DRAFT IMPLEMENTATION PLAN FOR THE EUROPEAN VACCINATION CARD (EVC)

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List of Abbreviations and Acronyms

Abbreviation / Acronym		Meaning
CBOR	Compact Binary Object Representation	A concise binary data serialization format based on JSON.
CDS	Clinical Decision Support System	A health information technology that provides person-specific information to help health and health care.
COSE	CBOR Object Signing and Encryption	A security standard for the CBOR format.
EHR	Electronic Health Record	Systematized collection of patient health information in a digital format
ePIL	Electronic Patient Information Leaflet	Regulatory patient information leaflet, presented as an online digital resource
EVC	European Vaccination Card	A portable, self-contained, dual format document provided to citizens to carry their vaccination history without loss of information across different health jurisdiction.
GDHCN	Global Digital Health Certification Network	An open, interoperable public infrastructure to facilitate the verification and secure exchange of verifiable digital health certificates.
GDPR	Global Data Protection Regulation	European Union regulation of personal information privacy.
IIS	Immunisation Information System	Information system that collects vaccination data about all persons within a geographic area.
ISO 27001	ISO/IEC 27001:2022	International standard for information security management.
JSON	JavaScript Object Notation	Open standard file format that uses human readable text to transmit data objects consisting of attribute-value pairs and arrays.
MR	Master Record	A vaccination record held by any authorized EHR application in Europe attesting that the vaccination was performed or recorded by an accredited health professional using this system.
MS	Member State	Any European country of the European Union
NUVA	Nomenclature Unifiée des Vaccins	A public ontology of vaccines designations, aligned with many vaccine code systems.

PDF	Portable Document Format	A standard file format to present documents in a manner independent of application software, hardware and operating systems.
PKI	Public Key Infrastructure	Set of roles, policies, hardware, software and procedures needed to create, manage, distribute, use, store and revoke digital certificates and manage public-key encryption.
RFC	Request for Comments	A publication in a series from the principal technical development and standard-settings bodies for the Internet.
QR Code	Quick Response Code	A type of two-dimensional matrix bar code, used to store information as a machine-readable optical image.
WHO	World Health Organisation	Agency of the United Nations responsible for international public health.
X509	ITU X.509 standard	Standard defining the format of public key certificates, binding an identity (a hostname, or an organisation, or an individual) to a public key using a digital signature.

The purpose of EUVABECO is to deliver to Member States implementation plans for several tools able to support existing or future vaccination practices.

These implementation plans are practical guides for a Member State to decide upon the launch of an implementation project, assign adequate resources, deploy the given tool and keep it operational after deployment.

They are structured with three main sections:

- *Description of the tool is a functional analysis of the tool with an overview, the stakeholders using or contributing to the use of the tool, their respective functional requirements, the non-functional requirements, and a collection of use cases illustrating the desired functions.*
- *Prerequisites lists the contextual conditions that must be met before the project is launched, and a few workarounds that could be used to anticipate upon their fulfilment.*
- *Implementation addresses the actual implementation, with the architecture, resources, workflow and planning for the build phase, and the missions to be ensured during the run phase to keep the tool operational.*

1 Description of the tool

This section provides a functional overview of the intended tool and its usage. It outlines the goals and features without referring to any specific implementation.

1.1 Objectives

This section is the overall rationale for the tool.

The European Vaccination Card (EVC) is a portable, self-contained document, provided to citizens to enable them to carry their vaccination history without loss of information across various national or regional health jurisdictions in Europe.

The primary goal of the EVC is to support is the continuity of car. With access to a reliable record of an individual's vaccination history, health professionals are better equipped to ensure that a person is protected from vaccine-preventable diseases (VPD)

The EVC has a dual format:

- A human-readable text version
- A digital format readable by health applications.

The digital format offers several key functionalities:

- **Data Integration**: Upload vaccination data to any electronic health records (EHR) system, allowing for easy sharing within health facilities or organizations.
- **Multilingual Support**: Automatically present vaccination information in the language of the reader, even if it differs from the original language of the text version.
- **Clinical Decision Support**: Provide input for a Clinical Decision System (CDS) to determine the when the next vaccinations are due.
- **Vaccine Information Access**: Link to informative resources, such as electronic Patient Information Leaflets (ePIL), for details on the vaccines received.
- **Authenticity Verification**: Verify the record's authenticity through a digital signature.

1.2 Involved stakeholders and their expectations

This section outlines the various stakeholders within the implementing Member State who will use or contribute to the tool. Their expectations represent essential requirements for any implementation.
The key stakeholders involved in the European Vaccination Card (EVC) system are:

- **Citizens**: Individuals who retrieve, carry, or share their EVC. This includes either the person whose vaccination history is recorded or their legal representative (e.g., parents of a child).
- **Healthcare Professionals**: Those responsible for issuing, importing, or reading the EVC as part of the patient care process.
- **Health Authorities (Issuing):** The health authority from the jurisdiction where the EVC is issued, responsible for accrediting health professionals to create and maintain the record.
- **Health Authorities (Receiving):** Health authorities in the jurisdiction where the EVC is presented or shared are responsible for establishing infrastructure that enables the trust chain to be ensured.
- **EHR Suppliers:** Providers of Electronic Health Record (EHR) systems that must support the delivery or interpretation of the EVC in their platforms.
- **e-Health Infrastructure Operators:** Organizations managing the digital infrastructure that supports the sharing and processing of health data, including the EVC.
- **Accredited Digital Signature Operators**: Entities responsible for issuing and verifying the digital signatures that ensure the authenticity of the EVC.
- **European Commission:** Acts as the guardian of the EVC's portability, ensuring it functions across European borders.
- World Health Organization (WHO): Serves as the global reference for trust and reliability through the Global Digital Health Certification Network (GDHCN), supporting cross-jurisdictional validation.

1.2.1 Citizens

For citizens, the EVC replaces the traditional, paper-based vaccination card, offering several advantages. The EVC is authentic, easily replicable, explicit, automatically translatable into any language, and easy to share with health professionals or health applications.

Citizens expect the EVC to be convenient, presented in a physical document, in a familiar format, and easy to access and to transfer when needed.

1.2.2 Health professionals

Health professionals play a key role in delivering and accepting EVCs. They are likely to adopt the EVC only if it provides clear benefits in their workflow.

