DRAFT IMPLEMENTATION PLAN FOR A CLINICAL DECISION SUPPORT SYSTEM (CDS)

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List of Abbreviations and Acronyms

Abbreviation / Acronym		Meaning
API	Application Programming Interface	Software interface between two computer systems.
CDC	Centre for Disease Control	US public health agency
CDS	Clinical Decision Support System	A health information technology that provides person-specific information to help health and health care.
CDSi	Clinical Decision Support for Immunisations	Process defined by the US CDC to determine the US recommended immunisations needed for a patient.
EHR	Electronic Health Record	Systematized collection of patient health information in a digital format
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.
FHIR	Fast Healthcare Interoperability Resources	Standard for exchanging electronic health care data.
GDPR	General Data Protection Regulation	European Union regulation 2016/679 on personal information privacy.
GNN	Global NITAG Network	Platform for sharing experiences and best practices among NITAGs
HALO	Health, Age, Living conditions and Occupation	Factors conditioning the immunisation recommendations for a patient.
HPV	Human Papillomavirus	Vaccine preventable infection by a virus from the Papillomavirus family.
IIS	Immunisation Information System	Information system that collects vaccination data about all persons within a geographic area.
MDR	Medical Device Regulation	European Union regulation 2017/745 of medical devices.
SMS	Short Message Service	Text messaging component of mobile phone services.
NITAG	National Immunization Technical Advisory Group	Expert body that provides evidence-based recommendations on immunization policy and practice.
NUVA	Nomenclature Unifiée des Vaccins	NUVA, developed by vaccinologists, is both a vocabulary and a comprehensive knowledge base

List of Figures

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 CDS tool delivers personalized immunization recommendations to both citizens and prescribing health professionals. These recommendations are tailored based on individual factors such as health status, age, living conditions, occupation, and intended travel plans.

The tool supports patient adherence by providing detailed, scientifically supported justifications for due vaccinations and helps health professionals in staying updated with the latest recommendations from national or regional health authorities.

When integrated with an Electronic Health Records (EHR) application or an Immunisation Information System (IIS), the CDS can accurately assess the ratio of the population that is protected against vaccine preventable diseases.

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.

Key stakeholders include:

- Citizens or their legal guardians
- Prescribing health professionals
- National Immunization Technical Advisory Groups (NITAGs)
- The health authority
- Implementers of EHR applications or IIS

1.2.1 Citizens

Citizens seek reliable, clear, and justified vaccination recommendations based on their individual situation in terms of Health, Ageing, Living conditions (including travels) and Occupation (HALO conditions).

The tool must apply the appropriate rules for the citizen's health jurisdiction, typically based on their place of residence or work, or in some cases, their intended travel destination.

Input of personal data should be quick, straightforward, and guided, while ensuring strong data protection.

Results must be provided in less than two seconds.

1.2.2 Health professionals

Health professionals share similar expectations with citizens but require more in-depth justifications for the recommendations. Given their time constraints, they expect seamless integration with EHR systems, allowing them to reuse patient data without re-entering it into the CDS tool.

1.2.3 NITAG

The NITAG expect their recommendations to be easily and promptly transcribed. They need a simple, streamlined process to submit and validate both the transcription of the recommendations and the associated justification messages prior to publication.

1.2.4 Health authority

The health authority's primary concern is ensuring the CDS service is reliable and available, supported by robust quality processes for both the CDS engine and immunization knowledge digitization. The recommendations provided must clearly distinguish between those endorsed by the health authority and general scientific recommendations.

1.2.5 Implementers of EHRs

Implementers will require standardized application programming interfaces (APIs), along with robust documentation and reference implementations. Any changes in these interfaces must be well-planned.

Additionally, they must have access to non-production instances of the CDS for testing during development.

The terms of medical responsibility towards their customers must be clearly defined in the contracts.

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

A CDS tool processes data categorised as special under Article 9 of the General Data Protection Regulation (GDPR). It includes direct health-related data, such as a person's medical condition (e.g., known diseases) or indirect health-related data (e.g., likelihood of having a disease based on the vaccination history or other relevant factors such as sexual behaviour). Data that do not belong to the special categories but would be considered as sensitive, such as the use of drugs or living in a prison, could also be collected.

Even non-nominative data, like a lifelong vaccination record, could be sufficient for identifying an individual.

