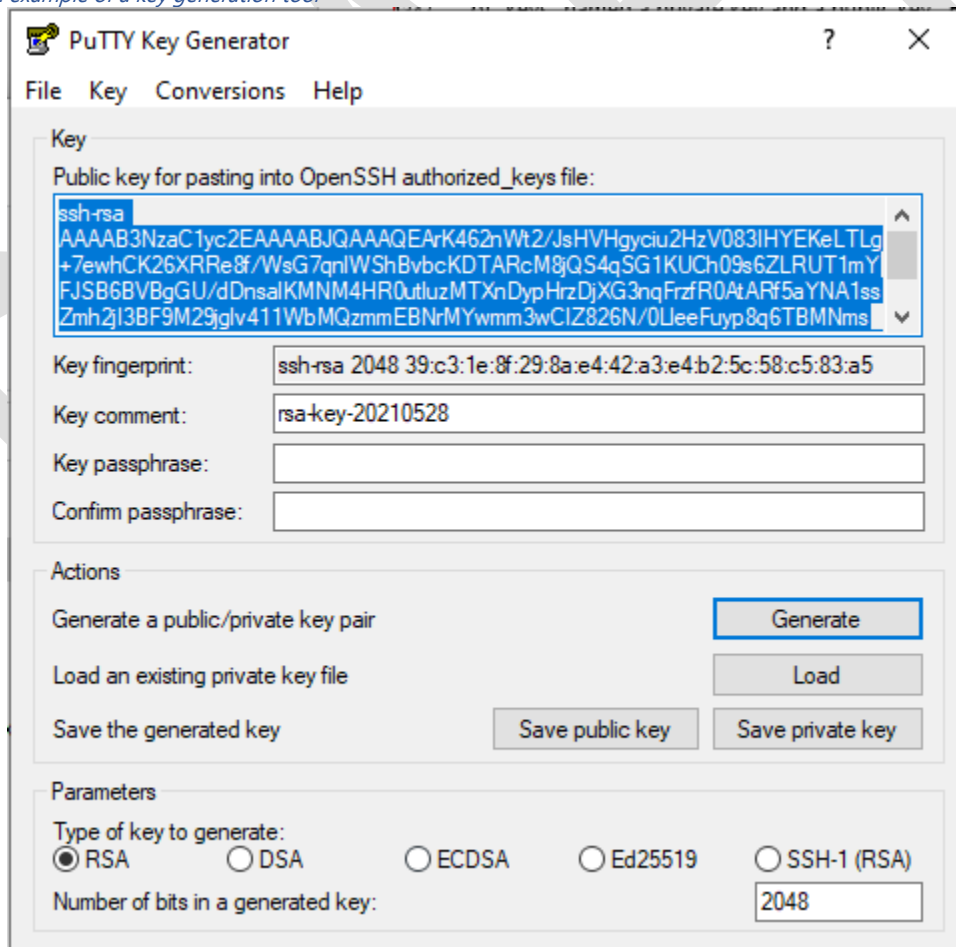
147 Comment: "rsa-key-20210528"

148 AAAAB3NzaC1yc2EAAAABJQAAAQEAk462nWt2/JsHVVHgyciu2HzV083IHYEKeLTLg
149 g+7ewhCK26XRRe8f/WsG7qnlWShBvbcKDTARcM8jQS4qSG1KUCh09s6ZLRUT1mYF
150 JSB6VBVbgGU/dDnsalKMMN4HR0utluzMTXnDypHrzDjXG3nqFrzfR0AtArf5aYNA1
151 ssZmh2jI3BF9M29jglv411WbMQzmmEBNrMYwmm3wCIZ826N/OLleeFuyp8q6TBMN
152 msRIOaIpGsTeYI2GKU/oRtxzYcP2gI0vLE/uGoySIEYI3ME6DSJbmUHtxqKsCm
153 13ggQvEwreysLX6oL0uaUyYfHTTff2kzCH8MwiB1iQP2z4izQw==

154 ----- END SSH2 PUBLIC KEY -----

155

156 *Figure A3.2 An example of a key generation tool*



157

158

159 A digital certificate (or public key certificate) is a file that contains a public key along with extra
160 information such as the name of the issuer and the validity dates for using the key. A standard such
161 as X509 is used to describe the elements in such a file.