The primary benefit is realized when importing an EVC, as it saves time by eliminating the need to manually input the vaccination history into their EHR system.

However, health professionals have limited immediate incentives for delivering an EVC, unless it's requested by patients or mandated by legal requirements. Therefore, the process for issuing an EVC must be simple and efficient, requiring minimal effort when using the healthcare provider's EHR application.

In countries with a shared Immunisation Information System (IIS), where health professionals can access or publish data, the need to issue or import EVCs may be reduced as the same data can be retrieved from or published to the IIS. Yet, the EVC remains valuable in certain scenarios:

- for **patients not recorded in the IIS**, such as foreign nationals or those who opt out,
- for **local patients travelling abroad** who need portable records of vaccination.

Where there is an IIS, it would serve as the central tool for importing and delivering vaccination data.

When health professionals import an EVC, they should be confident about the authenticity of the data they receive.

It is crucial that the system clearly distinguishes between two types of records:

- Primary vaccination data: Vaccinations administered or recorded directly by the professional or their institution.
- Secondary vaccination data: Historical, certified vaccination information imported from other trusted sources.

1.2.3 Issuing health authority

The issuing health authority must accredit the health professionals authorized to issue an EVC. This includes health professionals such as medical doctors, nurses, pharmacists, midwives, etc., who are permitted to administer or record vaccinations in line with local regulations.

The health authority must also identify and approve the different software applications used to generate EVCs, and o establishing a rigorous certification process to ensure that these EVCs are readable across all compliant applications.

Additionally, it is essential that the authenticity of each EVC is guaranteed through reliable digital signatures and binding to master records. The issuing authority should also collaborate with other health authorities to investigate and verify the accuracy of any EVCs received.

1.2.4 Receiving health authority

The receiving health authority must establish trust in the information received. This should be done by using a common infrastructure, specifically the WHO Global Digital Health Certification Network (GDHCN), with all issuing health authorities to validate digital signatures.

Additionally, the receiving authority must set up an alert system to report potential fraud. In cases of suspicion, it should coordinate with the health authority of the country responsible for the master records to carry out further investigations.

1.2.5 EHR suppliers

EHR suppliers, responsible for editing the EHR applications that import or deliver EVCs, require a technical toolbox to ensure compliance and streamline operations. This toolbox could encompass:

- An open-source implementation under a liberal license
- Reference implementations and compliance test suites for validation

Alternatively, EHR suppliers can delegate the processing of EVCs to another system with preexisting interfaces, such as an IIS or a national repository of structured health documents.

1.2.6 E-Health operators

The e-Health operator may be mandated by the health authority to:

- Managing the technical authentication of accredited health professionals.
- Establishing the infrastructure for the digital signature of the EVC, which may require collaboration with an external digital signature operator.

In some cases, an e-Health operator may also need to integrate the import and delivery of EVCs into national resources, such as an IIS or a national repository of health documents. In these situations, the operator's requirements will align closely with those of an EHR supplier, ensuring compatibility and compliance.

1.2.7 Digital signature operators

Depending upon the organisation within the MS, the digital signature operators accredited for signing digital health records may be either the same as the e-Health operator or have a broader role covering all official signatures.

These operators manage their own public key infrastructure (PKI) policies, ensuring secure and regulated use of their keys.

To ensure global interoperability, they must participate in the WHO GDHCN, allowing their public keys to be recognized and accepted by any other country.

1.2.8 European Commission

Unlike other tools in the EUVABECO project, the EVC is effective only if it is implemented consistently across all MS. Once the EUVABECO project concludes, it will be the responsibility of the EC to oversee the long-term management of the interoperability resources – both structural and semantic -needed to maintain the EVC system.

1.2.9 WHO

Trust in EVCs is anchored in the WHO Global Digital Health Certification Network (GDHCN), a common repository of trusted digital signatures managed by the WHO. All digital signature operators must adhere to the GDHCN's compliance rules.

As of April 10th, 2024, among the 27 EU MS:

- **15 were already fully onboarded in GDHCN:** Belgium, Cyprus, Czechia, Estonia, Finland, France, Ireland, Lithuania, Malta, Netherlands, Slovakia, Slovenia, Spain, Poland and Portugal.
- **5 were in the process of onboarding**: Croatia, Greece, Latvia, Luxembourg and Sweden.
- **7 had yet to apply**: Austria, Bulgaria, Denmark, Germany, Hungary, Italy and Romania.

Globally, there were 74 participants in the GDHCN.

1.3 Constraints

Constraints are the non-functional requirements that, while not directly related to the tool's specific functions, are critical to its overall viability.

1.3.1 Personal data protection

The EVC is considered a private document held by a natural person and does not fall under the scope of the General Data Protection Regulation (GDPR).

Most of the means used to create or process the data are EHR applications that are already authorised to handle personal data, as they operate for the purpose of preventive or occupational medicine (GDPR Article 9.2.h).

However, special has attention must be given to the digital signature infrastructure, ensuring that it protects the confidentiality of the data being signed. Only statistical data related to the use of the infrastructure should be stored.

1.3.2 Transparency

No information on the EVC should be concealed from the citizen. Every EVC can be printed with a readable content. While the printed section of the EVC may be simplified - showing only key details such as the date and vaccine product for administration - dedicated online readers or mobile applications should provide full access to all of the information contained in the EVC to ensure transparency and easy access.

1.3.3 Non-discrimination

Paper-based vaccination cards have been in use for over a century, and the EVC is simply an enhanced version of these records. No individual should be denied rights or services for not having an EVC. All use cases that rely on the EVC must also be achievable with traditional vaccination cards, even if doing so requires additional effort or the involvement of a health professional as an intermediary.

1.4 Use cases

The following use cases illustrate how different stakeholders can use the EVC tool to meet their expectations. Each scenario demonstrates a specific function of the tool.

The use cases below are built across the fictitious states of Alpharia, Betaria and Gammaria.

1.4.1 UC01 – Delivering an EVC

1.4.1.1 Actions

In the fictitious state of Alpharia, Dr. Costa is providing care for her regular patient, Anna, a 27-year-old nurse who is about to move to Betaria for an extended period. Anna requests to carry her vaccination information with her.

