

RED AMERICANA
DE COOPERACION
SOBRE SALUD
ELECTRONICA



Data model document

Component 1 LACPASS



Version 4
March 2022

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Introduction

Continuing with the process of exchanging people's clinical information between different countries in the region, it is necessary to have the required information for each of the data points that will be needed to perform the exchange.

The current document expands on the information included in the [Functional and Non-Functional Requirements for a Proof of Concept document](#). This document includes the list of details that need to be included in the certificates and IPS, the structure the data needs to have, and the conditions under which the information will be displayed or not.

Using this information, the countries in the region wanting to participate in the exchange of clinical information will need to identify the data that they have available and the structure of the data. It is a tool that will allow them to unify the structure of the data for all countries to have the same data with the same structure.

For the data contained in COVID-19 certificates, the information about the structure corresponds to the one used by the European Union. They are currently conducting the process amongst their member countries, in addition to any countries following the same structure defined by the EU.

For the IPS related data, the data will be presented using a structure based on HL7 FHIR.

Generating a consensus between countries regarding the information that will be exchanged guarantees that the information included in the exchange will be verified correctly.

Data Modeling

Basic Concepts

The goal of the information exchange is to permit the free movement of people between countries during the COVID-19 pandemic.

The certificate must contain a minimum amount of coded data which will be digitally signed. It must also comply with the following considerations:

- Issuance: the certificates must be issued by the National Health Authority, who will digitally sign the certificate.
- Portability: users must be able to Access the certificate digitally or in paper format.
- Verification: there will be authorized organizations in charge of verifying the authenticity of the signature present in the certificates.

Each person must be able to access their own certificate in three ways:

- Paper
- Digital, offline
- Digital, online

It is important to include information regarding the version. The version control follows the semantic versioning specifications (<https://semver.org>). In production, it must correspond to one of the officially launched versions. Whether it is current or a previous one, it must always be an officially launched one. The format for the versioning is the following:

ID Field	Field Name	Instructions
view	Schema version	Must match with the identifier for the schema version used to produce the EUDCC. The following is a versioning example for the European Union: "view": "1.3.0"

Certificates must be divided into three groups, and each one must contain a group. No empty groups are allowed.

Identifier Group	Group Name	Input
v	Vaccination Group	If present, it must contain a single entry describing a vaccination dose.
t	Testing Group	If present, it must contain a single entry which describes the test results.
r	Recovery group	If present, it must contain an input queue which describes the recovery statement.

Minimum Amount of Data – Vaccination Certificate

The minimum dataset allows us both to have basic information in a structured way and for the data to guarantee the interoperability between the different vaccination certificates.

The minimum dataset for a vaccination certificate will have three structures:

- Person identification
- Vaccination information
- Certificate metadata

Patient Identification Data

In the first section, we will find the data related to the person's identification. This data is as follows:

Element Data	Description	Mandatory	Obs.
Person's Last Name/s	nam/fn Refers to the last name (s) of the vaccinated person.	Yes	Must exactly provide a non-empty field including all of the last names. In case of multiple last names, they will be separated using spaces. Any last names with special characters will remain the same. "fn": "Musterfrau-GöBinger" "fn": "Musterfrau-GöBinger Muller"
Person's Standardized Last Name/s	nam/fnt Refers to the last name (s) of the vaccinated person.	Yes	Refers to the last name(s) transcribed using the convention used for machine readable travel documents. Provide a non-empty field which only includes the Arizona character and a maximum length of 80 characters. "fnt": "Musterfrau<GöBinger" "fnt": "Musterfrau<GöBinger <Muller"
Person's First Name/	nam/gn Refers to the name (s) of the vaccinated person.	Yes	Must exactly provide a non-empty field including all of the first names. In case of compound or multiple names, they must be separated using spaces. "gn": "Ana Inés"
Person's Standardized First Name	nam/gnt Refers to the name	Yes	Refers to the first name(s) transcribed using the convention used for machine readable travel

	(s) of the vaccinated person.		documents. Provide a non-empty field which only includes the Arizona character and a maximum length of 80 characters. "gnt": "Ana<Ines"
Person's Identifier	Refers to the identifier presented by each country in accordance with their policies.	No	The identifier is not the same in all of the region.
Person's Birth Date	dob Refers to the date of birth of the vaccinated person. If they do not have one, use the birth date for administrative purposes.	Optional	Whether complete or partial, with no time restrictions for the rank. Provide a non-empty field for the complete or partial date. For cases in which there is no known birth date, there must be an empty string configuration "", but the existing information regarding the complete or partial birth date must match the birth date in the travel document. ISO 8601 format. No other options allowed. Corresponds to: YYYY-MM-DD YYYY-MM YYYY "dob": "1978-01-28" "dob": "1978-01" "dob": "1978" "dob": "" When performing the verification, the application can complete any missing information regarding the birth date using the XX convention. "Dob": "1978-XX-XX"
Sex	Administrative gender	No	

Vaccination Data

In addition to the above, any data related to the vaccination must be added. For this purpose, it will be necessary to have the following information:

Element Data	Description	Mandatory	Obs.
Disease ¹	v/tg Refers to the disease the vaccine is fighting.	Yes	The following standards are recommended: <ul style="list-style-type: none"> • Snomed-ct • ICD 11 • ICD 11(2022) Refers to a non-empty value corresponds to <i>enfermedad-agente-objetivo.json</i> This value has a single entry which corresponds to the SNOMED-CT entry. “tg”:”840539006”
Prophylaxis	v/vp Refers to the generic description of the vaccine/prophylaxis or their components.	Yes	The following standards are recommended: <ul style="list-style-type: none"> • Snomed-ct • ATC • J07 Classification Refers to a coded value corresponds to <i>vacuna-profilaxis.json</i> The values are distributed by the EUDCC since version 1.1. Provides a non-empty field. “vp”:”1119349007” This code corresponds to an ARNm vaccine.
Vaccine Medication Product ²	v/mp Refers to the name of the medication	Yes	Should correspond to the name of the product as registered in the country. Refers to the medication used in the vaccine. The value is coded, and corresponds to <i>vacuna-medicacion-producto.json</i> The values they may take are defined by EUDCC in version 1.1. Provides a non-empty field.

¹ See Annex 1

² See Annex 2

			“mp”:"EU/1/20/1528/" (comirnaty)
Vaccine authorization ³	v/ma Refers to the name of the vaccine authorization owner. If it is not available, the name of the vaccine manufacturer MUST BE REQUESTED.	Yes	Refers to the owner of the commercialization authorization. If it is not present, it will be a coded value corresponds to <i>vacuna-mah-manf.json</i> The values they may take come from EUDCC version 1.1. The field will be a single one, non-empty. “ma”:"ORG-100030215" corresponds to Biontech
Dose	v/dn Refers to the number of doses that must be administered for each of the vaccines.	Yes	The number of administered doses corresponds to a whole positive number. It is a non-empty field. “dn”:"1" corresponds to the first dose of the series. “dn”:"2" corresponds to the second dose of the series. “dn”:"3" corresponds to the third dose of the series, or the dose called “booster shot”.
Total Dose	v/sd Refers to the total number of doses in the series.	Yes	Refers to a whole positive number, in a complete vaccination series in accordance with the employed vaccination protocol. Since there are differences in how vaccines are administered in each country, it may happen that there are only one or two doses administered to a person who has had the disease, or they might not be a booster shot. For this purpose, the value of the field must be set to 1, and it must be a non-empty field. “sd”:"1" applicable to all vaccination schemes with only

³ See Annex 3: Owners of the COVID-19 Vaccine Commercialization

			<p>one dose.</p> <p>“sd”:"2" applicable to all vaccination schemes with two doses.</p> <p>“sd”:"3" applicable to all vaccination schemes with a booster shot.</p>
Lot	<p>Refers to a combination of letters and numbers which allow us to identify the specific vaccine and to ensure traceability.</p>	No	<p>It is not mandatory data because not all countries have the information in the vaccination certificate.</p>
Vaccination Date	<p>v/dt</p> <p>This information will depend on the number of doses required for the vaccination.</p>	Yes	<p>Refers to the date on which the vaccination was administered with format YYYY-MM-DD, without the time. No other formats are supported.</p> <p>Must provide a non-empty field.</p> <p>“dt”:"20021-06-13"</p> <p>Must be done in accordance with the ISO 8601 regulation.</p>
Next Vaccination Date	<p>Refers to the date of the next vaccination dose that will be administered.</p>	No	<p>Must be done in accordance with the ISO 8601 regulation.</p>
Administration Center/Vaccination Center	<p>The identifier for the vaccination center or responsible health authority.</p>	No	
Professional	<p>The identifier for the professional who carried out the vaccination process.</p>	No	
Professional's Signature	<p>Valid only for paper certificates.</p>		
Country	<p>v/co</p> <p>Country in which</p>	Yes	<p>Must be done in accordance with ISO 3166-1 alpha 3 regulation (or numeric) with 2 letters or a</p>

	<p>the vaccination process is carried out.</p>		<p>reference to an international organization responsible for the vaccination event, such as WHO or Acnur.</p> <p>It is a coded value corresponding to <i>country-2-codes.json</i>. The values they may take correspond to the ones established in EUDCC as of version 1.1. A field must be provided.</p> <p>“co”:"CZ" “co”:"ACNUR”</p>
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Certificate Data

The third component in the vaccination certificate must contain the following metadata:

Element Data	Description	Mandatory	Obs.
Issuing Entity	v/is Corresponds to the entity issuing the vaccination certificate.	Yes	Identifiers are allowed as part of the name, but we do not recommend individual uses without the name as a text. It must contain a maximum of 80 UTF-8 characters. A non-empty field must be provided. "is": "Ministry of Public Health of the Oriental Republic of the Uruguay" "is": "Vaccination Center Number 3"
Certificate Identifier	v/ci Unique certificate identifier.	Yes	The unique certificate identifier will be based on the specification named <i>directrices_interoperabilidad-a prueba de vacunación_en.pdf</i> (europa.eu) Including a checksum is optional. The prefix "URN:UVCI:" can be added. "ci": "URN: UVCI: 01: NL: 187/37512422923" "ci": "URN: UVCI: 01: AT: 10807843F94AEE0EE5093FBC254BD813 # B"
Period of Validity From	Refers to the start of the certificate's period of validity.	Yes	Must be done in accordance with the ISO 8601 regulation.
Period of Validity Until	Refers to the end of the certificate's period of validity.	Yes	Must be done in accordance with the ISO 8601 regulation.
Versioning	Refers to the certificate versions.	Yes	

Minimum Amount of Data –COVID-19 Test Certificates

In relation to the COVID-19 Test Certificates, it is of the utmost importance to note that a single test result must be described in the certificate. In addition, it will follow the same data structure in relation to the patient's Identification, which was described above for the COVID-19 vaccination certificates.