162

163 **How does a PKI work for vaccination certificates?**

164 For the purposes of the DDCC:TR, the PKI is used to establish data provenance, as per example 2
165 above, which works as follows.

- 166 A) A certificate authority, such as a public health authority, is nominated within a particular
167 country, region or jurisdiction, and that certificate authority becomes the “trust anchor”
168 responsible for issuing certificates. Trust begins at this point, and this entity has to be a
169 recognized and authorized actor.
- 170 B) The certificate authority doesn’t sign vaccination documents and data. The signing of
171 vaccination documents and data is handled by other agencies, such as public health actors
172 and other stakeholders.
- 173 C) Therefore, the certificate authority issues private–public key pairs to these other actors in the
174 form of document signer certificates (DSCs), providing them with the information needed to
175 digitally sign documents.
- 176 D) These different agencies then use the private key in their DSC to perform this signing activity.
177 Signing involves encrypting the information using the private key so that it is rendered into a
178 format that is not human-readable.
- 179 E) Any electronic information can be signed in this way. The health certificate identifier (HCID)
180 could be signed, a representation of the whole vaccination record could be signed, or some
181 other combination of information, as determined by the certificate authority, could be
182 signed.
- 183 F) An interested party (i.e. a Verifier) who wants to decrypt the encrypted information for the
184 vaccination certificate must have two key things.
- 185 The public key corresponding to the private key in the DSC; and
 - 186 Trust that the public key, from the DSC, came from a certificate authority that the
187 interested party trusts.
- 188 G) To facilitate the two points in (F), a certificate authority usually sets up an online service for
189 this purpose. The Verifier can interrogate the service and:
- 190 1. Ask for the public key if it does not have it. The Verifier can provide the HCID and
191 check that the authority has that HCID in its records and that the HCID is linked to a
192 valid public key. This is the role of the DDCC:TR Registry Service in this paper.
 - 193 2. Once the Verifier has the public key, it can also check with the authority that the
194 public key is valid and has not been revoked.
- 195 H) Finally, now that the Verifier knows that the public key came from a trusted source, the
196 Verifier can decrypt whatever information has been provided for the vaccination certificate. If
197 the decryption reveals the data, the Verifier can be confident that:
- 198 the information could only have been encrypted by someone with the private key,
199 therefore it must have come from someone in possession of the DSC;

- 200 the information has not been altered or tampered with after it was signed, otherwise
- 201 the decryption would not work; and
- 202 the information can be trusted, because the Verifier trusts the certificate authority,
- 203 and trusts the certificate authority to have issued the DSC, which must have been
- 204 used to encrypt the information.

205 I) If the public key decrypts the encrypted information so that it looks identical to the
206 unencrypted version provided, the Verifier can be confident that only the entity in possession
207 of the private key sent this data, and that it has not been altered since by any other party.

- 208 For the vaccination certificates, the HCID must resolve back to a digital record that is
- 209 digitally signed in the manner described.
- 210 Optionally, the DDCC:TR core data set could also be encoded into a barcode to
- 211 enable the Verifier to perform an offline check, but the Verifier would still need to be
- 212 able to validate that the public key was a valid one.

213
214 A PKI is only as secure as the IT infrastructure on which it is implemented; although PKI gives a high
215 degree of trust, care must be taken to design and run the system in a manner that maintains security.

216

Annex 4: Non-functional requirements

This section contains a suggested set of generic non-functional requirements (see Table A4.1). Along with the functional requirements in sections 3.3 and 4.3, these non-functional requirements provide a set of requirements can be adapted when specifying a digital solution for the scenarios in this paper. Non-functional requirements explain the conditions under which any digital solution must remain effective and are organized into the following categories.