Dr. Costa accesses Anna's patient record in her EHR application, where all of her vaccinations is already recorded. To meet Anna's request, Dr. Costa selects the "EVC" option within the EHR application and downloads a PDF version of the EVC. Dr. Costa offers Anna two delivery methods: secured file transfer or a printed copy. Anna prefers to receive the EVC via secured file transfer, which Dr. Costa performs (details of the file transfer process are out of the scope of this document due to the variety of different solutions in different Member States). Dr. Costa also retains a local copy of the EVC in Anna's digital record within the EHR application for future reference, ensuring that the information can be retrieved for, or resent to, Anna as needed.

1.4.1.2 Behind the scenes

Vaccination Event in EVC: A vaccination event in an EVC consists of three essential elements:

1. **Date of vaccination administration**
2. **Vaccination Identifier**: A unique identifier for the administered vaccination
3. **Master record reference:** A reference to a master vaccination record stored within any authorized EHR application in Europe, attesting that the vaccination was performed or recorded by an accredited health provider using this system. Multiple master records can exist for a single vaccination event if multiple health professionals endorse the information.

EHR Assembly Process: The EHR application assembles a comprehensive vaccination history from the records it holds. For each vaccination event, it may use an existing master record or create a new one if the EHR system declares itself as the master record holder.

Processing by eHealth Operator's National Pool: Once the vaccination history is assembled, the EHR system submits it for compacting and digital signature to a national pool of servers managed by the eHealth operator. A server in the pool receives the vaccination history data and packs it for signature.

Digital Signature Process: A server in the pool prepares the vaccination history for digital signing and sends it to a digital signature operator.

Generating the EVC: The signed vaccination history, which forms the EVC, is returned the digital signature operator to the eHealth operator server and subsequently back to the originating EHR application.

Final EVC Format: The EHR application then generates a PDF document containing two main elements:

- The vaccination history printed as plain text
- The signed digital information embedded within the QR Code and as metadata within the PDF.

1.4.2 UC02 – Translating an EVC

1.4.2.1 Actions

Anna, now residing in Betaria, holds an Electronic Vaccination Certificate (EVC) issued in Alpharian, her native language. However, she requires a version of the EVC in Betarian to use within the local healthcare system.

To achieve this, Anna accesses a public online EVC viewer service provided by the Betarian eHealth operator. She uploads the EVC she previously received from Dr. Costa into the system. The viewer application translates the vaccination history into Betarian based on the digital information encoded within the EVC. Anna reviews the vaccination history displayed in the new language and proceeds to download the translated EVC as a PDF document. Despite the language change, the underlying digital information of the EVC remains unaltered, ensuring consistency and security across different languages and healthcare systems.

1.4.2.2 Behind the scenes

Public EVC Viewer Service: The EVC viewer application is a service provided by the Betarian eHealth operator. It allows users to upload their EVCs and view them in the local language. Upon receiving Anna's EVC, the system retrieves the identifier of the cryptographic key used to sign the certificate.

Signature Validation: The system then fetches the corresponding public key from a local, synchronized copy of the WHO GDHCN database. This database stores public keys for validating vaccination certificates issued worldwide. Using the public key, the system confirms that the signature on Anna's EVC is valid, thereby verifying the integrity and authenticity of the vaccination history.

Textual Representation in Betarian: Once the EVC is authenticated, the system extracts the vaccination information from the digital data and displays it in Betarian.

Unchanged Digital Representation: The digital representation of Anna's EVC remains unchanged during the translation process. As it remains exactly the same as the original version issued by Dr. Costa in Alpharia, regardless of the language used for textual representation, this ensures that the EVC maintains its original integrity and can be verified by any system.

1.4.3 UC03 – Importing an EVC for a new patient

1.4.3.1 Actions

Upon arriving in Betaria, Anna visits her new doctor, Dr. Muller, at the hospital where she will work. She presents Dr. Muller with a printed copy of her EVC, issued in Alpharia.

Dr. Muller opens his EHR application to create a new patient record for Anna. Using a 2D barcode reader, he scans the QR Code on the printed EVC. The system automatically retrieves Anna's basic information - name, given name and date of birth - and presents it to Dr. Muller for confirmation. Once he verifies that this information corresponds with his new patient, Dr. Muller validates the import, and all of Anna's vaccination records from the EVC are seamlessly entered in her new patient record.

1.4.3.2 Behind the scenes

QR Code Scanning and Data Extraction: The QR Code on Anna's printed EVC contains the complete digital content of her vaccination records. When Dr. Muller scans the QR Code, the EHR application captures the encoded data, which includes the patient's identity information (name, given name, and date of birth) as well as the entire vaccination history.

EVC Validity Check: Before importing the vaccination data, the EHR application validates the authenticity of the EVC using the same mechanism as the public EVC viewer described in use case UC02 – Translating an EVC.

Digital Content Unpacking: Once the EVC is verified, the EHR application then unpacks the digital content. The system first presents Anna's identity traits (name, given name and date of birth) to Dr.

Muller for confirmation. After verifying that these details are correct, Dr. Muller confirms the import of the vaccination history into Anna's patient record.

Handling Vaccination Records: Each vaccination record imported into Anna's new patient record is associated with a corresponding master record, which verifies that the vaccination was previously recorded by an accredited health professional in Alpharia. This link to the master record provides a trust chain for the imported vaccination data.

- **Option for Master Record Creation**: An alternative approach for Dr. Muller would be to endorse the vaccination records locally, essentially establishing new master records for Anna's vaccinations within the Betarian healthcare system. However, this would require Dr. Muller to assume more responsibility for the accuracy and validity of the vaccination records.

Non-EVC Enabled EHR Option: In the case where Dr. Muller did not have an EVC enabled EHR application, he could still verify the authenticity of Anna's EVC using the public EVC viewer. This would allow him to check that the digital representation of the vaccination records aligns with the printed text version. Afterward, Dr. Muller could either keep the printout as part of the patient's paper record or manually enter the vaccination details into the EHR.

1.4.4 UC04 – Updating an EVC

1.4.4.1 Actions

As part of her new role in a paediatric service in Betaria, Anna is required to receive a booster dose of the pertussis vaccine. During her visit to Dr. Muller, he administers the booster dose and records it in his EHR application. Once the vaccination is recorded, Dr. Muller generates an updated version of Anna's Electronic Vaccination Certificate (EVC) to include the newly administered pertussis vaccine. He provides Anna with the updated EVC, either as a digital document or a printout, depending on her preference.