Because of this, the CDS falls under Article 9's regulations on processing personal data for preventive medicine purposes, which is lawful but imposes strict obligations on data processors. These include:

- Conducting a Data Protection Impact Assessment (Article 35)
- Ensuring decisions that significantly affect individuals are not based solely on CDS outcomes (Article 22)
- Appointing a representative within the European Union (Article 27)
- Designating a Data Protection Officer (Article 37)
- Documenting all data processing activities, regardless of the size of the entity (Article 30)

1.3.2 Medical device regulation (MDR)

When used by health professionals to support patient care, the CDS tool qualifies as a medical calculator under the Medical Device Regulation EU 2017/745 (MDR). The Working Group on Borderline and Classification confirmed this in the September 2023 publication of their Manual on borderline and classification for medical devices[1].

The CDS tool's classification is guided by Rule 11 of Annex VIII of the MDR. While some argue that vaccination decision tools belong in Class I (non-therapeutic), the prevailing consensus is that they should be considered Class IIa devices.

This This classification imposes stringent quality assurance requirements to ensure patient safety and demonstrate compliance throughout the development process, and in the clinical evaluation of benefits.

The CDS tool's quality assurance process must cover not only the software engine computing the recommendations, but also the medical rule set used to generate recommendations.

1.3.3 Medical responsibility

The CDS tool is a decision support system, meaning that the ultimate responsibility for vaccination decisions lies with the health professional administering the care. The tool cannot replace the need for proper training by Member State (MS) health authorities, ensuring that professionals can make appropriate vaccination decisions even without the tool or in cases where the CDS recommendations are questionable.

All CDS-generated decisions must be clearly documented and sourced, giving health professionals access to supporting materials such as the product information leaflet (ePIL) or locally endorsed vaccination recommendations.

1.4 Use cases

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

1.4.1 UC01-Obtaining a personal recommendation from a questionnaire

Jane, a 35-year-old pregnant schoolteacher in France, wants to know if she needs any vaccines.

She accesses the public CDS interface and completes a questionnaire about her health, occupation, and living conditions. She also inputs her vaccination history, and receives personalized recommendations based on the current national recommendations and programmes.