- **Accessibility:** The provision of flexibility to accommodate each user’s needs and preferences, along with appropriate measures to ensure access to persons with disabilities on an equal basis with others; for example, the solution should still be accessible to those with visual impairment.
- **Availability (service level agreements; SLAs):** The definition of when the system will be available to the user community, how such metrics will be measured, and the functionality in the tool for managing planned downtime.
- **Capacity – current and forecast:** The number of concurrent users that can interact with the system without an unacceptable degradation in performance, speed or responsiveness. User populations are never static, and so the ability to handle current typical and peak volumes of usage and predicted future states, and the strategy for handling a traffic surge, must be considered.
- **Uptime SLAs – disaster recovery, business continuity, resilience:** The requirements for the system in terms of how it recovers from critical, unexpected failure and the support for business continuity. This includes time to recovery, how recovery is established, and at what levels resilience and redundancy are built into the system to minimize any data loss.
- **Performance/response time:** The speed with which the system is expected to respond under normal and exceptional loads, with a definition of what those terms mean.
- **Platform compatibility:** The different operating systems, machines and configuration on which the solution is expected to run.
- **Security and privacy:** The levels of security that the solution must provide in terms of user authentication and data protection.
- **Regulation and compliance:** Any regulatory/legal constraints with which the system must comply, such as data protection policies, WHO cloud policies, and information management and retention rules of the jurisdiction(s) in which the solution will run.
- **Reliability:** A measure of the reliability of the tool, for example the acceptable mean time between failures of the solution (both hardware and software components).
- **Scalability (horizontal, vertical):** The ability to, and strategy for, handling an increasing load on the solution (in terms of increased number of users it can support, higher volumes of data it can handle, quicker performance and response, etc.). A solution can be scaled either horizontally (adding more elements to the solution, such as extra load-balanced servers) or vertically (adding extra capacity in existing elements, such as upgrading an existing server).

- **Supportability:** The requirements for engineers to detect, diagnose, resolve and monitor any issues and faults that arise while the solution is being used. This covers the features/functions that will be built into the system to facilitate technical support work.
- **Usability by target user community:** The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use. This includes optimization of the interface for clarity and efficiency, and ensuring that the solution is appropriate to the needs and the experience level and expectations of the target users.
- **Data retention/archiving:** Requirements relating to how information will be archived from its normal location and then retained, including the frequency, the approval process, and any process for restoring information from the archive.

Table A4.1 Non-functional requirements for the DDCC:TR

Requirement ID	Category	Non-functional requirement
DDCC.NFXNREQ.001	Accessibility	Any solution SHALL provide optimization for delivery to users with low bandwidth, as in a low digital maturity setting users will often have limited (or intermittent) Internet connectivity.
DDCC.NFXNREQ.002	Accessibility	Any solution SHOULD provide offline availability that permits a user to continue to work with data while offline, such as by creating a set of requests to be sent when next online.
DDCC.NFXNREQ.003	Accessibility	Any solution SHALL provide a mechanism for the resynchronization/dispatch of data created offline when the solution is reconnected.
DDCC.NFXNREQ.004	Accessibility	Any solution SHOULD follow best practice to deliver interfaces that are clear, intuitive and consistent (standardized colour schemes, icons, placement of visual elements – titles, buttons, filters, navigation, etc.)
DDCC.NFXNREQ.005	Accessibility	Any solution SHOULD follow best practice to deliver interfaces that are accessible by the widest range of users, including considerations for different cultures (e.g. left-to-right and right-to-left scripts), visual impairment (e.g. colour blindness) and physical disability (e.g. the need to interact using one hand).
DDCC.NFXNREQ.006	Accessibility	Any solution SHOULD automatically optimize its interface (layout of elements, organization of information, etc.) to adapt to the device on which it is being used, so that it is accessible on personal computers (desktops, laptops), tablets and smartphones using principles of adaptive design.
DDCC.NFXNREQ.007	Availability	Any solution developed SHOULD NOT be able to accept more than 10 minutes of outage during normal usage and cannot accept more than 1 minute of data loss of queries and responses.
DDCC.NFXNREQ.008	Availability	It MAY be possible to provide an indication of the availability status of any solution so that users can check the system's "health". The same functionality MAY also notify of any planned downtime, retired functionality, release notes, etc.
DDCC.NFXNREQ.009	Capacity – current and forecast	The system SHALL be able to support the potentially large number of concurrent users performing read and write operations during normal operation. This metric will vary significantly between different country contexts and will depend on the design, but should be used as the anticipated capacity standard.
DDCC.NFXNREQ.010	Capacity, current and forecast	During periods of peak usage, system traffic MAY surge the number of concurrent users performing read and write operations.
DDCC.NFXNREQ.011	Capacity, current and forecast	Forecast growth of the user base is anticipated to be high. As a safety contingency, the system SHOULD support, or have scaling plans to support, growth of 25% per year.