1.4.4.2 Behind the scenes

Recording the New Vaccination: Once Dr. Muller administers the pertussis booster to Anna, the vaccination is recorded in his EHR system. Since this vaccination is performed locally in Betaria, the EHR system immediately registers the vaccination as a new master record.

EVC Elaboration Process: After recording the pertussis vaccination, the process of updating Anna's EVC closely mirrors the original workflow used in Alpharia by Dr. Costa, but the signature is performed by the Betarian infrastructures.

1.4.5 UC05 – Reconciling two EVCs

1.4.5.1 Actions

While unpacking after her move to Betaria, Anna finds a partial EVC that she was issued at a travel vaccination centre three years ago after receiving her yellow fever vaccination. She had never reported this vaccination to Dr Costa in Alpharia and, as a result, it is missing in her most recent EVC.

On her next visit to the hospital, Anna presents the old EVC to Dr. Muller. He scans it using his EHR system, which compares it to the existing records in Anna's current EHR. The system displays a comparison screen highlighting the differences:

- Vaccinations administered prior to the yellow fever administration are found both in the old EVC and the current EHR.
- The yellow fever is vaccine appears in the old EVC but is missing from the EHR.
- Vaccinations administered after yellow fever administration are recorded in the EHR but are missing from the old EVC.

Dr Muller reviews the differences and revalidates all new records from the EHR, except the yellow fever one, adding the missing yellow fever vaccination from the old EVC. He then issues a new, reconciled EVC for Anna, ensuring her full vaccination history is up to date.

1.4.5.2 Behind the scenes

Comparison Function in the EHR: The EHR application includes a comparison function that allows it to reconcile vaccination records between the current patient records and an external EVC.

Tolerance for Differences in Precision: During the comparison, the EHR system accounts for tolerances in how vaccines are recorded. For example, if two vaccinations occur on the same date but with varying levels of precision in the vaccine product encoding (e.g., "FLUARIX" versus "Flu vaccine"), the system can still identify them as the same vaccine. This is achieved using a structured vaccine terminology, such as the NUVA terminology used by the EUVABECO project.

1.4.6 UC06 – Obtaining a vaccination certificate

1.4.6.1 Actions

Anna, now working in the paediatric department of a hospital in Betaria, is required to provide proof that she has received all mandatory vaccinations as outlined by Betarian law for nurses in her role. However, the hospital's administrative services do not need to see the full details of her vaccination history; they only require a vaccination certificate to confirm her compliance with the law. To meet this requirement, Anna accesses the vaccination certificates platform provided by the Betarian eHealth operator. She selects the purpose of the certificate. She then uploads her EVC to the platform and, in return, receives a simplified vaccination certificate.

This certificate, delivered as a PDF document, contains digitally signed content that confirms Anna is compliant with current vaccination requirements. However, it does not disclose her complete vaccination history. Anna can then submit this certificate to the hospital administration, satisfying the legal requirements without revealing unnecessary personal health details.

1.4.6.2 Behind the scenes

Clinical Decision Support System Evaluation: The vaccination certificates platform runs a Clinical Decision Support System (CDS) to determine whether Anna received all the vaccine series required for her occupation.

Rule-Based Compliance Check: The CDS runs a rule-based check to compare Anna's vaccination history against the mandatory vaccine series outlined by Betarian law for her role.

Generating the Vaccination Certificate: Once the CDS verifies that Anna has met all the required vaccination criteria, the platform generates a simplified vaccination certificate. This certificate is similar to the original EVC in that it uses the same digital signature technology to ensure authenticity. However, its content is limited, including only:

- Identity Information: Basic identifying traits from the EVC (e.g., name and date of birth).
- Purpose of the Certificate: The specific reason for the certificate (e.g., occupational health compliance for nurses).

Compliance Status: A binary statement that Anna is fully compliant with the vaccination requirements as of the current date.

Multi-Purpose Platform: The vaccination certificates platform is designed to issue certificates for different purposes, each governed by its own set of rules. For instance, there might be a separate set of criteria for issuing certificates required for children to attend kindergarten. The platform dynamically adjusts the content of the certificate based on the selected purpose, ensuring the appropriate content is provided for each case.

1.4.7 UC07 – Checking upon a fraud suspicion

1.4.7.1 Actions

In her service, Anna attends to a child exhibiting symptoms of meningococcal disease, despite the child's EVC indicating that they have been vaccinated, according to a record held in Gammaria.

While providing treatment, Anna submits a verification request to the Betarian health authority. The request includes the identification of the master record in Gammaria and the child's date of birth (these are the only pieces of personal information provided, ensuring that re-identification is not possible). The Betarian health authority forwards this request to the Gammarian health authority, which identifies the specific healthcare structure that holds the master record. The request is then forwarded to that healthcare structure for further investigation.

Ultimately, it is discovered that although the vaccination was indeed administered and recorded by the healthcare facility in Gammaria, there was a documented issue with vaccine storage at the time, leading to potential vaccine ineffectiveness.

Gammaria reports back to Betaria, confirming that while the vaccination record is genuine, the vaccination administered was defective due to the storage problem. Anna updates the child's vaccination record into her own EHR application, creating a new master record to facilitate future tracking in case the issue is raised again.

1.4.7.2 Behind the scenes

This type of **forensic verification process** is exceptional and is not automated. Adequate communication channels must be established within each MS and between MS to transmit and track such requests effectively.

2 Prerequisites

Prerequisites represent the broader context or resources necessary for the successful implementation and operation of the EVC tool. Although not specific to the tool itself, these prerequisites are essential for ensuring its proper functioning once deployed.

2.1 Assessment of prerequisites

2.1.1 Operational

The implementing Member State must be able to identify which health professionals or health structures are authorized to administer vaccinations and, consequently, issue EVCs. These authorized health professionals must have access to an EHR application where master records can be securely stored.

Additionally, the Member State must have access to a digital signature operator that is part of the GDHCN.

2.1.2 Legal and ethical

Entities responsible for maintaining master vaccination records must be legally authorized to store these records for the lifetime of the individuals concerned, even if there is no continued interaction between the individual and the entity. This may require an exception to the MS general rules on health record retention, that could limit it to an age when death is not certain yet. Similar exceptions already exist for specific cases, such as the retention of records related to blood-derived products or radiation exposure.