[1] https://health.ec.europa.eu/system/files/2023-09/md_borderline_manual_en.pdf

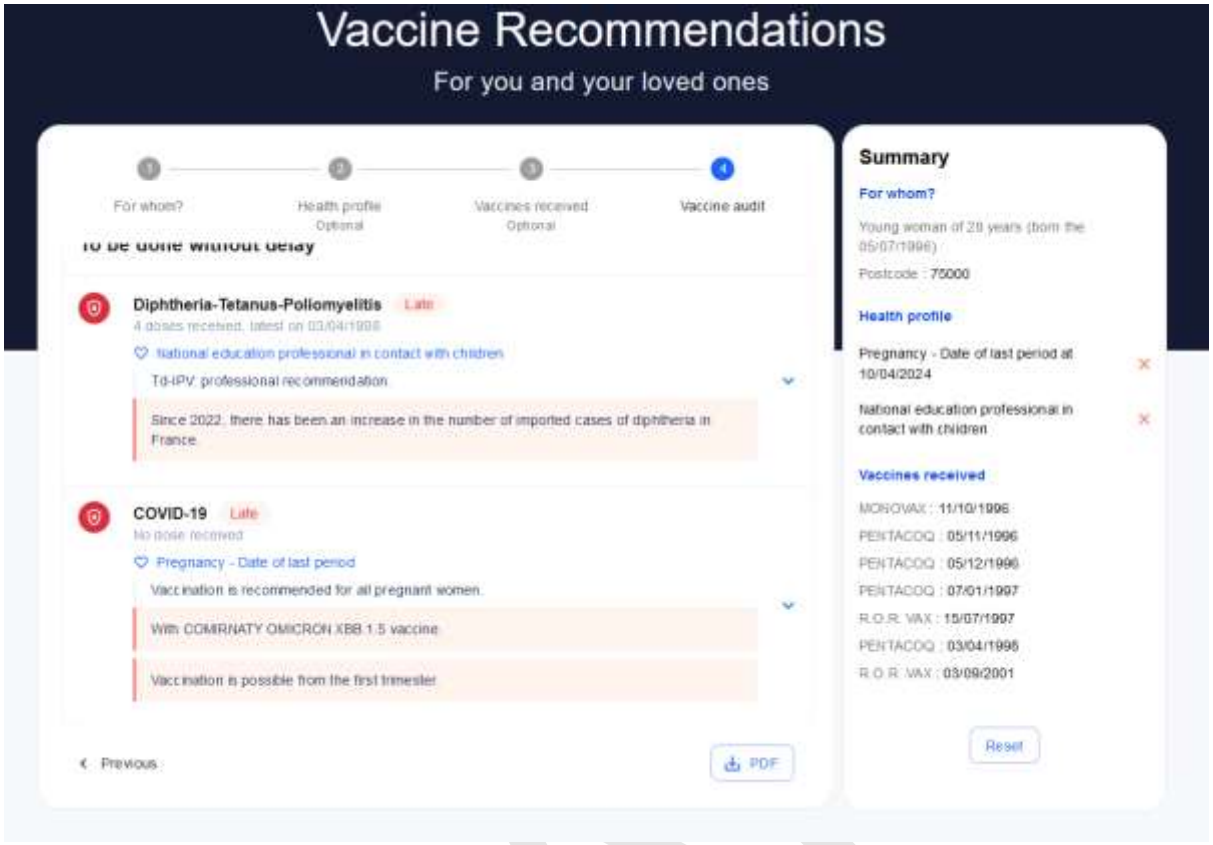

Figure 1- Questionnaire based recommendation

Since Jane is pregnant, she advised to receive the COVID-19 vaccine and is informed that pertussis vaccination is recommended between the 18th and 34th week of pregnancy. as Additionally, she is advised to get an Influenza vaccine when the flu season starts in October.

Jane also learns she should have received a Diphtheria-Tetanus-Poliomyelitis booster after age 20 due to her work with children.

To confirm her vaccination audit, she can consult her doctor.

Alternatively, to save the tedious work of entering all of the 23 vaccines she has received so far, she could have uploaded her European Vaccination Card (EVC).

1.4.2 UC02-Obtaining a personal recommendation from an EHR application

Dr. Stone, a health professional, meets with her patient Peter.

She opens his medical record and requests a vaccination audit through her medical software. The CDS prepopulates Peter's conditions from his EHR, and Dr. Stone verifies their accuracy, adding new information (Peter has a 3-month-old granddaughter at home).

The vaccination history is also retrieved from the EHR, and Dr. Stone simply validates the questionnaire to receive the appropriate recommendations.