DDCC.NFXNREQ.012	Disaster recovery, business continuity, resilience	All data and derived analysis SHALL be stored within an appropriate data architecture to ensure redundancy and rapid disaster recovery, to eliminate the risk of data loss.
DDCC.NFXNREQ.013	Disaster recovery, business continuity, resilience	The system SHOULD provide near-instantaneous switch-over if any one component of the system architecture fails critically (database server, web server, system monitoring job, service bus, etc.).
DDCC.NFXNREQ.014	Disaster recovery, business continuity, resilience	The system SHOULD provide near-instantaneous switch-over if any one component of the physical architecture fails critically (data centre destroyed, server destroyed, etc.)
DDCC.NFXNREQ.015	Disaster recovery, business continuity, resilience	All components of the solution SHOULD be underpinned by robust monitoring tools that track usage across space and time, so that system load and source can be queried.
DDCC.NFXNREQ.016	Disaster recovery, business continuity, resilience	Data concerning system usage SHOULD be available to system administrators via a dashboard to show current load, and recent load (last week, last month), and be able to perform custom queries by place and time. It SHOULD be possible to export this data.
DDCC.NFXNREQ.017	Disaster recovery, business continuity, resilience	It SHALL be possible to automatically log any periods of outage of the system and to supplement and update this record manually.
DDCC.NFXNREQ.018	Disaster recovery, business continuity, resilience	It SHALL be possible to trigger system alerts based on uptime and performance.
DDCC.NFXNREQ.019	Disaster recovery, business continuity, resilience	It SHOULD be possible to use system alerts to perform actions such as dispatch of a warning email/SMS to a system administrator or to execute a script that (for example) spins up a new virtual machine for load balancing.
DDCC.NFXNREQ.020	Performance/ response time	The solution SHALL follow best practices to deliver a responsive interface in which typical requests can be served (end-to-end interaction) in a maximum time specified in a number of seconds to be determined based on typical bandwidths. Degradation to a greater maximum time in number of seconds for limited-bandwidth scenarios is acceptable.
DDCC.NFXNREQ.021	Performance/ response time	The solution SHOULD be designed so that degradation of performance due to increased load (surge of users) is minimized.
DDCC.NFXNREQ.022	Performance/ response time	Where appropriate, long-running processes such as complex queries MAY be available for asynchronous execution, to allow a user to continue to interact with the system while the job executes and to receive a notification when the work is complete.
DDCC.NFXNREQ.023	Performance/ response time	The system MAY implement detection of a frozen ("hung") interface to give the user the option to cancel a current request.
DDCC.NFXNREQ.024	Performance/ Response time	The system SHOULD collect metrics on performance and response time to allow a system administrator to monitor system behaviour, identify bottlenecks or issues, and pro-actively address any risk of unacceptable degradation of speed.
DDCC.NFXNREQ.025	Performance/ response time	As with system availability, the solution SHALL provide dashboards of performance metrics, allow querying of the performance log and export of performance data for reports.
DDCC.NFXNREQ.026	Performance/ response time	As with system availability, the solution SHALL have the ability to set thresholds on performance and use the breach of those thresholds to raise alerts that can trigger email notifications or automated system actions (bring an extra server into a load-balanced set, for example).
DDCC.NFXNREQ.027	Security and privacy	Tools to request an account, log in, log out, set and change passwords, and receive password reminders SHALL be provided.
DDCC.NFXNREQ.028	Security and privacy	All interactions between a client and a server component of the solution SHALL be securely encrypted to prevent "man in the middle" interference with data in transit.
DDCC.NFXNREQ.029	Security and privacy	Any cloud components of the solution SHALL store their cloud data-at-rest in an encrypted format.