Test Certificate Data

Element Data	Description	Mandatory	Obs.
Pathogen	t/tg Refers to the disease or COVID-19 SARS-CoV agent or any of its variants.	Yes	The value has a single entry which corresponds to code 840539006 in SNOMED CT for COVID-19. The field cannot be empty. Example: "tg": "840539006" The coded value established corresponds to <i>enfermedad-agente-objetivo.json</i>
Test Type ⁴	t/tt Refers to the type of test used.	Yes	The value corresponds to the type of test performed on the person. Empty fields are not allowed. For tests, the standard used is LOINC. Example: "tt": "LP6464-4" corresponds to the nucleic acid amplification with probe detection. "tt": "LP217198-3" corresponds to the rapid test. The coded value corresponds to <i>test-type.json</i> .
Test Name	t/nm Refers to the name of the nucleic acid amplification (NAAT) test performed.	Yes	Regarding the name of the nucleic acid amplification (NAAT) test performed, it must include the manufacturer name and the commercial name for the test. Both names must be comma separated. In the case of NAAT tests, the field is optional. For RAT tests (rapid antigen tests), however, the field should not be used because the name of the test is provided indirectly through the test identifier (t/ma).

⁴ <https://covid-19-diagnostics.jrc.ec.europa.eu/devices>

			<p>When the field is provided, it must NOT be empty.</p> <p>Example: “nm”:"ELITechGroup,kit ELITe MGB[®] SARS-CoV-2”</p>
Test Device	Identifier for RAT tests only.	Yes	<p>RAT identifier. It can be accessed through the following link:</p> <p>https://covid-19-diagnostics.jrc.ec.europa.eu/</p> <p>All rapid antigen tests in the HSC common list are readable by humans.</p> <p>The certificate issuers must issue a certificate for valid tests when carrying out the test. In addition, the value must be updated every 24 hours.</p> <p>It may happen that values falling outside of the set of values are used by other countries to issue certificates. However, the identifiers must belong to the ICCn or they must be allowed to use the identifiers provided directly by the test manufacturers.</p> <p>When performing the validation, the values that do NOT belong to the updated group must be detected and the status of the certificate changed to invalid.</p> <p>When deleting a test value from the updated list, all of the certificates which include the deleted value will be valid only for 72 hours after the value was deleted.</p> <p>Example: “ma”:"344” corresponds to SD BIOSENSOR Inc, ESTÁNDAR F COVID-19 Ag FIA</p>
Date and time when the test was performed	t/sc Refers to the date and the time when the sample was collected.	Yes	<p>The time must include information regarding the time zone in which the sample was collected, not the time zone for the result.</p> <p>The ISO 8601 format must be used. The following options are accepted: YYYY-MM-DDThh:mm:ssZ</p>

			<p>YYYY-MM-DDThh:mm:ss[+~]hh YYYY-MM-DD-Thh:mm:ss[+~]hhmm YYYY-MM-DDThh:mm:ss[+~]hh:mm</p> <p>Example: "sc": "2021-08-20T10: 03: 12Z" "sc": UTC time "2021-08-20T12: 03: 12 + 02" "sc": CEST time "2021-08-20T12: 03: 12 + 0200" " sc ":" CEST time</p> <p>2021-08-20T12: 03: 12 + 02: 00 " CEST time</p>
Results	<p>t/tr</p> <p>Refers to the test results.</p>	Yes	<p>A value must be provided. An empty field is not allowed.</p> <p>The result values are coded through SNOMED CT.</p> <p>The coded value corresponds to <i>resultado de prueba.json</i></p> <p>Example: "tr": "26041500" Not detected</p>
Center where the test was performed	<p>t/tc</p> <p>Refers to the organization in which the test was performed.</p>	Yes	<p>Refers to the name of the organization in which the test was performed.</p> <p>The name must contain a maximum of 80 UTF-8 characters. Identifiers can be used as part of the name.</p> <p>Example: "tc": "Test center east region 245"</p>
Country	<p>t/co</p> <p>Refers to the country in which the test information was loaded.</p>	Yes	<p>As regards the country, we recommend using an ISO3166 code; specifically, the two-letter code.</p> <p>The coded value corresponds to <i>country-2-codes.json</i></p> <p>Example: "co": "CZ" "co": "ACNUR"</p>
Certified Issuer	<p>t/es</p> <p>Refers to the entity issuing the certificate.</p>	Yes	<p>Refers to the name of the organization responsible for issuing the certificate.</p> <p>The name must contain a maximum of 80 UTF-8 characters. Identifiers can be used as part of the name.</p>

			Example: "uy": "Ministry of Public Health""es:" ASSE"
Identifier	t/ic Refers to the unique certificate identifier.	Yes	The unique identifier is specified in Examples: "ci": "URN: UVCi: 01: NL: 187/37512422923" "ci": "URN: UVCi: 01: AT: 10807843F94AEE0EE5093FBC254BD8 13 # B"

Minimum Amount of Data – COVID-19 Recovery Certificate

For recovery certificates, it is important to point out that when referring to person identifiers, the data is as described for the vaccination certificate. In addition, all elements are mandatory for the recovery certificate and empty values are not allowed.

Recovery Certificate Data

Element Data	Description	Mandatory	Obs.
Pathogen	t/tg Refers to the disease or COVID-19 SARS-CoV agent or any of its variants.	Yes	The value has a single entry which corresponds to code 840539006 in SNOMED CT for COVID-19. The field cannot be empty. Example: "tg": "840539006" The coded value established corresponds to <i>enfermedad-agente-objetivo.json</i>
Date of the positive result	r/fr Refers to the date in which the certificate owner had a positive result for a NAAT test.	Yes	Refers to the date in which a sample was collected to perform the test which had a positive result for a NAAT. The date format is YYYY-MM-DD, without the time. Other formats are not supported. Example: "fr": "2022-01-23"
Country	r/co Refers to the country in which the positive test result was loaded.	Yes	As regards the country, we recommend using an ISO3166 code; specifically, the two-letter code. The coded value corresponds to <i>country-2-codes.json</i> Example: "co": "CZ" "co": "ACNUR"
Certificate Issuer:	r/es Refers to the entity issuing the certificate.	Yes	Refers to the name of the organization responsible for issuing the certificate. The name must contain a maximum of 80 UTF-8 characters. Identifiers can be used as part of the name. Example: "uy": "Ministry of Public Health" "es:"

			ASSE”
Valid From	r/df Refers to the start of the issued certificate’s period of validity.	Yes	Refers to the first date from which the certificate is considered valid. It cannot be earlier than the r/fr calculated date (date of the positive result) + 11 days. The only date format allowed is YYYY-MM-DD, without the time. Example: “df”:"2022-01-23”
Valid Until	r/du Refers to the end of the issued certificate’s period of validity.	Yes	Refers to the last date in which the certificate is valid. It cannot be later than the r/fr calculated date (date of the positive result) + 180 days. The only date format allowed is YYYY-MM-DD, without the time. Example: “df”:"2022-07-23”
Identifier	r/ic Refers to the unique certificate identifier.	Yes	The unique identifier is specified in Examples: "ci": "URN: UVCi: 01: NL: 187/37512422923" "ci": "URN: UVCi: 01: AT: 10807843F94AEE0EE5093FBC254BD8 13 # B"

Minimum Amount of Data - IPS

The following is a detailed description of the data that make up each of the IPS attributes.

All of the IPS data is based on HL7 FHIR, who have developed a CDA template for patient summaries which can be used during emergency or unplanned healthcare events.

The following table includes the abbreviations that will be included in each of the data contained in the IPS attributes, in addition to the description, depending on the different data types making up the IPS. This way, the transmission and reception of data will be coherent.

Value	Description	Observation
M	Mandatory	The data must always be present, and the value displayed must be valid. If a mandatory value is NOT present in the document, the IPS will be invalid.
R	Required	A value considered to be required must always be present, and the value must be valid. If a required field is NOT present in the document, the IPS will be invalid.
RK	Required if known	Refers to a value that, if known, must be present in the document, and the value must be valid. For cases in which the data is not available, it can be omitted.
C	Conditional	Refers to data which depends on a condition to be present in the document in a specific description or even omitted. An element is considered to be a condition when the data depends on the condition of another value which is required or optional.
O	Optional	Refers to data that can be omitted from the IPS document.

It is important to note that the IPS document has a structure which contains each of the attributes that must be present in the IPS. These can have different values (M, R, RK, C and O), which have been described in the table above.

IPS Data – Patient Attributes

Refers to a series of data used for administration, identification, and identity guarantee purposes within the patient summary. It is the set of non-clinical data for the patient.