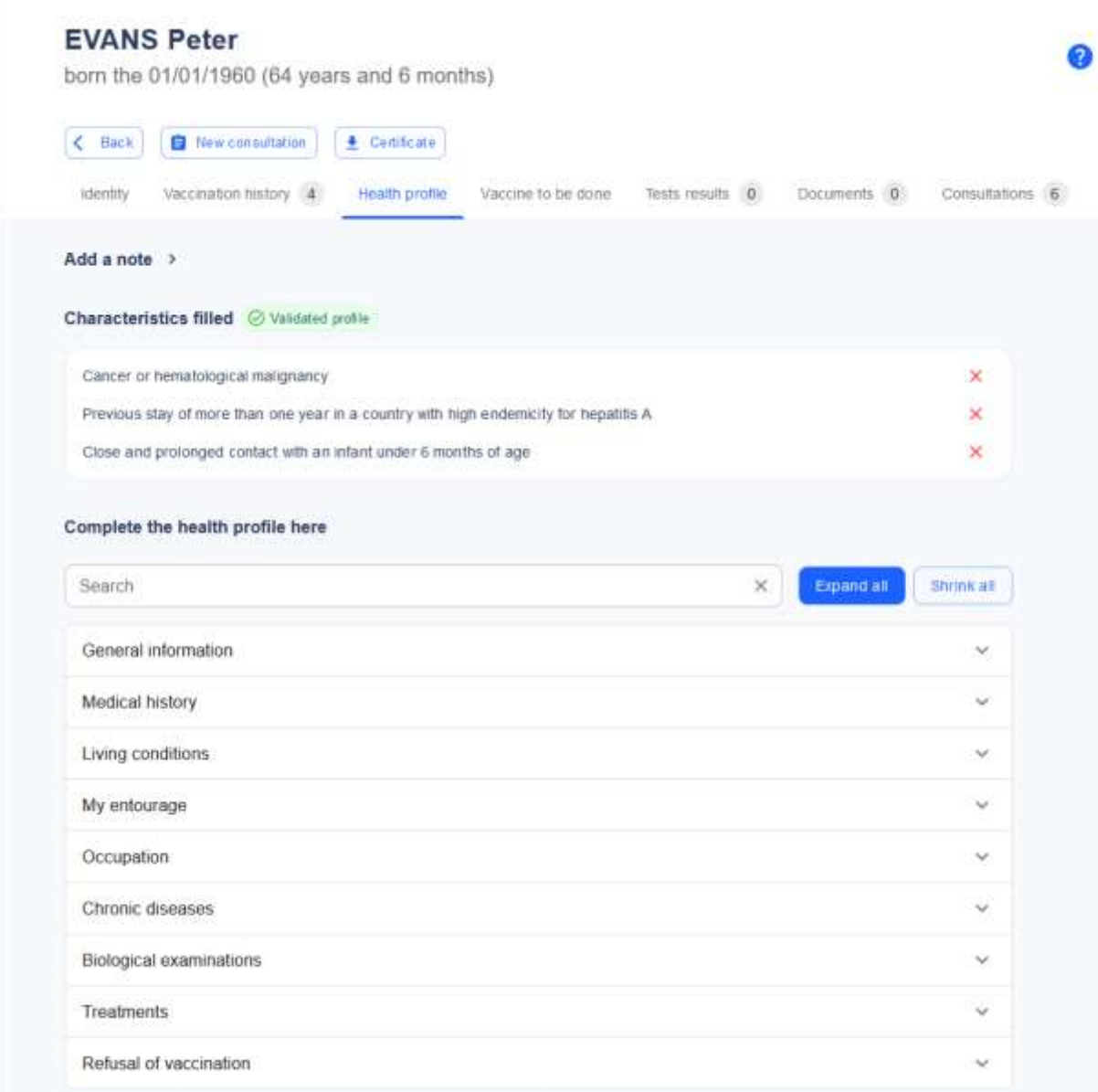

Figure 2-Questionnaire in an EHR

The matching of EHR data to the CDS questionnaire can be done dynamically through common representations which could be either semantic (SNOMED-CT or LOINC codes) or structural (fetching from a known structure, such as the MyHealth@EU Patient Summary)

1.4.3 UC03 - Obtaining immunization status of a population

A Member State maintains a nationwide Immunization Information System (IIS).

Faced with a resurgence of measles, public health authorities need to assess the risk of an outbreak in different regions.

They use the data linkage tool to gather pseudonymized information from the IIS, tax authority (for household composition), and public health insurance (for health conditions and past infections). This data is submitted to the CDS, and the results are visualized through a geographical information system. This allows authorities to determine vaccine needs by region for the next six months.

1.4.4 UC04 - Feeding a reminder-recall infrastructure

Jane, a parent, uses the public CDS system to track her son Tom's vaccination status.

At the time of entering his data, HPV vaccination was not required for boys. However, a new recommendation has been issued advising HPV vaccination for boys aged 11 to 14.

The system regularly recomputes vaccination profiles and detects that Tom will be eligible for HPV vaccination when he turns 11 in two weeks. Based on Jane's settings, she receives an SMS notification that a vaccination is due soon, prompting her to log in for more details.

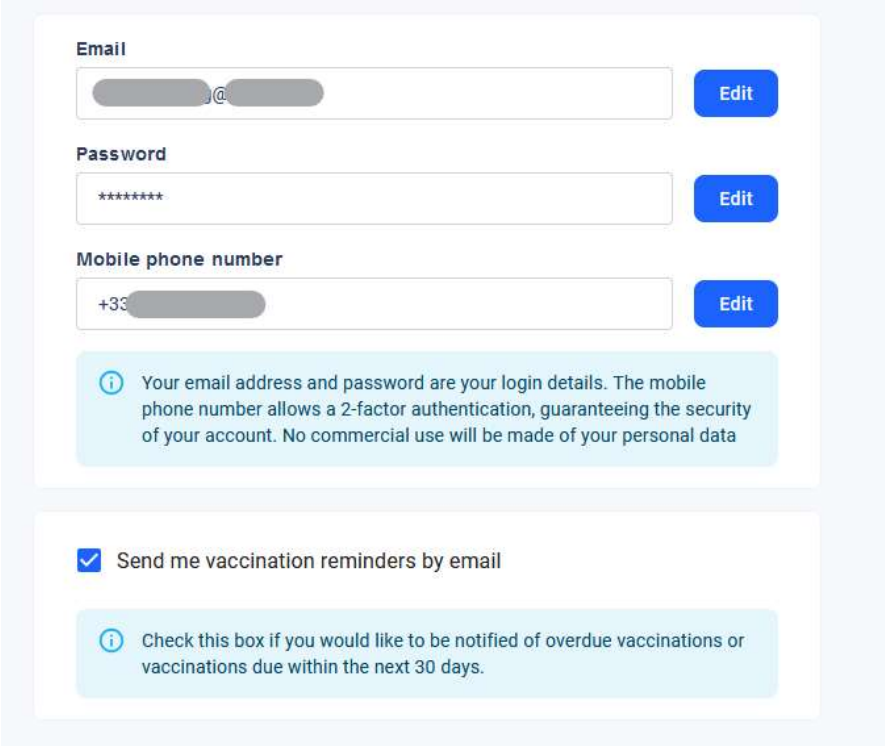

Figure 3 - Configuring for reminders

1.4.5 UC05 - Using the CDS as an educational tool

Tomas, a medical student, is practicing vaccination decision-making as part of his coursework.