DDCC.NFXNREQ.030	Security and privacy	The solution SHALL have a security model that is robust and flexible and controls both access to data and the operations that can be executed against data.
DDCC.NFXNREQ.031	Security and privacy	Information about the governance and restricted use of data SHOULD be available within any solution alongside the data concerned, so that users have a clear and consistent reminder of the level of confidentiality, the sensitivity, and the permitted use of the data they are currently viewing.
DDCC.NFXNREQ.032	Security and privacy	Dashboards, reports, standard queries and exports of security information SHOULD be provided to assist system administrators in the management of access permissions. Queries to highlight conflicting permissions SHOULD be available.
DDCC.NFXNREQ.033	Security and privacy	The confidentiality of data must be managed with utmost care. In shared data environments, there SHALL be a clear separation of between the system's data and any other hosted clients' information. Dedicated hosting and data sources are preferred.
DDCC.NFXNREQ.034	Regulation and compliance	Any solution SHOULD be designed mindful of existing reference architecture guidelines and standards for distributed trust framework solutions and tools for exchanging vaccination data.
DDCC.NFXNREQ.035	Regulation and compliance	Any solution SHALL be compliant with any data policies and legal requirements identified by the country in whose jurisdiction the solution will operate.
DDCC.NFXNREQ.036	Regulation and compliance	It MAY be possible to tag data sets with any regulation and compliance information relevant to them so that this is readily available with the data set. Such information might include the data provider, intended purpose of the data, restrictions on the use of the data, and restrictions on where data can be stored.
DDCC.NFXNREQ.037	Regulation and compliance	Any solution SHALL be compliant with any data storage, retention and destruction laws mandated by the data policies and data laws of the countries in which data are located.
DDCC.NFXNREQ.038	Reliability	Any solution SHOULD be designed to maximize the mean time between failures, with appropriate best practice to deliver a robust, well-tested and reliable platform.
DDCC.NFXNREQ.039	Reliability	Any solution SHOULD provide a log in which failures in any part of the system are logged, so that mean time between failures can be calculated and tracked.
DDCC.NFXNREQ.040	Scalability	Any solution SHOULD be designed so that elements can be scaled horizontally by (for example) adding extra resources (more servers, extra virtual machines, etc.) and the mechanisms for coordinating their activity (load balancing, session management, etc.)
DDCC.NFXNREQ.041	Scalability	Any solution SHOULD be designed so that elements can be scaled vertically by (for example) adding extra capacity to solution elements (increased CPU, increased RAM, etc.)
DDCC.NFXNREQ.042	Scalability	It MAY be possible to configure rules for automatic horizontal scaling of the system to respond to increased load (e.g. spinning up a new virtual machine and adding it to a load-balanced pool of resources). Rules will be based on thresholds for system load and performance.
DDCC.NFXNREQ.043	Scalability	Any solution SHOULD log sufficient information about performance and load so that technical staff can refine the system's scaling strategy based on actual usage.
DDCC.NFXNREQ.044	Supportability	Any solution SHOULD provide a feedback channel as described in functional requirements for collecting information and support requests.
DDCC.NFXNREQ.045	Supportability	Any solution MAY provide access to learning material to support a user's understanding of how to use the tool and achieve specific aims.
DDCC.NFXNREQ.046	Supportability	The solution SHALL include a system log of activity in which events of interest, the time and date when they occur, their categorization, and the user (if appropriate) who triggered the event are recorded. The log must be of sufficient detail to assist technical staff with debugging issues.