Element Data	Description	Value	Obs.
Patient Name	First Name / Last Name	M	<p>The name is composed of a sequence of parts such as the first name, last name, prefix, or suffix.</p> <p>If some of the names do not have alphabetical representations, at least one must be provided.</p> <p>The HL7 FHIR HumanName must be used.</p>
Addresses and telecommunications for the patient	Address	RK	<p>Addresses must not be documented as a single string.</p> <p>Even though the patient's address is administrative information, it is important to point out that it can be used as a way to identify the patient.</p> <p>For the address registry, the following guidelines must be followed: AD for addresses ADXP for address portions. Both correspond to the HL7 FHIR Address.</p>
Addresses and telecommunications for the patient	Telecommunications	RK	<p>The patient's phone numbers or emails are considered telecommunications.</p> <p>PH Point of Contact HL7 FHIR.</p>
Administrative Gender	Gender	RK	<p>It may happen for some countries to require gender as part of the patient identification. Refers to coded data.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Birth Date	Date/Time	R	<p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD hh:mm.</p> <p>If the time of birth is provided, it must include the time zone.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date</p>

Patient's Preferred Language	Language	O	Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Identification related to healthcare	Healthcare ID	RK	Refers to a list of patient identifiers. It is useful to have a healthcare identification number. However, not all countries have a registration system such as this one, or systems where the person has several separate healthcare identification numbers where each one is a different healthcare provider.
Patient Identifier	Patient ID	RK	The identifier is not necessarily numeric; it can depend on the different jurisdictions. Some countries use the insurance number as a patient identifier because, in addition to identifying them, it refers to the healthcare identifier. The HL7 FHIR is used as a reference.
Insurance Information	Information	O	Information regarding the insurance is not always required within the patient summary. However, for countries in which this information is required, it will need to be present in the document.
Insurance Identifier	Insurance ID	RK	The insurance ID is important because many countries use it as a way to identify a person. In addition, by using the ID, others can access information regarding how healthcare is financed.

IPS Data – Healthcare Provider Attributes

This attribute refers to the details of the healthcare actor who can be assigned one or more advanced directives for a person's care.

Element Data	Description	Value	Obs.
Healthcare provider for the person	Person	C	<p>Professionals in charge of healthcare can fall within the framework of healthcare providers.</p> <p>Healthcare organizations refer to the only responsible entities for financing or reimbursing costs generated by the provision of healthcare.</p> <p>It is based on regulation ISO 13940:2015, section 5.2.3</p>
Name	Person	R	<p>The name is composed of a sequence of parts such as the first name, last name, prefix, or suffix.</p> <p>If some of the names do not have alphabetical representations, at least one must be provided.</p> <p>The HL7 FHIR HumanName must be used.</p>
Role	Person	O	<p>Refers to a coded element.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Telecommunications	Person	RK	<p>The patient's phone numbers or emails are considered telecommunications.</p> <p>PH Point of Contact HL7 FHIR.</p>
Healthcare provider (organization)	Provider	C	Preferred healthcare provider.
Name	Provider	R	It is based on regulation ISO 13940:2015, section 5.2.3
Telecommunications	Provider	RK	<p>The patient's phone numbers or emails are considered telecommunications.</p> <p>PH Point of Contact HL7 FHIR.</p>

IPS Data – Patient Address List Attribute

This attribute attempts to list all organizations or healthcare professionals who can be of vital importance in case of an emergency healthcare event for a patient.

Element Data	Description	Value	Obs.
Preferred healthcare providers	Organization	RK	Refers to the address details for persons or organizations that were relevant for the patient's health care. Refers to a list. Preferred healthcare provider.
Preferred healthcare provider	Organization	R	Refers to the healthcare provider. Indicates the most relevant entity to contact to use it in the patient summary.
Address details for others	Organization	O	Refers to a list which contains the information necessary for the patient's healthcare which corresponds to the different healthcare professionals. It can be related to the urgency of care required by the patient.
Recipient	Organization/ Person	R	The recipient can vary. It can be an organization, a healthcare professional, or a legal guardian who can make decisions for the patient.
Role	Organization/ Person	RK	Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Name	Organization/ Person	R	The name is composed of a sequence of parts such as the first name, last name, prefix, or suffix. If some of the names do not have alphabetical representations, at least one must be provided. The HL7 FHIR HumanName must be used.
Address	Organization/ Person	O	Addresses must not be documented as a single string. For the address registry, the following guidelines must be followed: AD for addresses ADXP for address portions. Both correspond to the HL7 FHIR Address.
Telecommunicat	Organization/	RK	The patient's phone numbers or emails are

ions	Person		considered telecommunications. PH Point of Contact HL7 FHIR.
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IPS Data – Advance Directives Attribute

Refers to information considered to be relevant when faced with an unplanned healthcare situation where there might be a risk of life for the patient, where there must be someone to make decisions for the patient.

Element Data	Description	Value	Obs.
Directives	Advanced	R	Refers to a list including the patient's wishes regarding their life or care after death.
Directives	Advance	R	Refers to the consents which will be validated depending on the jurisdictions.
Directive authorization	Person	RK	For cases in which the person making decisions is not the patient but a legal guardian, it must be able to contact them to learn about or clarify aspects regarding the patient's wishes. The data for the person to be contacted must be listed in the patient's address list.
Name	Person	RK	The name is composed of a sequence of parts such as the first name, last name, prefix, or suffix. If some of the names do not have alphabetical representations, at least one must be provided. The HL7 FHIR HumanName must be used.
Role	Person	RK	Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Telecommunications	Person	RK	Phone numbers or emails for the organization or person are considered telecommunications. PH Point of Contact HL7 FHIR.
Directive Category	Person/Categorization	O	Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Directive Description	Person/Detail	C	Refers to the description of the directive in text. Reference ISO 21090:2011 ED, TEXT.ED.;SD.TEXT;Narration HI7 FHIR chain. The chain must include at least one character or must have a null value. HL7 FHIR string.
Reference to the legal document	Organization/Documentation	C	The directive can be a reference to a legal document such as a will or a textual description.

IPS Data – Allergies and Intolerances Attribute

This attribute is of utmost importance for the patient’s healthcare because it can have valuable information to be used when facing serious events or events that limit the patient’s ability to make decisions in specific health situations.

Element Data	Description	Value	Obs.
Status of the allergies/intolerances	Categorization	C	Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference. This element must be included. In case of absence, it is necessary to indicate it.
Allergies or intolerances	Pathology	C	Element is selected from a predetermined list.
Allergies or intolerances	Pathology	M	Element selected from a list of allergies/intolerances.
Description of allergies or intolerances	Pathology	R	Refers to the description of an allergy or intolerance in text. Reference ISO 21090:2011 ED, TEXT.ED.;SD. TEXT;Narration HI7 FHIR Chain. The chain must include at least one character or must have a null value. HL7 FHIR string.
Clinical status	Pathology	R	Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference. The elements that are usually used are: <ul style="list-style-type: none"> • Active • Inactive • Resolved
Start date	Pathology	RK	The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date.
End date	Pathology	C	The date depends on the end of the pathology. A date will only appear when the status of the pathology is Resolved. The date can be complete or partial depending

			<p>on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p>
Criticality	Pathology	O	<p>This attribute refers to the potential risk when faced with adverse reactions. It can be used as a synonym of severity.</p> <p>Its use can reflect the time in which the worst-case scenario that the patient might face when dealing with an unexpected medical event.</p> <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Certainty	Pathology	O	<p>The degree of certainty is associated with the propensity; that is to say, the potential risk of having the reaction.</p> <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Propensity Type	Pathology	RK	<p>It is related to the type of allergy or intolerance. The following values can be found:</p> <ul style="list-style-type: none"> • Allergies • Intolerances • Propensity to adverse reactions <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Diagnosis	Pathology	O	<p>Refers to the code which indicates the type of reaction as well as the agent. If there is no coded information, it must be entered as a text.</p> <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Reaction	Pathology	RK	<p>Refers to elements which might be related to specific reactions.</p>
Expression of the reaction	Pathology	RK	<p>Refers to the clinical description of the allergic reaction. It can be entered as a text if there is no code.</p> <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>

Severity	Pathology	RK	<p>Coded element which describes a subjective evaluation of the severity of the condition as evaluated by the healthcare personnel. The following possible values can be found:</p> <ul style="list-style-type: none"> • Severe • Moderate <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Agent	Pathology	R	<p>Description of the specific allergen which might cause for the patient to have a reaction.</p>
Agent code	Pathology	R	<p>Refers to a description of the allergen, which will be taken from a list.</p> <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Category	Pathology	O	<p>Refers to the substance's category. The values which can be included are the following:</p> <ul style="list-style-type: none"> • Food • Medication • Environment • Biological <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>

IPS Data – Functional Status Attribute

A disability refers to the ability of an individual to carry out daily tasks that are necessary to satisfy basic needs. Therefore, it is of utmost importance to know about the existence of a person's disability to evaluate specific treatments that they might need.

Element Data	Description	Value	Obs.
Disabilities	Pathology	C	Refers to the term which includes impairments, activity limitations, and other restrictions. An impairment might refer to a problem, and that problem can be presented in a list format.
Disability	Pathology	R	The value is obtained from a list of disabilities.
Description of the disability	Pathology	R	Refers to the description of the disability in text. Reference ISO 21090:2011 ED, TEXT.ED.;SD. TEXT;Narration HI7 FHIR Chain. The chain must include at least one character or must have a null value. HL7 FHIR string.
Disability Code	Pathology	O	Refers to a description of the disability which will be taken from a list. Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Start date	Pathology	O	The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date.
Functional Evaluations	Pathology	C	Refers to a list of mobility reviews for an individual which make it possible to determine their autonomy.
Functional Evaluation	Pathology	R	Refers to a label for an evaluation or a group of evaluations. A coded description must also be provided if it exists.
Description of the Functional Evaluation	Pathology	R	Refers to a textual description of the evaluation.
Evaluation date	Pathology	RK	The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD

			<p>hh:mm.</p> <p>If the time is provided, it must include the time zone.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Type of Functional Evaluation	Pathology	RK	<p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Results of the Functional Evaluation	Pathology	C	<p>If any exist, it refers to the results.</p>
Functional Evaluation	Pathology	C	<p>Refers to a label for an evaluation or a group of evaluations. A coded description must also be provided if it exists.</p>

IPS Data – History of Previous Problems Attribute

This attribute includes the history of problems and diseases and therefore provides context for the current health situation of an individual.

These are all of the problems that the patient already had with a closed or resolved status. Active problems must never be displayed in this attribute.