He logs into a training platform and is presented with 20 theoretical clinical cases from a database of synthetic or anonymized patient profiles. For each case, Tomas must decide which vaccinations should be administered in the next six months, specifying the timing of each.

The same cases are processed by the CDS, and Tomas' decisions are compared with the tool's recommendations. He can see which vaccines he identified correctly, which he missed, and any vaccines he wrongly recommended. Detailed justifications and reference materials are provided for each case, and at the end, Tomas receives a scorecard for self-evaluation.

Figure 4 - Vaccinology quiz

By the end of each sequence, he gets a scorecard for his own evaluation.

1.4.6 UC06 - Using the CDS to deliver vaccination certificates

Alan is applying for a job on an oil rig, which requires proof of vaccination against certain diseases.

He has a EVC, but the hiring team is not entitled to access his medical data. The employing company has subcontracted a compliance service that exposes a CDS tool with vaccination rules tailored to the job requirements.

Before his job interview, Alan uploads his EVC to the CDS platform and receives a digitally signed compliance certificate, confirming that his vaccinations meet the job requirements. He can present this certificate at his interview without disclosing additional medical information.

The same method is applicable to any situation where vaccination status is required for "administrative" purposes (according to the Medical/Administrative/Personal mapping used throughout the Vaccines-EU study[2]).

[2] https://data.europa.eu/doi/10.2925/236134

2 Prerequisites

2.1 Assessment of prerequisites

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

2.1.1 Operational

To ensure trust in the recommendations delivered by the CDS, a credible and functioning National Immunization Technical Advisory Group (NITAG) is essential. NITAGs provide the scientifically grounded recommendations that are endorsed by health authorities. The NITAG Maturity Assessment Tool[3].developed by the Global NITAG Network (GNN) in collaboration with the Centres for Disease Control and Prevention, the World Health Organization and the Task Force for Global Health, provides a solid framework for assessing the credibility of NITAGs. This tool evaluates NITAGs across seven indicators:

1. Its formal existence, with written rules on its composition, a diversity of expertise and clear membership rules.
2. Transparency and independence of members.
3. Appropriate resources and secretariat support.
4. Regular meetings with formal rules for operations and evaluation.
5. Recommendations based on evidence and communicated in a structured way.
6. An established process of collaboration with the Ministry of Health for enforcing and monitoring recommendations.
7. Recognition of their role by the stakeholders and the general public.

Of these, at least indicators 2, 4, 5 and 7 should reach the Intermediate level (level 3 on a scale of 5).

2.1.2 Legal and ethical

All CDS users (data processors) and suppliers (subcontractors) must comply with the personal data protection requirements outlined in the Constraints chapter 1.3.1.

Additionally, the CDS solution (software engine and ruleset) must be registered as a medical device under the MDR regulation.

2.1.3 Political

In most countries, only a very limited set of vaccinations are mandatory, in which case they are also paid by the health insurance system. The CDS tool's purpose is not to impose additional obligations, but to simplify complex decision-making processes. However, in settings where vaccine hesitancy is prevalent, even offering "recommended vaccinations" could be controversial.

If the health authority's legitimacy is not well established, the CDS could become a target for political disputes.

2.1.4 Technical

The CDS service must be accessible in all locations where vaccinations are performed, with constant updates to reflect the latest official recommendations. Whether centralized or distributed, the system requires a reliable Internet infrastructure to ensure seamless connectivity between any point in the Member State and the CDS data distribution centres.

[3] https://www.nitag-resource.org/external/nmat/#/

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 CDS 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.

This section provides hints on how a CDS project could be launched although the prerequisites above are not satisfied yet. It will impede reaching the full expected benefits but provide enough visibility and momentum to justify the effort of achieving the prerequisites.

2.2.1 Operational

In the absence of a relevant and credible NITAG, an alternative trusted medical authority could be used. This could be a supranational organization, such as the WHO's Essential Program on Immunization (EPI), or a respected local health institution, possibly specialized in specific patient conditions (e.g., cancer or diabetes) or traveller vaccination programs.