DDCC.NFXNREQ.047	Supportability	It MAY be possible to configure system logging in a verbose and a standard format. Verbose format will be used for periods of testing or bug fixing, and standard for production use of a stable system in which smaller log size is prioritized over a high level of detail.
DDCC.NFXNREQ.048	Supportability	It SHOULD be possible for technical support staff to filter and query system logs to quickly identify sections of interest.
DDCC.NFXNREQ.049	Supportability	It MAY be possible to trigger alerts from the creation of pre-defined log entries (e.g. an error, warning, failure). Alerts can be used to take actions such as email dispatch.
DDCC.NFXNREQ.050	Supportability	Any solution SHALL have a published strategy for the release of patches, maintenance releases and version upgrades.
DDCC.NFXNREQ.051	Usability	Any interface created SHOULD be mindful of best practices for user design/adaptive design to ensure the best chance of presenting a clear and concise, and intuitive user experience. This is particularly important for any interface dealing with data entry.
DDCC.NFXNREQ.052	Usability	It SHOULD be possible to deliver definition/explanation text in the language currently selected for the interface via the solution, so that acronyms, jargon, technical terms, etc., can be clarified where necessary.
DDCC.NFXNREQ.053	Usability	The user interface MAY be designed so that navigation via keyboard (tab movement between fields, use of shortcut keys) is possible if the user does not have access to a pointer device.
DDCC.NFXNREQ.054	Usability	When the solution adapts for display on a smartphone/tablet, the interface SHALL be designed mindful of touch-screen interaction.
DDCC.NFXNREQ.055	Usability	The solution MAY provide an efficient and easy way to manage taxonomy (for administrator users) – to record standard definitions, relationships between terms, etc.
DDCC.NFXNREQ.056	Data retention/archiving	It SHOULD be possible to manually request an archive of a selected subset of information.
DDCC.NFXNREQ.057	Data retention/archiving	It MAY be possible to schedule the archiving of a selected subset of information and to set a recurrence for this operation. The archive operation will execute when the scheduled date and time arrives.
DDCC.NFXNREQ.058	Data retention/archiving	It MAY be possible to trigger a notification alert when an archive operation completes (including success and failure reports).
DDCC.NFXNREQ.059	Data retention/archiving	Any archive function SHALL not affect the performance of the system.
DDCC.NFXNREQ.060	Data retention/archiving	Any archive material SHOULD be labelled with metadata about the information it contains and the date and time it was created, to facilitate quick navigation of all archived material.
DDCC.NFXNREQ.061	Data retention/archiving	It SHOULD be possible, with the necessary authority and permissions, to restore information from a chosen archive back into the operational set of information.
DDCC.NFXNREQ.062	Data retention/archiving	All archival operations SHALL be logged.
DDCC.NFXNREQ.063	Data retention/archiving	It SHOULD be possible, with the necessary authority and permissions, to perform a limited search of the contents of archives to identify information of interest.
DDCC.NFXNREQ.064	Data retention/archiving	All information written to archives SHALL be in an encrypted format to prevent misuse if accessed by an unauthorized system or person.

268

269 CPU, central processing unit; RAM, random-access memory.

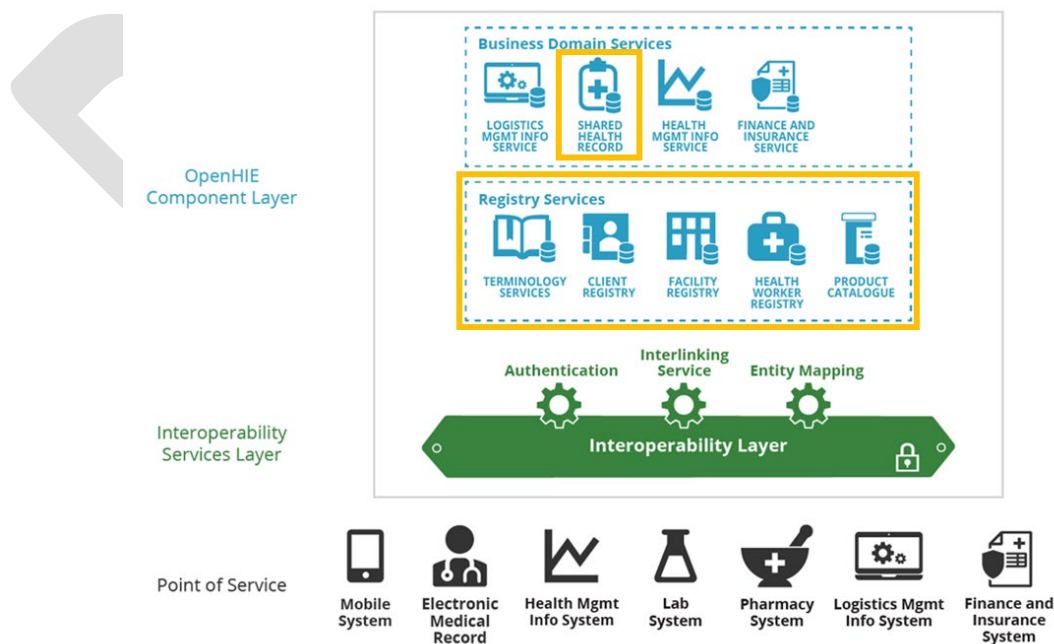
Annex 5: Open Health Information Exchange (OpenHIE)-based architectural blueprint

This section illustrates how a standards-based health-data-sharing infrastructure could support point-of-care digital health solutions. If digital health solutions are employed in real time during the vaccine administration event, it is anticipated that complementary digital health infrastructure, such as the architectural elements described by the OpenHIE specification, could be leveraged.