Element Data	Description	Value	Obs.
Past problems	Pathology	R	Refers to the list of problems or diseases that the patient has at present with a closed or resolved status.
Past problem	Pathology	R	Refers to each one of the problems or diseases which were listed.
Type of problem	Pathology	RK	Refers to the categorization that can be assigned to the mentioned problem.
Description of the problem	Pathology	R	A textual description of the problem, including the different resolution alternatives.
Diagnosis	Pathology	R	Refers to the code which indicates the type of problem the patient suffered. If there is no coded data, it must be entered as a text. Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Severity	Pathology	O	Coded element which describes a subjective evaluation of the severity of the condition as evaluated by the healthcare personnel. The following possible values can be found: <ul style="list-style-type: none"> • Severe • Moderate Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Start date	Pathology	RK	The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date.
Status of the problem	Pathology	O	The status of the problem must be resolved or closed, since it refers to a list of previous

			problems.
End date	Pathology	RK	<p>The date depends on the end of the pathology. A date will only appear when the status of the pathology is Resolved or Closed.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Specialist contact	Provider	O	Contact information can be added in the attribute for a specialist dealing with one of the patient's issues in case they need to be contacted regarding the person's current health situation.

IPS Data – Pregnancy History Attribute

This attribute will describe the current status of a woman regarding their ongoing pregnancy in addition to any chronological information for previous pregnancies.

Element Data	Description	Value	Obs.
Current status of the pregnancy	Pregnancy	R	The information regarding the current pregnancy must be emphasized.
Description of the pregnancy	Pregnancy	C	Details are included regarding the current pregnancy. It can be a text entry or structured, but it must NOT be presented in both formats.
Details of the pregnancy	Pregnancy	C	Refers to a label in the pregnancy description.
Observation date	Pregnancy	R	<p>The date in which the current pregnancy was observed must be specified.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Status of the pregnancy	Pregnancy	R	<p>Coded element with the following values:</p> <ul style="list-style-type: none"> • Pregnancy • No pregnancy • Unknown <p>Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.</p>
Estimated delivery date	Pregnancy	RK	<p>If the information is known, it must be included.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Specialist	Pregnancy	O	Contact information can be added in the attribute

contact			for a specialist in case they need to be contacted regarding the person's current health situation.
Pregnancy history	Pregnancy	O	If the information is known, it must be included.
Status of previous pregnancies	Pregnancy	C	Refers to a coded element which can have the following values: <ul style="list-style-type: none"> • Yes, previous pregnancies • No, previous pregnancies • Unknown If the information is known, it must be present.
Details of previous pregnancies	Pregnancy	R	If the information is known, it must be present.
Date of previous pregnancies	Pregnancy	RK	If the information is known, it must be present. The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date.
Details of previous deliveries	Pregnancy	R	Coded information which can have the following options: <ul style="list-style-type: none"> • Live birth • Due • Stillbirth
Specialist contact	Pregnancy	O	Contact information can be added in the attribute for a specialist in case they need to be contacted regarding the person's current health situation.
Summary metrics	Pregnancy	C	It is an alternative where a previous pregnancy can be recorded including narrative details or a resolved list. The following concepts must be included: <ul style="list-style-type: none"> • Pregnancy: number of pregnancies regardless of the result. • Parity: refers to the number of live births or stillbirths after the first 24 hours. • Number of pregnancies lost before 24 weeks.

IPS Data – Procedure History Attribute

This attribute lists all of the procedures, with their descriptions, which were performed on the patient, including surgical ones.

Element Data	Description	Value	Obs.
Status of the procedure content	Provider	C	Refers to a coded element. It can be empty if the information is not available. Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Procedures	Provider	C	All procedures performed on the patient must be listed.
Procedure	Provider	R	Each of the elements in the list of procedures must be described, identifying the real procedure that was carried out and when it happened.
Procedure code	Provider	R	Refers to a coded element. Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Description of the procedure	Provider	RK	A textual description of the procedure performed on the patient must be displayed.
Site of the procedure	Provider	O	The location in the body where the procedure was performed must appear. Refers to a coded element. The HL7 FHIR CodeableConcept code is used as a reference.
Procedure date	Provider	R	If the information is known, it must be present. The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date.

IPS Data – Vaccinations Attribute

This attribute aims to list all of the vaccines administered to the patient. Keeping in mind the current situation regarding COVID-19, the information for that vaccine can be included if the patient received it.

Element Data	Description	Value	Obs.
Vaccination status	Provider	C	<p>If there is information regarding the person's current vaccination status, it must be included.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Vaccines	Provider	C	<p>The information will be obtained from a list of vaccines.</p>
Vaccine	Provider	R	<p>Information related to the vaccine and its administration.</p>
Vaccine for the type of disease	Provider	R	<p>Refers to the type of vaccine for a specific disease against which the patient has been immunized.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Diana Disease	Provider	O	<p>Refers to a list of diseases.</p>
Goal Disease	Provider	R	<p>Coded element which comes from the list of diana diseases.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Vaccination date	Provider	R	<p>If the information is known, it must be present.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
Administered product	Provider	O	<p>At least the name of the brand must be provided. If the information is not available, the Lot information can be added.</p>

Brand name	Provider	RK	The brand name for the vaccine must be displayed in text format if there is no code.
Process of administration for the product	Provider	O	Data regarding the moment of administration must be include.
Executor	Provider	O	If it exists, the name of the healthcare provider or the person who carried out the administration process must be included.
Administration route	Provider	O	Refers to information regarding the administration route for the product. ISO 11239:2021

IPS Data – Medical Devices Attribute

In this section, information is added regarding the medical devices the patient might have and which are crucial when providing care to the patient.

These devices can be internal, which refers to devices implanted on the patient's body, or external, which refers to medical devices on which the patient's current health status depends.

Element Data	Description	Value	Obs.
Status of the device	Provider	C	The HL7 FHIR CodeableConcept code is used as a reference.
Devices	Provider	C	The information is obtained from a list of devices.
Device	Provider	R	Refers to the device implanted on the patient's body or the device on which the patient's current health status depends. The value is obtained from a list of devices. Each device in the list must follow the same structure.
Type of Device	Device	R	Refers to the category of the device. The HL7 FHIR CodeableConcept code is used as a reference.
Identifier for the device	Device	RK	Refers to the device's unique identifier. The optional value is added in the HL7 IPS.
Start date	Provider	R	Refers to the date and time in which the device was implanted, or the external device was used for the first time. The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date. If the time is provided, it must include the time zone.
End date	Provider	O	Refers to the date and time in which the device was removed from the patient, or the last time the device was used. The date can be complete or partial depending on whether it is known or not. When it is a

			<p>complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
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IPS Data – Medication Summary Attribute

This attribute is of utmost importance when providing care to a patient. Because of this reason, this attribute is based on ISO IDMP, which refers to a set of five standards developed by the WHO to have a global way to unambiguously identify medicinal products.

The five standards regarding identification of medicinal products are:

- Identification of Medicinal Products (MPID), ISO 11615. Refers to the elements and data structures for the unique identification and the exchange of information regarding regulated medications. The elements included in the identification of the medicinal product refers to the name of the medication, clinical detail, pharmaceutical product, medication container, commercialization authorization, and manufacturer, among others.
- Pharmaceutical product Identifier (PhPID), ISO 11616, is a unique identifier for medical products which have the same or a similar pharmaceutical composition according to the following elements: substance, concentration, and dosage form.
- Substance identifier (SubID), ISO 11238. Defines the substances which constitute the medication by their main general characteristics.
- Pharmaceutical form and administration route, ISO 11239. Refers to the pharmaceutical form, units of presentation, administration routes, and packaging.
- Unit of measurement (UM), ISO 11240. Specifies the regulations for the use of units of measure, sets the requirements to offer traceability, defines the requirements for the units of measure in coded form, provides structure and regulations for mapping purposes between different unit vocabularies and language translations.

The general structure medications must have is the following:

Element Data	Description	Value	Obs.
Status of the content of the medication summary	General	C	Refers to a coded element. It is recorded if there is information regarding the medication. If there is no information, a reason why must be specified. The HL7 FHIR CodeableConcept code is used as a reference.
Medications	General	C	There must be a list of medications, in addition to instructions associated with the administration of each of the listed medications.
Medication	General	M	Refers to a complex structure which contains a list of coupled concepts.

The following is a detailed description of all of the data that must be included in the medication summary:

Element Data	Description	Value	Obs.
Reason	Medication	O	Refers to the reason why the medication was prescribed.
Medicinal product	Medication	R	Refers to the substances or combination of substances which might be administered to prevent or treat pathologies, to diagnose, or even to adjust biological modifications. Identification of Medicinal Products (MPID), ISO 11615
Product code	Medication	O	Refers to a more general term for the medication identification. Identification of Medicinal Products (MPID), ISO 11615. The HL7 FHIR CodeableConcept code is used as a reference.
Name of the product	Medication	RK	Refers to the name of the pharmaceutical product which includes the concentration of its components. If the common name according to the WHO does not exist, the one recommended by the jurisdiction must be used. Pharmaceutical product Identifier (PhPID), ISO 11616 PhPID_L2IDMP
Pharmaceutical dose	Medication	R	Can refer to the pharmaceutical form of the administration dose or the fabrication dose. Identification of Medicinal Products (MPID), ISO 11615.
Pharmaceutical dose form	Medication	R	Identification of Medicinal Products (MPID), ISO 11615.
Name of the brand	Medication	O	Required when dealing with a biological medicinal product or when justified by the healthcare professional.
Active ingredients	Medication	R	Refers to a list of substances, alone or combined, with one or more ingredients which produce the correct activity of the medicinal product.
Active ingredient	Medication	R	Refers to an element obtained from the list of active ingredients.

Substance code	Medication	R	Identification of Medicinal Products (MPID), ISO 11615.
Strength	Medication	R	Refers to the content of the substance(s) expressed quantitatively by unit of dosage, unit of presentation, unit of volume, or unit of mass, depending on the pharmaceutical form.
Administration instructions	Medication	R	The instructions associated with each medicinal product.
Administration	Medication	O	Refers to the textual description of the administration form for the medicinal product selected from the list.
Start date	Medication	R	<p>Refers to the date and time in which the medication was prescribed.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
End date	Medication	O	<p>Refers to the date and time in which the indicated treatment was finished.</p> <p>It might be possible that the treatment has not been finished, so the end date is not necessary.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
Number of units per intake	Medication	R	Refers to the number of medication intakes the patient must perform in accordance with the medical indication.