2.1.3 Political

2.1.3.1 Opposition to the principle of the EVC

Due to the experience with the Digital Covid Certificate precedent, there is a vocal minority that opposes the concept of the EVC, conflating it with a mandatory, centralized document that governs rights. This group overlooks the differences between a voluntary, personal health record and a mandatory, centralized document. However, this opposition should not be significant enough to prevent the project from moving forward.

2.1.3.2 Reluctance of the EHR suppliers

There may also be resistance from the EHR suppliers who are hesitant to address the challenges associated with implementing the EVC feature in their systems.

2.1.4 Technical

A robust and reliable communication infrastructure must be in place to facilitate seamless interactions between EHR applications and the signature servers responsible for securing EVCs.

2.2 Filling the gaps

Meeting the prerequisites is often a long-term endeavour that goes far beyond the scope of the implementation plans. This section suggests potential workarounds for launching the EVC project even when some prerequisites are not fully met. Although these measures may not deliver the full benefits immediately, they can create the visibility and momentum needed to justify further efforts to meet the prerequisites.

2.2.1 Operational

As a transient solution, health professionals or structures that issue EVCs can be registered within the digital signature infrastructure without being integrated into a national identification scheme.

Additionally, the signature infrastructure can be prepared in compliance with the GDHCN procedures, even if the formal application process for full compliance is still underway.

2.2.2 Legal and ethical

Health structures typically retain patient records for extended periods, often up to 10 years after the patient's last visit. This provides a buffer period during which measures can be put in place to ensure the lifetime retention of master vaccination records.

2.2.3 Political

It is essential to clearly communicate the differences between a vaccination card and a vaccination certificate or passport.

A public, standalone solution for importing and issuing EVCs could be proposed as an initial step, encouraging EHRs suppliers to integrate the feature. This approach could be particularly effective if the MS already has a centralized infrastructure for managing health records.

2.2.4 Technical

To address connectivity challenges, the digital signature servers could be decentralized. While this may complicate the management and security of cryptographic keys, it could compensate for unreliable communication between the EHR systems and the signature infrastructure.

3 Implementing

3.1 Build

This section is the core of the implementation plan. It details how the tool is constituted, which roles should be present in the project team, the tasks they will have to perform, and a typical planning for implementation. Additional resources developed during the EUVABECO project can complement this plan.

3.1.1 Architecture

The EVC is a PDF document that presents vaccination history in three formats:

- A human readable list of administered vaccines,
- A QR code within the document,
- Metadata within the PDF file, containing information identical to the QR code.

The digital components of the EVC (QR code and metadata) consist of records that are digitally signed by a signature server. This server is operated by a member of the WHO GDHCN and adheres to the rules and protocols set by the GDHCN.

Carnet de Vaccination Électronique au 24/10/2024

Statut Vaccinal

ÉCHÉANCES VACCINALES DÉPASSÉES

Covid 19, Hépatite B, Pneumocoque, Zona

ÉCHÉANCES VACCINALES PROCHAINES

MALADIE	À PARTIR DU	AVANT LE
Grippe saisonnière	30/10/2024	

VACCINATIONS À JOUR

Diphtérie, Haemophilus influenzae b, Tétanos

Historique Vaccinal

DATE	ÂGE	NOM DU VACCIN	MALADIES
22/02/2022	Adulte	ROTATEQ	Rotavirus
23/02/2022	Adulte	ROTATEQ	Rotavirus
23/02/2022	Adulte	PENTAVAC	Coqueluche, Diphtérie, Haemophilus influenzae b, Poliomyélite, Tétanos
23/02/2022	Adulte	HEXYON	Coqueluche, Diphtérie, Haemophilus influenzae b, Hépatite B, Poliomyélite, Tétanos
24/02/2022	Adulte	PENTAVAC	Coqueluche, Diphtérie, Haemophilus influenzae b, Poliomyélite, Tétanos
20/10/2022	Adulte	ABHAYRAB	Rage
06/10/2023	Adulte	FENDRIX	Hépatite B
06/10/2023	Adulte	C.D.T.	Diphtérie, Tétanos

European Vaccination Card (EVC)

Figure 1 - Example of an EVC

For each administered vaccine, the records include a reference to a master record, that is held by an accredited health facility within a participating MS.

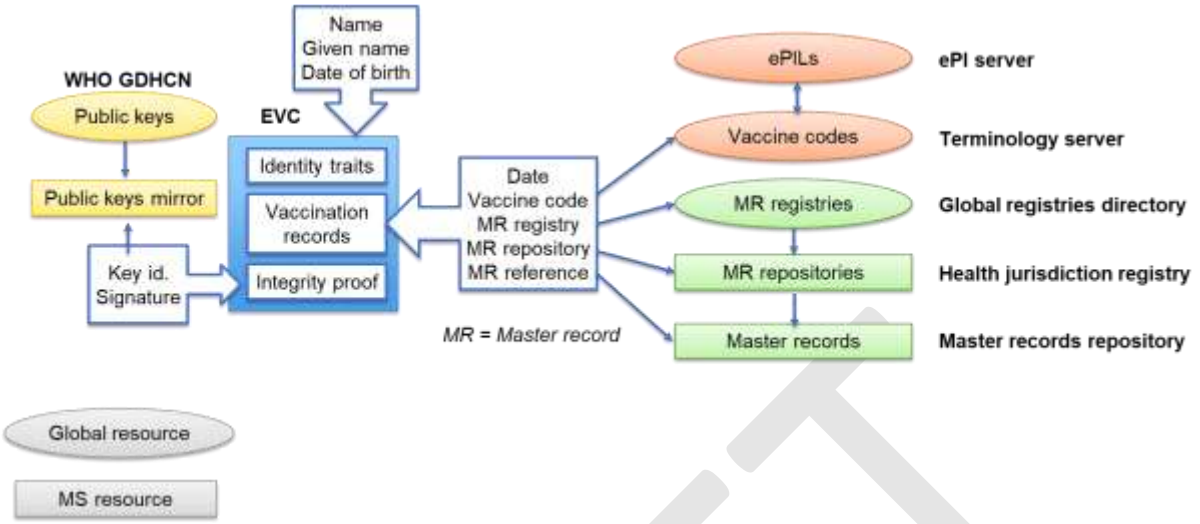

Figure 2-EVC trust infrastructure

The creation of the digital components of the EVC involves three key stages:

- **Collating the data** to be included into the EVC.
- **Compacting this data** to ensure it can be efficiently stored and transmitted.
- **Digitally signing the compacted data** to ensure authenticity and integrity.