OpenHIE describes a reusable architectural framework that leverages health information standards, enables flexible implementation by country partners, and supports exchange of individual components. OpenHIE also serves as a global community of practice to support countries towards “open and collaborative development and support of country-driven, large-scale health information sharing architectures”.⁴⁰

The OpenHIE high-level architecture⁴¹ is shown in Figure A5.1. To show how a health-data-sharing infrastructure could support point-of-care digital health solutions to issue Digital Documentation of COVID-19 Certificates: Test Result (DDCC:TR), a set of digital health interactions are described in terms of the conformance-testable Integrating the Healthcare Enterprise (IHE) specifications referenced by the OpenHIE specification.

Figure A5.1 OpenHIE architecture^a



OpenHIE 2020-05-28; CC BY 4.0

^aYellow boxes indicate registries and repositories relevant to DDCC:TR.

⁴⁰ OpenHIE. In: OpenHIE [website]. OpenHIE; no date (<https://ohie.org/about>, accessed 29 June 2021).

⁴¹ OpenHIE Architecture Specification. OpenHIE; September 2020 (<https://ohie.org/wp-content/uploads/2020/12/OpenHIE-Specification-Release-3.0.pdf>, accessed 29 June 2021).

293
294
295
296
297
298
299
300
301
302
303
304
305
306
307
308
309
310
311
312
313
314
315
316
317
318
319
320
321
322
323
324
325
326
327
328
329
330
331
332
333
334
335
336
337

The registries and repositories defined in the OpenHIE architecture (see Fig. A6.1) may play a role in providing data that are part of the DDCC:TR core data set defined in Chapter 5. These registries and repositories include:

Terminology services: A registry service used to manage clinical and health system terminologies, which health applications can use for mapping to other standard or non-standard code systems to support semantic interoperability. For example, a terminology service can be used to manage terminology mappings of existing code systems to the International Classification of Diseases, 11th revision (ICD-11).

Client registry: Also referred to as a patient registry, a demographic database that contains definitive information about each Tested Person. This database can include a Tested Person's name, date of birth, sex, address, phone number, email address, as well as other person-specific information such as parent-child relationships, caregiver relationships, family-clinician relationships and consent directives. It is also in the client registry that the list of unique identifiers (IDs; e.g. national ID, national health ID, health insurance ID) for a particular Tested Person can be found. The data elements in the DDCC:TR core data set that may be populated with data from the client registry include:

- name
- date of birth
- sex
- unique IDs.

Facility registry: A database of facility information, including data such as the facility name, a Public Health Authority (PHA)-issued unique ID, the organization under whose responsibility the facility operates, location (by address and/or Global Positioning System [GPS] coordinates), facility type, hours of operation, and the health services offered. The data elements in the DDCC:TR core data set that may be populated with data from the facility registry include:

- administering centre: facility name or unique ID can be used to represent this
- country where test was conducted.

Health worker registry: A database of health worker information that contains information such as name, date of birth, and qualifications of health workers (including cadre, accreditations, and authorizations of practice). The health worker registry also references unique health worker IDs that may have been issued by a PHA, care delivery organizations or individual health facilities.

Product catalogue: A system used to manage the metadata and multiple IDs for medical commodities. Depending on whether the product catalogue includes vaccine products, the data elements in the DDCC:TR core data set that could be obtained from the product catalogue are:

- test type
- test brand
- test manufacturer
- disease or agent targeted.

338 **Shared health record (SHR):** A repository that may be used to maintain longitudinal health
339 information about a Tested Person and to support continuity of care over time, across different care
340 delivery sites. Health data in the SHR can include content such as the Tested Person’s medication list,
341 allergies, current problem list, immunization records, history of procedures, medical devices,
342 diagnostic results, vital sign observation record, history of illness, history of pregnancies and current
343 pregnancy status, care plan and advance directives. Such health data may be expressed using health
344 data content standards such as the Health Level Seven (HL7) Fast Healthcare Interoperability
345 Resources (FHIR) International Patient Summary (IPS) specification. Data in the SHR can be important
346 for delivering guideline-based care during vaccine administration. Furthermore, data generated
347 during test events could be added to the SHR, if in use, in order to support future provision of health
348 services.

349

350