Frequency	Medication	R	Refers to the time specification which indicates the frequency with which the medication must be ingested.
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IPS Data – General Description of the Healthcare Plan Attribute

This attribute lists the data that must be included in the Healthcare Plan for the patient, which must be dynamic and customized depending on the patient's situation. The plan might involve several different healthcare actors and will include a description of the different healthcare activities and healthcare goals related to one or more health issues. As a reference for the healthcare plan, the ISO 13490:2015, section 9.2.3. regulation is used.

Element Data	Description	Value	Obs.
Plans	General	R	Refers to a list of the plans that the patient might have.
Plan	General	R	The plan is obtained from the aforementioned list. It can be a textual plan, or it can be presented in a structural manner. Only future plans must be listed; any previous plans are not important.
Type of plan	General	O	The creation of the plan can involve one or multiple professionals, and must include: <ul style="list-style-type: none"> • Planned observation • Planned procedure • Planned meeting • Planned immunization The HL7 FHIR CodeableConcept code is used as a reference.
Plan date	General	RK	Refers to the date and time in which the healthcare plan was created. The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY YYYY-MM The format reference corresponds to HL7 FHIR dateTime, Date. If the time is provided, it must include the time zone.
Description of the plan	General	C	Refers to the narrative part of the healthcare plan. It might be a single narrative block, or it might be composed of separate narrations.
Recommendation	General	C	Reusable content for a potential healthcare plan, for a specific set of circumstances. Each of the recommendation must have the

			<p>following structure:</p> <ul style="list-style-type: none"> • Recommended treatment. • Start date for the indicated treatment. • End date for the indicated treatment.
Recommendation/Treatment	General	R	Refers to the textual description of the indicated treatment provided by the healthcare professional.
Recommendation/Date	General	RK	<p>It might be possible that the current plan has a separate structure for the date in which it was carried out, or it might contain a single date with several structures for the plan.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
Application date	General	RK	<p>Refers to the application date for the recommended treatment. Plans are prospective, but there might be dates in the future.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
Extensive Plan	General	C	Can be used as an alternative to the recommended treatment. It refers to a reference to a healthcare plan document separate from the IPS.

IPS Data – Problem Summary Attribute

This attribute attempts to provide a general vision of any health conditions affecting the patient. It includes medical alerts in addition to any identified clinical risks.

It is a health condition that might be considered a problem by healthcare professionals. It is a list of current and active issues which have not been resolved or are currently worrisome and are still being monitored by the healthcare personnel.

Element Data	Description	Value	Obs.
Status of the content of the problems	General	C	It might be possible that the patient does not have any problems, or that no information exists regarding the problem. In case of any problems, they must be coded. The HL7 FHIR CodeableConcept code is used as a reference.
Problems	General	C	Refers to a list of problems which might have different statuses: <ul style="list-style-type: none"> • Active • Unresolved
Problem	General	M	Refers to a list of active or unresolved problems for a person.
Type of problem	General	RK	Each of the listed problems must be categorized and fall within the following two: <ul style="list-style-type: none"> • Medical alert • Clinical risk
Description of the problem	General	R	Refers to the problem narrative. It can be done with or without a diagnosis.
Diagnosis	General	R	Refers to the codification of the diagnosis. The HL7 FHIR CodeableConcept code is used as a reference. ⁵
Severity	General	RK	Refers to a problem qualifier which will indicate the importance of the problem.
Start date	General	O	Refers to the date in which the problem was identified. The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD. The date can be incomplete, obtaining only: YYYY

⁵ <https://www.hl7.org/fhir/profilelist.html>
<http://hl7.org/fhir/documentreference.html>

			<p>YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
Status of the problem	General	○	<p>The statuses of the problem can be:</p> <ul style="list-style-type: none"> • Active • Unresolved • Inactive <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Specialist contact	General	○	<p>Information regarding a specialist contact can be added within the problem summary.</p> <p>The specialist's phone numbers or emails are considered telecommunications.</p> <p>PH Point of Contact HL7 FHIR.</p>

IPS Data – Results Summary Attribute

This section gathers all of the relevant observation results obtained from the patient's situation. They might be laboratory results, pathological anatomy results, or other clinical results which might be relevant.

Element Data	Description	Value	Obs.
Results of the observation	General	R	Refers to the list of observations performed for the patient. They will be present if they exist.
Result of the observation	General	R	This result is obtained from the aforementioned list.
Observation date	General	R	<p>Refers to the date and time in which the observation was done. It might be a single date or a specific period of time.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p> <p>If the time is provided, it must include the time zone.</p>
Types of observations	General	R	<p>Within the list, you will find the types of results.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Description of the result	General	RK	<p>Refers to a descriptive narration of the observed condition.</p> <p>Different elements can be used for each of the narrations, or they can be within a single block in a single section.</p>
Value of the result	General	C	Refers to the value of the measurement.
Result of the observation	General	C	This result is obtained from the aforementioned list.
Executor	Provider	O	Identifies who is performing the observation. In some cases, it might be possible that the executor and the observer are the same person.
Observer	Provider	RK	Identifies the author of the observation.

IPS Data – General Description of the Social History Attribute

This attribute includes a description related to the person’s lifestyles which might be relevant for the healthcare process, such as their smoking status, or consumption of alcohol or drugs.

Element Data	Description	Value	Obs.
Lifestyle elements	General	R	Refers to a list of the current and past habits related to the lifestyle.
Lifestyle element	General	R	<p>The element is selected from the previous list. As a minimum, the consumption of alcohol or smoking status should be included.</p> <p>It will be descriptive, at least in a descriptive text or in a structured way.</p>
Description	General	R	<p>Refers to a narrative description of the observed condition.</p> <p>Different elements can be used for each of the narrations, or they can be included in a single block in a single section.</p>
Detail	General	O	A lifestyle element detail is usually represented by a simple pair of code values, with a codifiable concept describing the type of lifestyle element (for example, alcohol consumption), and a value which includes the types of measures applicable to the element (for example, units of alcohol consumed).
Reference date	General	RK	<p>Usually, the lifestyle elements cover a specific period of time.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>

IPS Data – General Description of the Vital Signs Attribute

This attribute gathers information regarding the patient's vital signs, which might be relevant when facing a potential healthcare situation.

Element Data	Description	Value	Obs.
Vital signs	General	R	Refers to a list of all vital signs related to the patient's health status.
Vital sign	General	R	Refers to each of the values listed above.
Date	General	R	<p>It might be possible that the vital sign includes a date and a time, or that it is contained within a period of time.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>If the time is provided, it must include the time zone.</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Type of description	General	R	<p>There might be different types of vital signs; some of them could include:</p> <ul style="list-style-type: none"> • Diastolic pressure • Systolic pressure • Cardiac rhythm • Pulse oximetry • Weight • Size • BMI, among others <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Description	General	RK	<p>Refers to a descriptive narration of the recorded vital signs.</p> <p>Different elements can be used for each of the narrations, or they can be included in a single block within the same section.</p>
Value	General	C	Refers to the value of the measurement.
Vital sign	General	C	Refers to each of the values listed above.

IPS Data – General Description of the Cross-Border Summary Attribute

Refers to information related to the source of the IPS.

Element Data	Description	Value	Obs.
Country of affiliation	General	M	<p>Refers to the designated country of origin where the patient is located and their healthcare information.</p> <p>It can be provided in a coded form.</p> <p>The HL7 FHIR CodeableConcept code is used as a reference.</p>
Specific requirements of the country	General	RK	<p>It is used to describe unique occurrences. Any cultural and legal details, jurisdictional matters of the region must be declared as part of the exchange agreement.</p> <p>They may include confidentiality/consent rules to share data, details regarding languages and translations. However, some of them might be considered in relation to the individual needs, such as country or national characteristics.</p>

IPS Data – Detailed Source Description Attribute

Refers to the attributes describing dates, natural sources, and legitimacy of the patient summary.

This is data that will provide confidence in the communication and the data that is being exchanged.

Data Element	Description	Value	Obs.
Claimant/Source of the information	General	RK	Usually refers to the patient.
Date of creation of the IPS document	General	M	<p>The IPS document can be created only once.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>If the time is provided, it must include the time zone.</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Language	General	O	The HL7 FHIR CodeableConcept code is used as a reference.
Update date for the IPS	General	R	<p>The document can be updated. If it is updated, it will need to display the date when it was last updated.</p> <p>The date can be complete or partial depending on whether it is known or not. When it is a complete date, the format is YYYY-MM-DD.</p> <p>The date can be incomplete, obtaining only: YYYY YYYY-MM</p> <p>If the time is provided, it must include the time zone.</p> <p>The format reference corresponds to HL7 FHIR dateTime, Date.</p>
Generation of the IPS content	General	R	This is the real container for the source data of the IPS: how it was created, using which sources, etc.

Nature of the IPS	General	R	Defines the context in which the IPS was created. The nature of the IPS considers two cases: created by a person or created automatically.
Healthcare service providers	General	R	Refers to the list of healthcare providers.
Healthcare service provider	General	R	A means to verify the source and to offer some form of confidence. At least one author organization will be included. If there are no healthcare professionals, at least one medical attention organization will be included.
Legitimacy	General	RK	
Legal authenticator	General	RK	The responsible author / healthcare provider. It might be possible that they will be required to attest or sign the patient summary or parts of it, depending on the jurisdiction.

Ethical Considerations and Information Privacy

As with any digital solution, there are ethical considerations which must be part of the specifications design. The following is a description of the ethical considerations and data protection principles.

Ethical Considerations for a DDCC:VS

Down below, we will detail the ethical considerations which must be taken into account to design, develop, and deploy a DDCC:VS. The priority scenarios to use a DDCC:VS correspond to:

- A registry which serves as the basis for an individual's continued medical attention.
- A registry which documents an individual's vaccination process.

How the DDCC:VS will contribute to governments in Public Healthcare activities when facing an infectious disease such as COVID-19 must be identified before its creation. For this purpose, we can mention three key goals in the actions of a Public Health authority, which are:

- To protect and promote the wellbeing of individuals, communities, and the population as whole.
- To ensure equal treatment for all individuals, to prevent and mitigate unfair healthcare inequalities.
- To create and maintain the trust in the Public Health authority's activities as part of the Healthcare System.