3.1.1.1 Collating the data

The EVC is always generated from a system operated by an accredited health professional. This could be a centralized IIS for a country or a region, or a local EHR application.

This system can obtain vaccine administration events from several sources:

- An existing EVC,
- Its own data if the vaccine was administered or registered locally,
- Connected trusted repositories, such as a national IIS.

When a vaccine is registered locally, it constitutes a master record for that administration. Multiple master records for the same administration can exist, and this is not contradictory.

Each master record is uniquely identified by:

- The master record holder, or repository, which is itself identified by a registry (typically one per health authority) and an index within this registry.
- The date of administration and an index (or reference) for that date. The repository software assigns these indexes, often using a counter for vaccines registered on a given day.

Once all master records for the administered vaccines are identified, the EHR application compiles them into a payload for the EVC and submits it for data compaction.

The payload is a JSON structure containing the following elements:

L1	L2	Card.	Type	Example	Comment
ver		1..1	string	1.0.0	Version of the structure
nam		1..1			Basic identity traits
	fnt	1..1	string	DOE	Name
	gnt	1..1	string	John	First or usual given name
dob		1..1	date	2017-07-19	Date of birth
pid		0..1			Optional digital identifier for the person
	oid	1..1	string	1.2.250.1.213.1.4.8	Object identifier for the identification scheme
	id	1..1	string	1630777186051	Person identifier within the scheme
v		0..*			Vaccine administration records
	reg	1..1	string	FRA	2 to 6 letters code for a registry
	rep	1..1	int	5	Index for a repository in a registry
	i	1..1	int	1296	Reference within a repository for a given date
	a	1..1	int	1386	Age in days when the vaccine was administered
	mp	1..1	int	29	NUVA code for the vaccine (here REPEVAX)

3.1.1.2 Compacting the data

Three options are possible for the compacting stage:

- **Local compaction by the health professional's system**: This method offers the highest level of data protection, as only an unidentifiable hash of the compacted data is sent to the signature server. However, it is also the most complex for the Electronic Health Record (EHR) system provider to implement.
- **Centralized compaction by the entity operating the signature server**: In this case, the collated data is transmitted to the signature server entity, which performs the compaction. This is applicable when the signing entity is closely linked to the health authority.
- **Compaction by an intermediate entity:** Here, an intermediary acts on behalf of the health authority, ensuring that health data remains hidden from the signing entity while still performing the compaction.

The choice between these options must be made during the initial setup of the implementation project.

The compacting process is systematic and consists in converting the JSON payload to Concise Binary Object Representation (CBOR), as described in RFC8949[1].

3.1.1.3 Signing the compacted data

The digital component of the EVC is always signed by a signature server, which is operated by a member of the WHO GDHCN and follows the GDHCN rules.

The signature adheres to the CBOR Object Signing and Encryption (COSE) standard, as outlined in RFC9052[2] and RFC9053[3].

[1] https://datatracker.ietf.org/doc/html/rfc8949
[2] https://datatracker.ietf.org/doc/rfc9052
[3] https://datatracker.ietf.org/doc/rfc9053

3.1.1.4 Creating the document

Once the digital part is signed, the system used by the health professional generates the complete EVC. The vaccination card includes all three representations (the human-readable list, QR code, and metadata) embedded into a single PDF file.

3.1.1.5 Importing an EVC

To import an EVC, a consuming system follows these steps:

- Acquires the digital format of the EVC, either by reading the file metadata or by capturing the QR code optically.
- Verifies its integrity by checking the digital signature using the public key available from the WHO GDHCN. This key corresponds to the key identifier present in the signed content.
- Expands the compacted data back into its original JSON format.
- Retrieves the necessary information from the JSON format and complements it with additional details from the NUVA terminology (e.g., vaccine names or alternate codifications).

3.1.1.6 Components to be deployed

To implement the EVC system, a Member State (MS) must deploy several components:

- One or more systems capable of creating or importing EVCs for use by health professionals.
- Optionally, an intermediate server for data compaction.
- A signature server that participates in the WHO GDHCN network
- One or more registries that reference the repositories where master records are stored
- Optionally, one or more repositories for master records, if they are not integrated into the systems used by health professionals.

These national components depend on global resources including:

- The NUVA terminology repository, which provides vaccine product codes.,
- The WHO GDHCN root server, which maintains the list of authorized signature keys,
- The EU directory of registries, which lists the registries of repositories held by MS.