2.2.2 Legal and ethical

The GDPR provides a harmonized data protection framework across Member States. However, protective measures vary depending on the CDS implementation. The EUVABECO project offers a sample Privacy Impact Assessment that can be adapted by the implementer, assisted by the CDS provider, to the specific context of the CDS project.

A CDS that has not yet achieved MDR compliance (due to lack of clinical evidence, for example) could still be used in non-clinical contexts, such as training health students, conducting retrospective decision analyses, or guiding citizens - an option preferable to general web searches.

2.2.3 Political

In contexts where vaccination itself is contested, endorsing the CDS through official channels might be counterproductive. A temporary solution could be to position the CDS as a private initiative, possibly delivered by non-governmental organizations (NGOs) and targeted at voluntary users, using publicly available vaccination recommendations.

2.2.4 Technical

Depending upon its design, the CDS may not require high-end connectivity. This should be considered when selecting a solution for countries where such services are not generally available.

3 Implementing

Once the prerequisites have been met or compensating actions are in place, the decision to launch the implementation project can be made.

The process is divided into two phases: **Build** and **Run**, to differentiate between the actions and resources needed to deploy the initial version of the CDS (before delivery to users) and those required to keep it operational and updated thereafter.

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.

The build phase is designed to be as generic as possible, considering the requirements and constraints identified in chapter 1-Description of the Tool. However, alternative designs are possible, and implementers should assess their impact when planning their projects.

3.1.1 Architecture

The CDS consists of two key components: a software engine and datasets representing knowledge about the vaccine's characteristics, the relevant conditions for assessing a vaccination audit, and the rules used to determine the recommended vaccinations to perform, complemented with the messages presented to justify these recommendations.

Any flaw in these components could result in inaccurate recommendations. To comply with MDR regulations, one entity must manage both the software and the embedded knowledge with secure, controlled processes. To ensure security and continuous updates, the CDS must be provided as a managed service by a CDS provider, who will handle updates in line with changing rules.

The provider is responsible for integrating knowledge into the system, using various technical methods (e.g., hardcoded logic, parametrization, rules engines) and operational processes. Even if a health authority provides a digitized recommendation, such as the CDSi[4] provided by the US CDC, the CDS provider remains accountable for the system's integrity.

Managing the system centrally, rather than distributing software to individual health facilities, simplifies the update process. This is the approach taken in this plan. However, the CDS service will be accessed by users through client software, which will generate requests, submit them to the CDS, and receive justified recommendations in response. For client systems to communicate effectively with the CDS, they must use a common vocabulary, specifically:

- **Administered vaccines**: In the scope of this project, we will use the NUVA[5] terminology also applied for the EVC.
- **Patient profiles (HALO conditions):** Health, Age, Living conditions and Occupation (HALO) profile relevant to vaccination rules.

Terminology servers will be publicly available to ensure the consistent use of these terms between the CDS and client systems.

[4] https://www.cdc.gov/vaccines/programs/iis/cdsi.html
[5] https://nuva.syadem.com/

The overall architecture is summarized as follows:

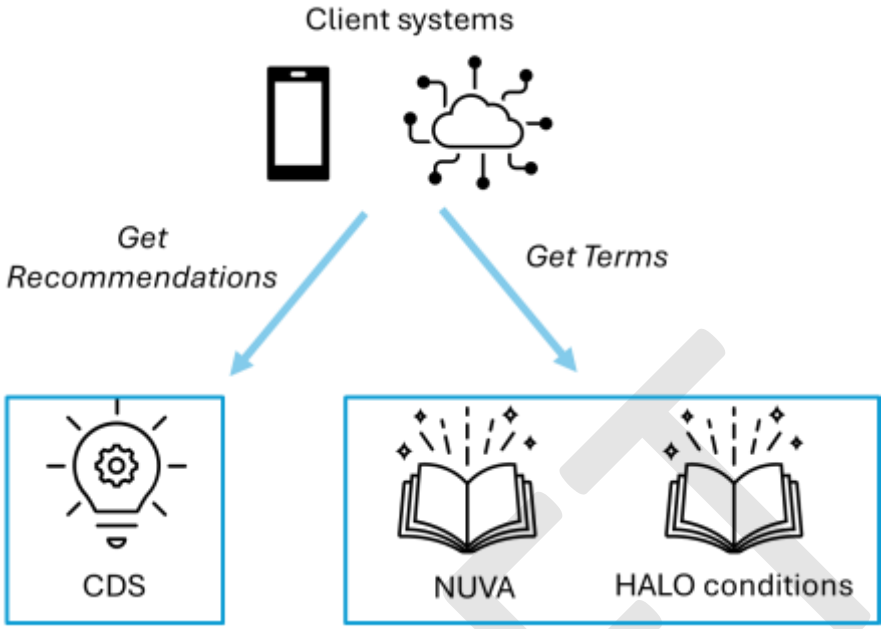

Figure 5-CDS overall architecture

In this architecture, the CDS is a stateless server, meaning it does not retain any data between transactions. This design offers several key benefits:

- **Scalability:** More CDS server instances can be added behind a load balancer to handle increasing client requests, with each request routed to a different server.
- **Resilience**: Multiple CDS server instances can be distributed across different locations, improving reliability in case of server or connectivity failures.
- **Personal data protection:** Since all data is transient and no directly identifying information is submitted, personal data protection is enhanced. Only the patient's characteristics and vaccination history are relevant for the CDS's operations.
- **Simplified support and maintenance:** A generic system can be adapted to different contexts, making it easier to maintain and support across diverse use cases.

3.1.2 Project team

The project team is composed of the following key members:

- **Project Manager**: Assigned by the Health authority, responsible for overall coordination and ensuring timely delivery.
- **Immunisation Experts:** Specialists from the implementing MS who will:
  - Collate reference documents for the project.
  - Assist with translation, if necessary.
  - Validate the ruleset and ensure the relevance of reference documents to the test cases.
- **CDS provider team**:
  - **Technical team**: Responsible for delivering the software platform that hosts the CDS.
  - **Medical team**: Develops the ruleset based on the reference documents, creates test cases, and drafts justification messages for system users.
- **Communication experts**: Experts from the MS responsible for adapting and translating the justification messages to suit the local context and ensure clarity for the target audience.

- **Client Medical Application Editors**:
  - Interface their applications with the CDS.
  - Document the CDS integration.
  - Deliver the CDS feature to end users.
  - Provide training and support for effective system usage.
- **Beta end users:** These are end users involved in testing the CDS feature for verification and feedback, ensuring that the solution meets practical requirements before full-scale implementation.

3.1.3 Workflow

The project follows three main workstreams, which will converge into a final delivery process:

A. **CDS server setup:** Ensuring the CDS server, along with the appropriate medical ruleset, is made available for use.
B. **Client System Integration:** Developing and implementing the interface between the CDS and the client systems.
C. **Data Mapping**: Mapping the existing data within client systems to align with the concepts required by the CDS.

The diagram provides a high-level view of the dependencies between tasks in the three primary branches of the project: setting up the CDS server, interfacing client systems with the CDS, and mapping client data to CDS concepts. Each task in these branches plays a critical role in delivering a functioning CDS system.

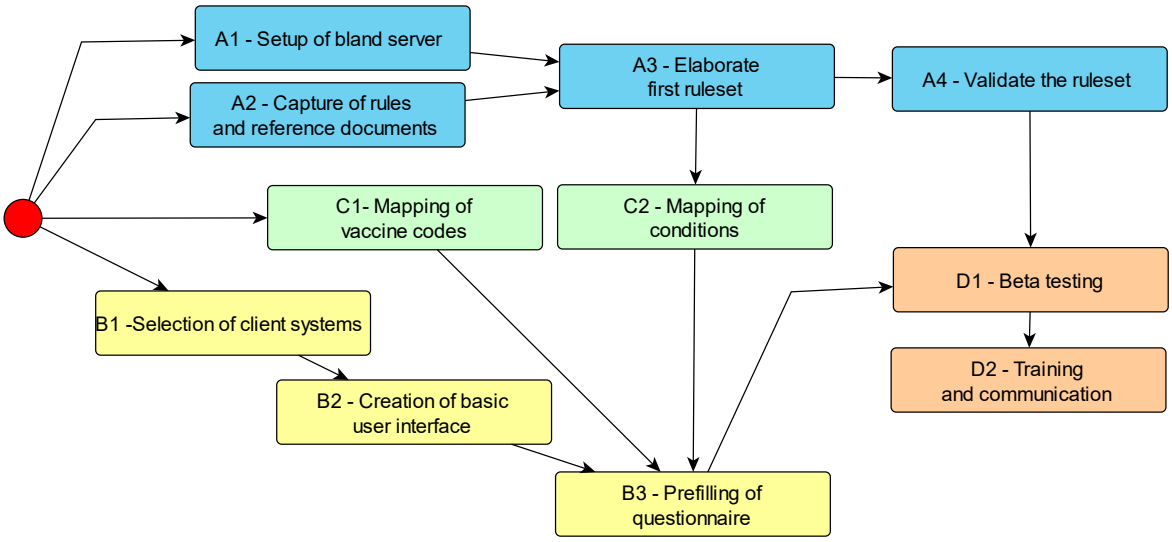

Figure 6 - Implementation workflow overview

The following sections provide a detailed breakdown of each task involved in the implementation process.