The use of the DDCC:VS promotes the wellbeing of individuals by testing out vaccinations and continuing to do so, which guarantees that individuals will not receive the incorrect vaccines, while monitoring any possible adverse effects the person might suffer after being administered the vaccine.

This certificate must not generate discriminations against anyone. For this purpose, it is necessary to correctly protect the data which guarantees that no individual will be forced to disclose or publicly show their certificate to access any public activity.

The proposed goals might generate ethical problems. For this reason, and to mitigate these risks, it is necessary to ensure that the processes comply with the following values:

- Transparency: offering clear, precise, and public access information, which contributes to a correct decision-making process.
- Inclusion in the decision-making process: all interested parties must participate in the creation and design of the different policies.
- Responsibility: it is necessary to have a clear framework of who is responsible for what, and how the regulations will be done, and who will be responsible to enforce them.
- Sensibility: provide the necessary mechanisms and opportunities that allow for the political decisions to be reviewed based on scientific evidence evolution and other relevant data.

It is important to highlight that using the DDCC:VS in the context of the COVID-19 pandemic is an important cornerstone of Public Health, because it not only allows for the level of vaccinated population coverage to be known; it also allows for modifications to be introduced in any Public Health policies such as waiving or modifying any social measures imposed within the context of the pandemic.

The DDCC:VS has started to become considered as a health passport in many countries. However, when facing situations where we need to provide specific documentation to perform any activities, the following situations may arise:

- When the benefits obtained by presenting a health passport are very important, they cause an increase in fraud attempts related to vaccination certificates. This causes an increase in exposure risks for unvaccinated individuals who are coming into contact with vulnerable people.
- There might be people who are not willing to offer information regarding their medical history.
- Because, in many countries, distributing the vaccine is very complex because of how it is distributed within the population, it generates disadvantaged situations among individuals.

Recommendations

The design, development, and implementation of a DDCC:VS must follow a set of recommendations, which refer to:

- The scope of use of the DDCC:VS must be clearly defined, so each country creating a DDCC:VS must have a clear idea of how it will be used to avoid an improper use. When it is used to restrict freedoms or rights, it will only be justified if it is used when facing a health emergency provided by the law, which will have a limited duration based on scientific evidence and not imposed in an arbitrary, irrational, or discriminatory way.
- The benefits, risks, and the potential costs must be evaluated before introducing a DDCC:VS.
- Acquiring and using a DDCC:VS must be as inclusive and fair as possible. Nobody should be excluded by a payment method to obtain or use a DDCC:VS.
- All necessary measures must be applied to protect the participant's healthcare continuity. Certificates will include confidential data related to the individual's healthcare, so they must be protected by applying the appropriate privacy measures and medical confidentiality.
- All communication must be clear and transparent. This is relevant so that people can communicate in a transparent way, thus contributing to the promotion of public confidence, and the acceptance of the DDCC:VS.
- The DDCC:VS must be constantly controlled to evaluate its impact and to adjust it as needed.

Data Protection Principles

The principles are aimed at national authorities in charge of creating or supervising the development of a DDCC:VS. The principles are the following:

- Legitimate basis, legitimate use, and fair treatment. The data must be compiled and processed fairly and non-discriminatorily, based on the interested party's consent. The processing of the data will have a legal basis, and must respect the highest confidentiality, moral conduct, and ethical standards.
- Transparency: all interested parties must receive easily accessible, concise, and easily readable information. The data will be shared, stored, and withheld by specific recipients determined by the authorities, and they will only be able to keep them for a specific timeframe.
- Purpose, limitation, and specification. The data cannot be used for a different purpose that is not the continuity of healthcare and any verification tests.
- Proportionality, necessity, and minimization of data. The processing of personal data must be relevant and limited to the goals with specific purposes that had been previously defined. These will be monitored so it does not exceed their legitimate use. The data accessed during the verification points must not be withheld or stored in any repository, database, or any other means.
- Confidentiality and security. The data must be kept confidential; it must not be disclosed and can only be accessed by the interested party or by explicitly authorized persons.
- The right to withhold data, to complain and to resolve by law. It includes the right to access, correct, delete, object, or restrict personal data, subject to the conditions regulated by the law through a complaint procedure in case of any damages or losses as a consequence of their wrongful use.
- Independent supervision and accountability. A public authority must be responsible for monitoring if any controlled data or data processor involved in the processing of the data is complying with the principles. They can recommend revoking the authorization to compile and process the data. This public authority should have access to all of the necessary information to fulfill their duties. There should be appropriate policies and mechanisms to guarantee that the principles are being respected.

VS Design Criteria

In relation to the ethical considerations and data protection principles described above, we considered the following design criteria:

- Implementation of the DDCC:VS: the VS must not increase any health inequalities or widen the technological gap.
- Any person who has been vaccinated has the right to obtain and have their DDCC:VS.
- The DDCC:VS must have an accessible format, digital and paper. All solutions will work in online and offline environments on multiple platforms.
- People will not be treated differently or have different levels of confidence because of the certificate format.
- No solutions must have an additional cost for people. The interoperability specifications used in the solutions will be based on open standards which guarantee equal access within a range of non-proprietary digital tools.
- The infrastructure on which the DDCC:VS is based must guarantee that the people and the different countries are not forced to commit to a single provider.
- Any solution must be as ecologic as possible. The most sustainable options must be found from an environmental point of view to reduce any additional damage to the environment.
- The solutions must be designed to improve and work within the context of existing healthcare information systems as applicable.
- No solutions must share or store more data than is needed to successfully complete tasks. Minimizing the healthcare content for purposes unrelated to medical attention and privacy protection functions must be integrated within the system and consequently respected.
- Fraud-fighting mechanisms must be integrated with any approach.
- Digital technology should not be the only available mechanisms for verification purposes. There will always be different ways to go back to a manual, paper review of the vaccination certificates. For example, a paper representation can be printed of the DDCC:VS, or captured in the International Vaccination and Prophylaxis Certificate, and combined with an identity verification as described in the policy set forth by the public health authority.

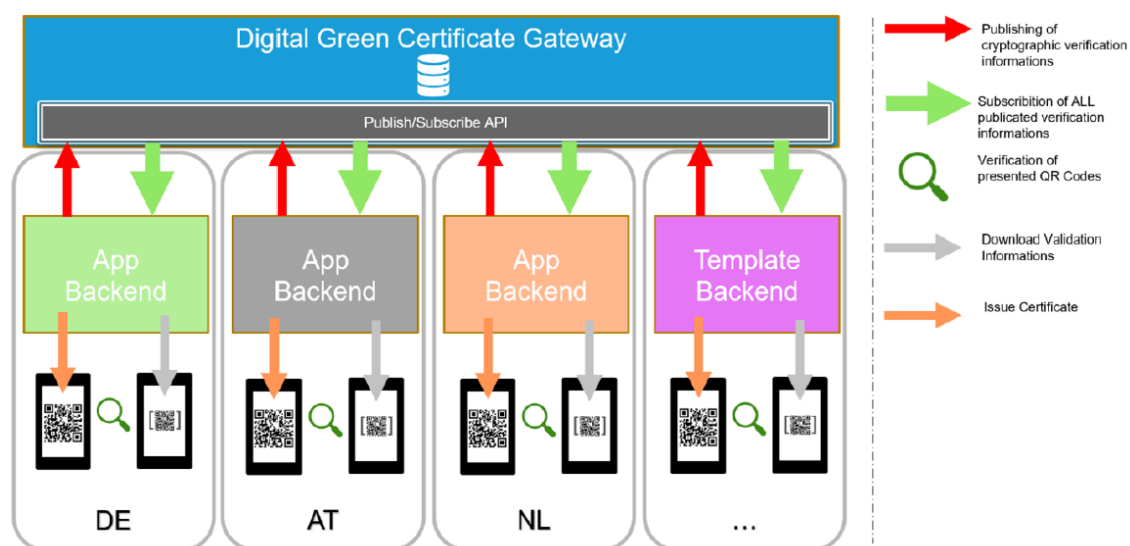
It is important to point out that, despite the described technological design criteria, it will be necessary for participating countries to ensure that their legal and political frameworks support the correct use of the certificate.

Exchange Model Consensus

The exchange of COVID-19 Certificates in the EU is governed by an exchange model that is common to all member countries and to any countries who want to join the exchange and do not belong to the EU.

This is the exchange model that will be adopted to exchange information regarding COVID Certificates in Latin America and the Caribbean.

To carry out this exchange process, we used the Certificate's Gateway, a repository of public signature keys for all states. These public keys correspond to the private keys which are used to sign COVID certificates; thus, they must be updated regularly. It is very important to point out that the private key must never be stored on the Gateway so that it may never be compromised in case of any attacks against the system.



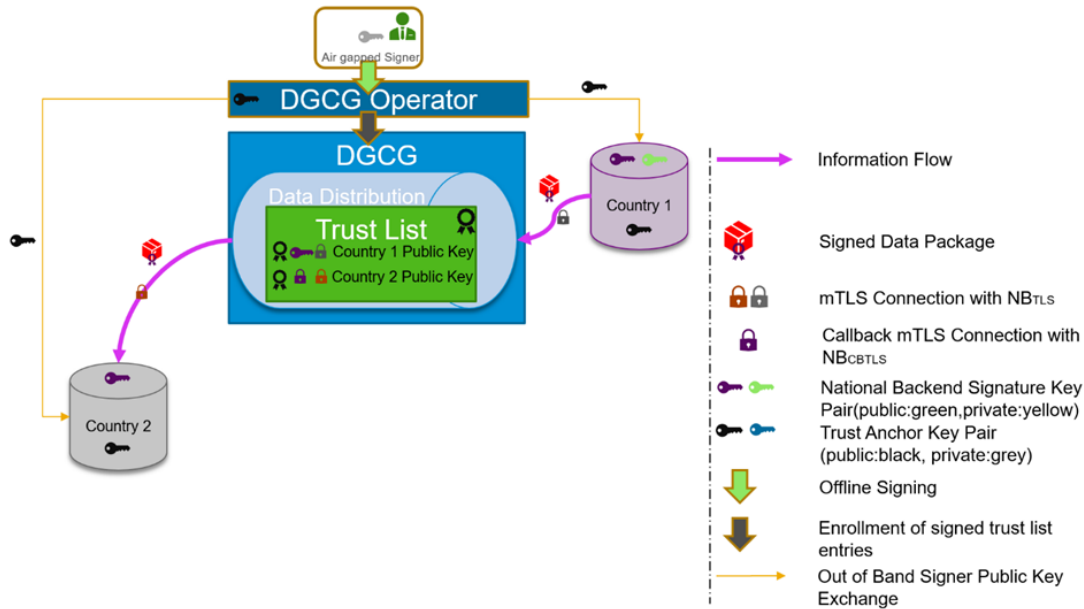
<https://github.com/eu-digital-green-certificates/dgc-gateway/blob/main/docs/software-design-dgc-gateway.md>

The information exchanged between countries corresponds to the CCD; that is, the digital COVID certificates which contain information regarding vaccinations, COVID tests, and recovery from the infection for the individual who owns the certificate.