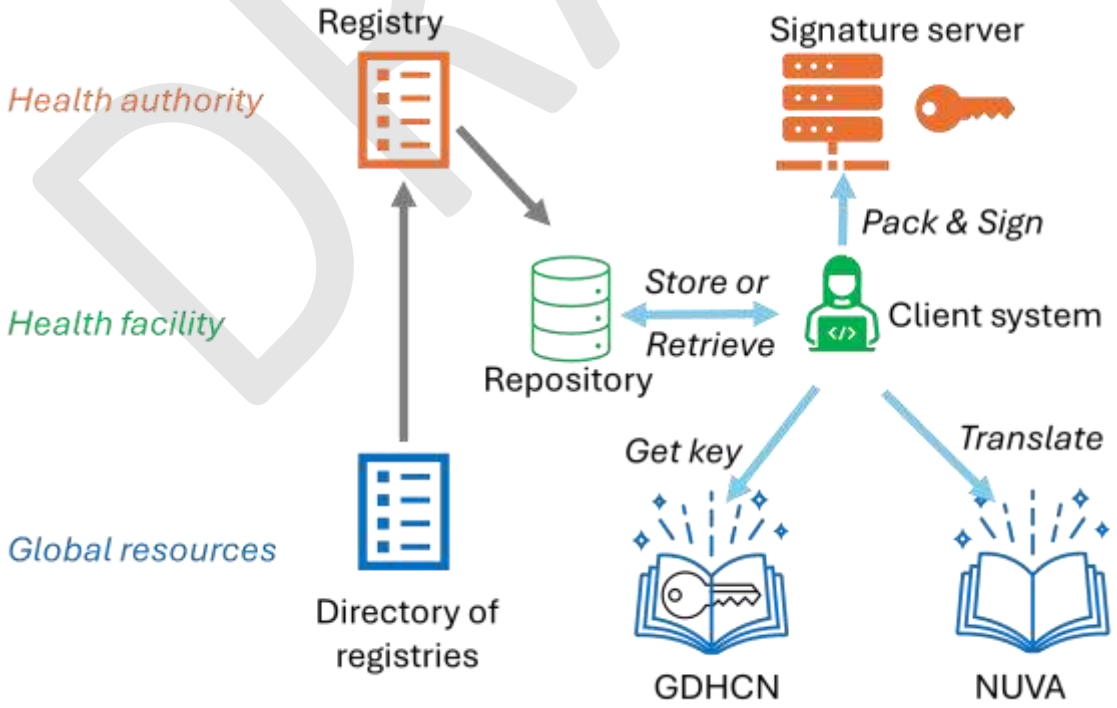

Figure 3- Components diagram

3.1.2 Project team

The project team consists of representatives from several key stakeholders:

- **Health authority**: Responsible for leading decisions on the overall project structure (Task A1 below) and establishing the regulatory framework for verifying compliance (Task C3).
- **eHealth operator:** In charge of deploying the repository registry (Task A3), possibly hosting its own repository, and providing the EVC viewer for accessing and displaying certificates (Task C1).
- **Digital Signature Operator:** This role may overlap with the eHealth operator and is responsible for providing the digital signature infrastructure (Task B1). Additionally, they will generate (Task B2) and distribute certificates to EVC issuers, allowing access to the signature infrastructure (Task B3).
- **Pilot EHR Suppliers:** One or more suppliers will implement the EVC creation and import features into their electronic health record (EHR) systems (Task C2) and conduct compliance testing to ensure their systems meet regulatory standards (Task C3).
- **Pilot Health Facilities:** These facilities will participate in testing the usability of the EHR systems provided by the pilot suppliers, ensuring that the applications are practical for day-to-day use in real-world healthcare settings (Task C3).

3.1.3 Workflow

Following an initial project framing, the implementation proceeds through three key branches:

A. Identifying the participating systems and actors
B. Setting up the signature infrastructure
C. Implementing into the selected EHR applications

The diagram below summarises the dependencies between the tasks in these branches.

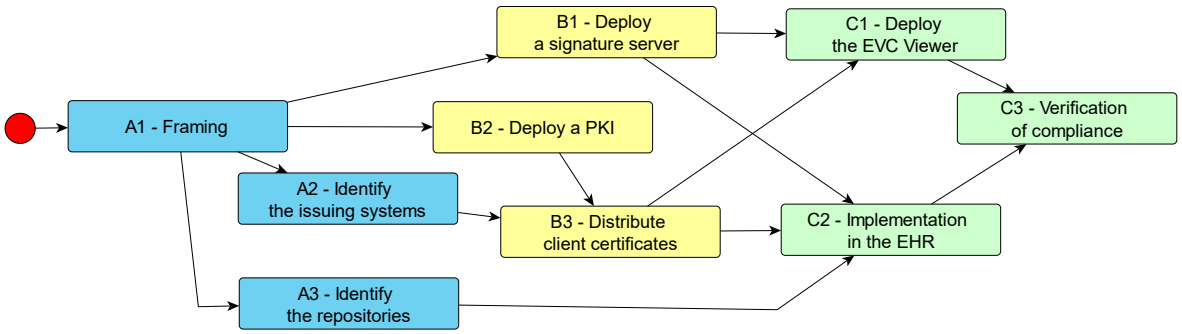

Figure 4- Implementation workflow overview

3.1.3.1 A1 – Framing

During the framing stage, key decisions regarding the overall structure within the Member State (MS) are made:

- Determining how many registries are needed, and who will manage them.
- Deciding where the master records will be stored.
- Identifying which health professionals will deliver EVCs.
- Defining the systems from which the EVCs will be issued.
- Assigning the operation of the signature servers.

The structure for registries and repositories is designed to accommodate various configurations. A country may have a single registry, or multiple registries maintained at the substate level and curated by local health authorities. Similarly, a health jurisdiction (state or substate) could have a central

repository, individual repositories for each health facility, or a hybrid model - such as a central repository for independent professionals and local ones within hospitals and vaccination centres.

The systems used by health professionals to issue EVCs might differ from the repositories holding master records, and these repositories could be shared across multiple systems. The systems themselves will be accredited to submit EVCs for signing; and they must locally manage the authorisation of health professionals, following the rules established during this framing stage (A1).

Even when a system functions both as an issuer and a repository, it will have separate identifiers for each role. The identifier as a repository is a mere index within the registry, while the identifier as an issuing system's identifier is a X509 Distinguished Name[4].

Signature servers should be deployed by the existing or intended national GDHCN participant.

3.1.3.2 A2 – Identify the issuing systems

The systems authorized to request an EVC signature must be uniquely identified. This identification will be used for distributing client certificates (B2).

If multiple issuing systems are involved, the process must be defined for updating the list of accredited systems.

3.1.3.3 A3 – Identify the repositories

Registry owners, identified in the framing stage (A1) must allocate unique identifiers to the repositories holding master records within their jurisdiction. Each repository must provide contact information and be mandated to process verification requests.

The identifiers do not need to be public but must be shared with the owners of both the repositories and the issuing systems for configuration during implementation (C2).

3.1.3.4 B1 – Deploy a signature server

The signature server, which also performs the data compaction process, is deployed by the digital signature operator. Based upon the specifications outlined in Chapter 3.1.5- (Build resources), the signature server may use a reference implementation or any other compliant solution.

The signature server is fully stateless, allowing it to be replicated as needed behind a load balancer to support incoming traffic.

It is exposed as a web service on the Internet, with access restricted via TLS client certificate authentication. The robustness of the cipher suites is verified upon deployment time and rechecked every six months.

3.1.3.5 B2 – Deploy a Public Key Infrastructure (PKI) for issuing systems

Each issuing system must authenticate to the signature server using a X.509 certificate[4] that was assigned during the identification stage (A2).

The digital signature operator creates a Public Key Infrastructure (PKI) to generate, distribute, and, if necessary, revoke these client certificates.