This CCD uses a public PKI key infrastructure, a trust framework based on public key certificates and certification authorities that regulate them. The PKI is used to authenticate any conducted transactions and to sign the data to guarantee the integrity of the communication channels between the countries and the issued certificates.

The PKI is a public key distribution system which makes it possible to trace any revocation processes in case the public keys have been compromised.

Through the use of the KPI, a certificate or document is linked to the identity of a legal person or organization, which allows for the recipient to confirm that the key can be trusted by an individual or organization.



<https://github.com/eu-digital-green-certificates/dgc-gateway/blob/main/docs/software-design-dgc-gateway.md>

For the specific case of COVID certificates, the KPI is used to learn about the origin of the data being sent. For these cases, an authority designated by the countries is responsible for issuing the certificate. This authority does not sign the signatures, because the signature is done by other authorities.

Public and private keys are also issued, which provides the necessary information to sign the digital certificate. The DSC is the signing certificate for a document; the certificate for the public key of the authority signing the certificate for a country is issued by the National Signature Authority.

Signing a document with the DSC is an information encryption process carried out by using a private key so that the information can be read by a human being. This is the way in which any information in electronic format is signed.

In this manner, any interested parties can decrypt the encrypted information; in this case, in COVID certificates.

Once the verifier accesses the public key, they can verify that the public key is valid and that it has not been revoked with the authority. If necessary, they can also decrypt the information contained in the certificates.

Each country has specific national authorities which sign these certificates. This authority acts as a trust anchor in order for countries which trust it to use the certificates to be able to validate them.

When the digital signature is used to authenticate the data, the countries participating in the exchange of certificates can verify the origin of the data and who is issuing it, thus deciding the trust they provide.

The data is then loaded into the COVID Certificate Gateway without any modifications introduced to the received information. The backend will perform the verification process for the uploaded data and use TLS, a security protocol in the transport layer with mutual authentication which allows for a secure connection to be established.

It is key to point out that each country is responsible for their own data and for protecting the private key that they use when connecting to the Gateway. The Gateway will use a pair of asymmetrical keys to sign the trust list and any offline certificates.

Once the different certificates are entered, and it is confirmed that they have been uploaded successfully, they are entered into a trusted list. The countries will then be able to access the list to perform their verification procedures.

Any countries interested in participating in the exchange of certificates must present certificates issued by a National Signature Authority and present the certificates to the Gateway. After certificates are recorded successfully, the Gateway will update the trust list with the certificates signed by the National Signature Authority.

It should be noted that the countries participating in the exchange must provide a list of the National Signature Authorities for the certificates in addition to a list of the signed certificates; these certificates must be valid and up to date. For the list, the Signature Authority must include the following items in each certificate:

- A valid country attribute which must match the code country of issuance.
- The attribute must be unique to the country.
- There must be a unique key identifier.

Each certificate must also meet the following requirements:

- It must be signed with a private key corresponding to a certificate for the National Signature Authority.
- It must contain an authority key identifier (AKI), which must be the same as the subject key identifier (SKI) for the issuing certificate.
- They must contain an online validity period greater than the validity period for all certificates signed by the authority.
- They must contain an identifier with a unique subject key identifier derived from the subject's public key.

In order to ensure the integrity and authenticity of the data, cryptographic methods will be used to maintain the confidentiality of the private keys, because these keys can be compromised in the following cases:

- The process of generating keys can fail, thus generating weak keys.
- The keys can be exposed by mistake, or even stolen.
- The keys can be calculated using cryptanalysis.

To avoid these risks, we recommend any participating countries to use a secondary backup signature algorithm based on parameters that are different from the primary one, thus avoiding a weak signature algorithm.

It should be noted that the EU member countries use a signed CBOR data structure (concise binary object representation in a JSON format) presented in the form of a 2D code, and, in order to validate this data structure, all countries must share their cryptographic public keys. The Gateway was therefore designed to allow for the distribution of information to all countries participating in the Exchange. This process corresponds to the design implemented by the EU to carry out the exchange of certificates, which also allows for the exchanged information to be expanded with other data or certificates beyond COVID certificates.

To optimize the 2D code, the encryption of the objects will be done via CBOR. When the 2D code is scanned, the verification algorithms will match the used cryptography; thus, the cryptographic key must be identified only by using a verifier.

This process is done by inserting a field into the COSE header. The identifier for the key is defined as the first 8 bytes of a SHA256. In order to save the necessary bytes into the 2D code, each of the names in the field must be reduced to acronyms; however, these names must have been selected beforehand so there are no issues when doing translations.

The serialization process starts with a JSON file which coincides with the pre-defined Green Digital Certificate. After being verified, however, they are transformed so they can be read by human beings, but the serialization must be done beforehand. The 2D code can later be scanned to extract the information related to digital certificates.

IPS Exchange Model

The clinical document for the international patient summary (IPS) is the information relevant to an individual's health situation. It was initially conceived as clinical information to be exchanged in case of the person needing cross-border medical attention. However, the healthcare situations that arose in the last two years have proven that this information can be very important to the different healthcare systems in each country, because they can have trustworthy information for patients who might need medical attention outside of their country of residence, where the clinical information is stored.

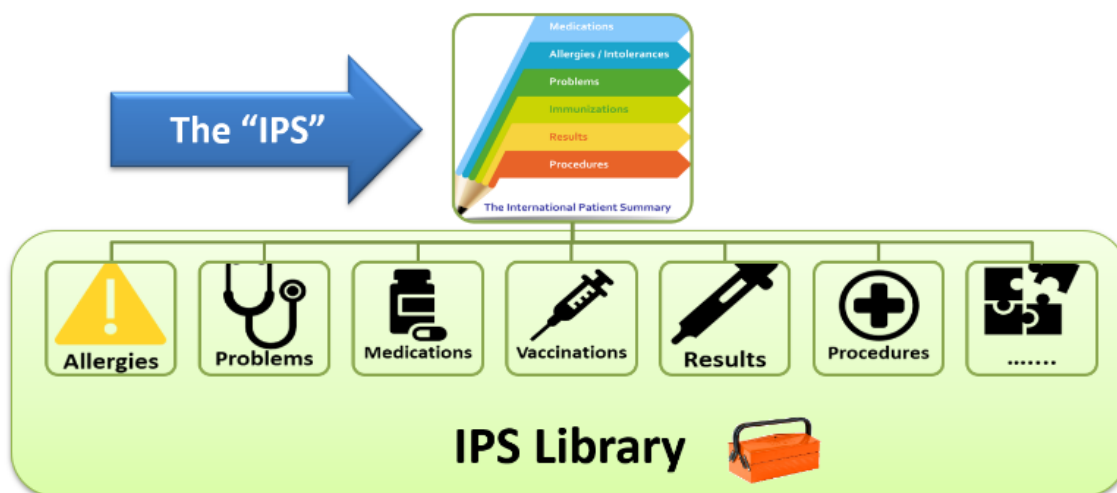
In relation to the IPS information, it should be noted that the HIR standard belonging to HL7 is used to exchange information.

By using the FHIR, information can be exchanged by using the API with rapid interoperability resources included in the standard.

For each of the elements that make up the IPS, there is an FHIR resource freely available in the following link: <https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition-Composition-uv-ips.html>

Within the HL7 page, you will find the IPS Implementation Guideline. These have been specified within the EN 17269 and the ISO/DIS 27269. This document was not only designed for cases of cross-border medical attention; it also seeks a global generic solution, whatever the country or region might be.

The IPS is made up of a set of well-defined elements, which can be found in the IPS Library:



- Questionnaires: there must be a verification that makes sure that responses for a given questionnaire are valid for the corresponding questionnaire.
- Business rules: these are created outside of the specification.

Annexes

Annex 1: COVID-19 Prophylaxis Vaccine

Code	Display	Code Name System	URL	System OID	System Version Code
1119305005	SARS-Cov-2 Antigen vaccine	TC Snomed	http://snomed.info/sct	2.16.840.1.1 13883.6.96	2121-01-31
1119349007	Sars-Cov-2 ARNm vaccine	TC Snomed	http://snomed.info/sct	2.16.840.1.1 13883.6.96	2121-01-31
J07BX03	COVID-19 Vaccines	Anatomic Therapeutic Chemical Classification System	http://www.who.int/classifications/atc/	2.16.840.1.1 1.3883.6.73	2021-01

The ATC code can be used for vaccines that are not antigen or ARNm vaccines, or in cases where the information is not known.

Annex 2: Vaccine Medication

Code	Display	Code Name System	URL	System OID	System Version Code
UE/1/20/1528	Comuna	Union Register of Medicinal Products	https://ec.europa.eu/health/index_es		
UE/1/20/1507	Spikevax	Union Register of Medicinal Products	https://ec.europa.eu/health/index_es		
UE/1/21/1529	Vaxzevria	Union Register of Medicinal Products	https://ec.europa.eu/health/index_es		
UE/1/20/1525	COVID-19 Janssen Vaccine	Union Register of Medicinal Products	https://ec.europa.eu/health/index_es		
CVnCoV	CVnCoV	Medicinal vaccine, non-centralized products authorized in the EU			1.0
NVX-CoV2373 (obsolete, see Annex A for more instructions)	NVX-CoV2373	Union Register of Medicinal Products (see “Nuvaxovid”)			1.0
Sputnik-V	Sputnik-V	Medicinal vaccine, non-centralized products authorized in the EU, under review			1.0

Convencia	Convencia	Medicinal vaccine, non-centralized products authorized in the EU			1.0
EpiVacCorona	EpiVacCorona	Medicinal vaccine, non-centralized products authorized in the EU			1.0
BBIBP-CorV	BBIBP-CorV	Medicinal vaccine, non-centralized products authorized in the EU			1.0
inactivado-SARS-CoV-2-Vero-Célula	inactivado SARS-CoV-2 (Célula Vero)	Medicinal vaccine, non-centralized products authorized in the EU			1.0
Coronavac	Coronavac	Medicinal vaccine, non-centralized products authorized in the EU, in continuous review by EMA			1.0
covaxina	covaxina (also known as bbv152 a, BEFORE CHRIST)	Medicinal vaccine, non-centralized products authorized in the EU			1.0
Coviescudo	Coviescudo (ChAdOx1_nCoV-19)	Medicinal vaccine, non-centralized products authorized in the EU			1.2
COVID-19-	COVID-19-	Medicinal			1.3

recombinant e	recombinant e	vaccine, non-centralized products authorized in the EU			
R-COVI	R-COVI	Medicinal vaccine, non-centralized products authorized in the EU			1.3
CoviVac	CoviVac	Medicinal vaccine, non-centralized products authorized in the EU			1.4
Sputnik-Luz	Luz Sputnik	Medicinal vaccine, non-centralized products authorized in the EU			1.4
Hayat Vax	Hayat Vax	Medicinal vaccine, non-centralized products authorized in the EU			1.5
Abdalá	Abdalá	Medicinal vaccine, non-centralized products authorized in the EU			1.5
WIBP-CorV	WIBP-CorV	Medicinal vaccine, non-centralized products authorized in the EU			1.5
MVCCOV19 01	MVCCOV19 01 Vaccine	Medicinal vaccine, non-centralized products authorized in the EU			1.6

UE/1/21/1618	Nuvaxovid	Union Register of Medicinal Products	https://ec.europa.eu/health/index_es		
Covovax	Covovax	Medicinal vaccine, non-centralized products authorized in the EU			1.8
Vidprevtyn	Vidprevtyn	Medicinal vaccine, non-centralized products authorized in the EU, in continuous review by EMA			1.8
VLA2001	VLA2001	Medicinal vaccine, non-centralized products authorized in the EU, in continuous review by EMA			1.8
EpiVacCorona	EpiVacCorona	Medicinal vaccine, non-centralized products authorized in the EU			1.8
Sputnik M	Sputnik M	Medicinal vaccine, non-centralized products authorized in the EU			1.8

Annex 3: Owners of the COVID-19 Vaccine Commercialization

Code	Display	Code Name System	URL	System OID	System Version Code
ORG-10001699	AstraZeneca AB	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/	2.16.840.1.1 13883.3.690 5.4	
ORG-100030215	Biontech GmbH Manufacturing	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/	2.16.840.1.1 13883.3.690 5.4	
ORG-100020693	China Sinopharm International Corporation – Peking location	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/	2.16.840.1.1 13883.3.690 5.4	
ORG-100010771	Sinopharm Weiqida Europe Pharmaceutical - Prague location	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/	2.16.840.1.1 13883.3.690 5.4	
ORG-100024420	Sinopharm Zhijun (Shenzhen) Pharmaceutical Co., Ltd. - Shenzhen location	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/	2.16.840.1.1 13883.3.690 5.4	
ORG-100032020	Novavax CZ como	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/	2.16.840.1.1 13883.3.690 5.4	
Gamaleya-Investigation Instituto	Gamaleya Investigation Instituto	Vaccine Manufacturers not in the WHO			1.0

Vector-Institute	Vector Insitute	Vaccine Manufacturers not in the WHO			1.0
Sinovac-Biotechnology	Sinovac-Biotechnology	Vaccine Manufacturers not in the WHO			1.0
Bharat-Biotechnology	Bharat-Biotechnology	Vaccine Manufacturers not in the WHO			1.0
ORG-100001981	Serum Institute of India – Private - Limited	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/		2.16.840.1.1 13883.3.690 5.4
Fiocruz	Fiocruz	Vaccine Manufacturers not in the WHO			1.3
ORG-100007893	R-Pharm CJSC	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/		2.16.840.1.1 13883.3.690 5.4
Chumakov-Federal-Scientific - Center	Chumákov Federal Scientific Center for Research and Development of Immune and Biological Products	Vaccine Manufacturers not in the WHO			1.4
ORG-100023050	Gulf Pharmaceutical Industries	EMA SPORT Organizations Management System	https://spor.e ma.europa.eu/sporwi/		2.16.840.1.1 13883.3.690 5.4
CIGB	Center for	Vaccine			1.5

	Genetic Engineering and Biotechnology (CIGB)	Manufacturers not in the WHO			
Sinopharm-WIBP	Sinopharm - Wuhan Institute of Biological Products	Vaccine Manufacturers not in the WHO			1.5
ORG-100033914	Medigen Vaccine Biologics Corporation	EMA SPORT Organizations Management System	https://spor.ema.europa.eu/sporwi/		2.16.840.1.1 13883.3.690 5.4
ORG-100000788	Sanofi Pasteur	EMA SPORT Organizations Management System	https://spor.ema.europa.eu/sporwi/		2.16.840.1.1 13883.3.690 5.4
ORG-100036422	France	EMA SPORT Organizations Management System	https://spor.ema.europa.eu/sporwi/		2.16.840.1.1 13883.3.690 5.4

Annex 4: Vaccine Codification Instructions Summary

Vaccine Name	Vaccine Code	Manufacturer or MAH Code	Type of Vaccine	Notes
Comuna	UE/1/20/1528	ORG-100030215	1119349007 o J07BX03	
Spikevax	UE/1/20/1507	ORG-100031184	1119349007 o J07BX03	Previously known as COVID-19 Moderna Vaccine.
Vaxzevria	UE/1/21/1529	ORG-100001699	J07BX03	Also used for AstraZeneca covid-19 vaccines, except for R-COVI, Covishield and Covid-19 (recombinante) of Fiocruz.
COVID-19 Janssen Vaccine	UE/1/20/1525	ORG-100001417	J07BX03	
CVnCoV	CVnCoV	ORG-100006270	1119349007 o J07BX03	
NVX-CoV2373	NVX-CoV2373	ORG-100032020	J07BX03	Do not use this code for new certificates. Check the Nuvaxovid entry.
Sputnik V	Sputnik-V	Gamaleya - Investigation Institute	J07BX03	
convencia	convencia	ORG-100013793	J07BX03	
EpiVacCorona	EpiVacCorona	Vector-Institute	J07BX03	
BBIBP-CorV	BBIBP-CorV	ORG-100020693	J07BX03	

SARS-CoV-2 inactivado (Célula Vero)	SARS inactivado CoV-2-Vero-Célula	ORG-100010771	J07BX03	Do not use this code for new certificates. Check the WIBP-CorV entry.
CoronaVac	CoronaVac	Sinovac-Biotechnology	J07BX03	
Covaxina (also known as BBV152 A, B, C)	covaxina	Bharat-Biotechnology	J07BX03	
Coviescudo (ChAdOx1_nCoV-19)	Coviescudo	ORG-100001981	J07BX03	
Covid-19 (recombinante)	COVID-19-recombinante	Fiocruz	J07BX03	
R-COVI	R-COVI	ORG-100007893	J07BX03	
CoviVac	CoviVac	Chumakov-Federal-Scientific-Center	J07BX03	
Luz Sputnik	Sputnik-Luz	Gamaleya Investigation Institute	J07BX03	
Hayat Vax	Hayat Vax	ORG-100023050	J07BX03	
Abdalá	Abdalá	CIGB	J07BX03	Also known as CIGB-66.
WIBP-CorV	WIBP-CorV	Sinopharm-WIBP	J07BX03	Previously known as SARS-CoV-2 inactivado
MVC COVID-19 Vaccine	MVC-COV1901	ORG-100033914	J07BX03	Also known as Medigen COVID-19 vaccine.
Nuvaxovid	UE/1/21/1618	ORG-100032020	J07BX03.	Previously known as NVX-CoV2373

Covovax	Covovax	ORG-100001981	J07BX03	Do not confuse with Nuvaxovid.
Vidprevtyn	Vidprevtyn	ORG-100000788	J07BX03	
VLA2001	VLA2001	ORG-100036422	J07BX03	
Sputnik M	Sputnik-M	Gamaleya Investigation Center	J07BX03	Do not confuse with Sputnik V or Sputnik Light.
EpiVacCorona-N	EpiVacCorona-N	Vector-Institute	J07BX03	Do not confuse with EpiVacCorona. Also known as Aurora-CoV.

Glossary

DGC	Digital Green Certificate
EU	European Union
EHN	European Health Network
EUDCC	EU Digital Covid Certificate
HSM	Hardware Security Module
DGCG	Digital Green Certificate Gateway
1D	Unidirectional
2D	Bidirectional
DDCC	Digital documentation of COVID-19 certificates
DDCC:VS	Digital documentation of COVID-19 certificates: vaccination status
HCID	Healthcare Certificate Identifier
ID	Identifier
PHA	Public Health Agency
NAAT Test	Nucleic acid amplification test (NAAT), such as polymerase chain reaction with reverse transcription (PCR-RT), loop mediated isothermal amplification (LAMP), or transcription-mediated assay (TMA) to detect the presence of ribonucleic acid RNA for SARS-CoV-2.
Rapid antigen test (RAT)	Test based on the detection of virus particles (antigens) via a lateral-flow immunoassay which provides results in less than 30 minutes.
Antibody testing	Laboratory test meant to detect if a person has developed antibodies for SARS-Cov-2, which indicates that the certificate owner has been exposed to SARS-Cov-2 and has developed antibodies, regardless of

	whether the person was symptomatic or not.
IHE	Integrating the Healthcare Enterprise
EHR	Electronic Health Record
IPS	International Patient Summary
BMI	Body Mass Index
ICC	International Chamber of Commerce

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