3.1.3.6 B3 – Distribute client certificates

The digital signature operator distributes client certificates to each structure managing a client system, both during the initial setup and for periodic renewals.

The method of distribution depends on the operator's existing infrastructure and processes, ranging from postal delivery of a physical support to online retrieval by an accredited administrator.

3.1.3.7 C1 – Deploy the EVC viewer

The participating eHealth operator deploys the citizen oriented EVC viewer, the first example of an EVC client system. Unlike standard EHR applications, the EVC viewer does not include a repository.

[4] https://datatracker.ietf.org/doc/html/rfc2459

A reference implementation for an EVC viewer is provided by the EUVABECO project.

The EVC viewer will be used as the initial testbed to check if EVCs produced by EHR implementations (C2) can be successfully read.

3.1.3.8 C2 – Implementation in the EHR application

Each EHR supplier must integrate EVC functionalities into their client systems, including:

- Reading an EVC:
  - Acquiring the digital section of an EVC, either by uploading a PDF file or scanning the QR code with a barcode reader.
  - Verifying the signature for the acquired data.
  - Unpacking the EVC data into a patient record, which may involve transcribing the administered vaccine codes from the NUVA universal encoding to the local code system.
  - Resolving conflicts with pre-existing records, following a policy document provided by the EUVABECO project.
- Writing an EVC:
  - If the master record repository for a given EHR application differs from the local storage, transferring patient vaccination events to the repository and retrieving the corresponding references for each record.
  - Assembling the EVC payload.
  - Submitting the payload to the compaction and signature server using the previously issued client certificate (B3).
  - Creating a PDF format enriched with the digital content returned by the signature server.

3.1.3.9 C3 – Verification of compliance

Compliant implementations must be capable of reading EVCs from any other compliant system and writing EVCs that can be read by other systems.

Compliance is verified through the following process:

- Reading a predefined sequence of reference EVCs for test patients
- Adding an imposed set of vaccines to these patients.
- Creating the corresponding EVCs and comparing them against expected results

The test suite, including reference EVCs, the list of vaccines, and a tool for comparing produced EVCs with expected results, is provided by the EUVABECO project.

3.1.4 Typical planning

	M1	M2	M3	M4	M5	M6
A1 – Framing						
A2 – Identify the issuing systems						
A3 – Identify the repositories						
B1 – Deploy the signature servers						
B2 – Deploy a PKI for client systems						
B3 – Distribute client certificates						
C1 – Deploy the EVC viewer						
C2 – Implementation in the EHRs						
C3 – Verification of the implementations						

3.1.5 Build resources

To implement and support the Electronic Vaccination Certificate (EVC) infrastructure, the following resources are provided:

- **Reference implementation for a signature server**
  - Source: https://github.com/EUVABECO/signer
  - Exposed at: https://signer.staging.mesvaccins.pro/jsonrpc
- **Toolbox technical documentation**:
  - Source: https://github.com/EUVABECO/evc_doc
  - Exposed at: https://euvabeco.github.io/evc_doc/introduction/introduction/
- **API contract for the signature server**
- **Software library for retrieving NUVA terminology:** https://docs.nuva.mesvaccins.net/en/nuva
- **Software libraries for various languages**
- **Test suite of typical EVCs:** Includes a set of reference EVCs and a checker tool for compliance verification.
- **Reference implementation of viewer for citizens**:
  - Source: https://github.com/EUVABECO/cve_demo
  - Exposed at: https://euvabeco.github.io/cve_demo/
- **Deduplication policy**: https://euvabeco.eu/evc-deduplication/
- **Registry management policy**: https://euvabeco.eu/evc-registry-management/

3.1.6 Verification

Functional verification for each issuing system follows the process outlined in task C3.

The maximal throughput of the signature server should be measured with a load testing tool such as Locust[5]. It should be above 100 EVCs per second.

The signature server should be graded A or above using Qualys SSL Server Test[6].

The digital signature operator should run an information security management system certified against ISO 27001, encompassing the service of signature of the EVCs.

3.2 Run

Once the tool has been deployed, there is still a need for lasting resources to support its adoption and ensure its maintenance. This section details these further actions.

3.2.1 Governance

3.2.1.1 Maintenance of the registry

Within each health jurisdiction, new repositories may be deployed, existing ones merged, or contact persons for repositories may change. The local health authority responsible for curating the registry must assign a unique identifier to each new repository and maintain the contact list for existing repositories.

[5] https://locust.io/
[6] https://www.ssllabs.com/ssltest/

3.2.1.2 Maintenance of the software applications

Each software application involved in the EVC process should be maintained by its respective provider:

Application	Maintained by
EHR software	EHR supplier
EVC viewer for citizens	eHealth operator
Signature server	Digital signature operator
Public Key Infrastructure	Digital signature operator

3.2.1.3 New EHR software

Any new EHR software introduced into the system must follow the same onboarding process as the initial systems, including the verification of compliance (C3).

3.2.1.4 New client systems

New client systems should be notified to the digital signature operator by the health authority, or by the eHealth operator on behalf of the health authority.

The digital signature operator is responsible for assigning client certificates to these new systems as well as renewing certificates for existing systems when they expire.

Certificates are issued only to systems running EHR software that has passed compliance verification (C3).

3.2.1.5 Response to investigations

Investigation requests regarding master records from other health authorities are first handled by the health authority maintaining the relevant registry. These requests are then forwarded to the contact person for the repository in question.

Requests from local health professionals should be processed by their direct health authority, possibly with the assistance from the eHealth operator for collecting and tracking the requests.

3.2.2 Monitoring

To plan for resource scaling, monitoring efforts should include tracking:

- The daily number of EVCs submitted for signature,
- The number of master records held by each repository

3.2.3 Communication

The EVC is intended as an equivalent to existing paper vaccination cards and should be offered in all contexts where paper cards were previously used. This can be achieved through the same distribution channels that provided blank paper cards to health professionals.

Given that the primary use of the EVC is for international mobility, it can also be offered when a person requires documentation for travel, such as a European Health Insurance Card.

Furthermore, the EVC can be promoted to specific populations who frequently move within the country or across Europe, such as military personnel, truck drivers, seasonal workers, ships crews, etc.

Additionally, the EVC will be used by value-added services that make use of vaccination history, such as Clinical Decision Support Systems (CDS) for vaccination, which can be made available to both the general public and health professionals.

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