3.1.3.1 A1 – Setup of bland CDS server

At the outset of the project, the CDS provider delivers a generic version of the CDS. This initial version is equipped with a default, English-language ruleset, and a minimalistic interface that enables users to submit queries and display recommendations.

This serves two purposes:

- **Interface Exposure:** It exposes compliant interfaces for the client systems, allowing the development teams to begin building the user interfaces.
- **Testing and Familiarization:** It allows the MS immunization experts to experiment with the CDS, gaining insights into how the system operates and what types of justification messages it can generate.

This basic CDS setup will be updated later (in Task A3) with a more customized ruleset specific to the project's objectives.

3.1.3.2 A2 – Capture of rules and reference documents

During this phase, immunization experts from the MS perform the following tasks:

- **Determine the Scope of the CDS:** The experts define the scope of the CDS according to the project's specific purpose. This can cover all vaccinations, or be limited to specific groups, such as children, adults, employees, or individuals with particular health conditions.). It may also target specific diseases or be used for defined purposes like travel vaccines or the issuance of certificates.
- **Collate and Translate Documents:** The experts gather all relevant recommendation documents, synthesizing the information and translating it into English for the CDS provider's medical team. These documents will serve as the foundation for drafting the ruleset that will guide the CDS.

3.1.3.3 A3 – Elaborate first ruleset

Based on the recommendations provided by the MS immunization experts, the medical team from the CDS provider digitizes these recommendations and creates the initial draft of the ruleset.
This draft includes:

- **First draft of the rules**: The ruleset offers recommendations for selected diseases and provides status classifications (such as due, overdue, immune, contraindicated, complete, or aged out) as well as, where applicable, due dates for vaccinations. These recommendations come with initial justification messages, written in English, that explain the reasoning behind the guidance.
- **Creation of a Clinical Case Base:** The CDS provider medical team creates a foundational set of clinical cases, which will be used to test the proper application of each rule in the ruleset.

The clinical case base serves two essential functions:

- **Validation:** It will be used as the foundation for the MS immunization experts to validate the ruleset (as described in Task A4).
- **Test Bed for Future Changes:** The case base will act as a testing ground for validating any future modifications to the ruleset.

During this development phase, the CDS provider medical team may engage with the MS immunization experts to clarify and expand on the recommendations provided, ensuring that the ruleset aligns with the intended medical guidelines.

3.1.3.4 A4 – Validate the ruleset and tune the justifications

Once the first version of the ruleset has been developed, it is deployed on the CDS server provided at the project's initiation. At this stage, **Member State (MS) immunization experts** are tasked with validating the ruleset by:

- **Testing Against Clinical Cases**: The experts will test the ruleset's recommendations using the base of clinical cases.
- **Interactive Testing**: MS immunization experts can also test the system using real-world data from their national immunization systems by querying the CDS server directly.

Concurrently, the MS immunization experts will work with the **MS communication team** to replace the preliminary English-language justifications (created in Task A3) with more customized messages tailored to their respective national audiences.

Interactions between the MS immunization experts and the CDS provider's medical team will be needed to:

- **Address Discrepancies**: Any differences between the actual recommendations produced by the CDS and the expected outcomes need to be corrected.
- **Refine Justification Targeting**: Additional rules may be necessary to adapt certain parts of the justification messages for specific patient subgroups or to address nuanced local needs.

3.1.3.5 B1 – Selection of client systems

The **MS project management team** will identify one or more systems to interact with the CDS, depending on the existing national infrastructure and the intended audience.
The systems selected may include:

- **Standalone interface:** This interface enables users (health professionals or the general population) to manually enter or download data and send queries to the CDS on an ad-hoc basis (use cases UC01, UC05).
- **Centralized Service:** This service would store immunization histories and personal profiles, making them accessible upon request (UC02) or periodically for tracking individual or collective vaccination statuses (UC03 and UC04). This is typically used in national Immunization Information Systems (IIS).
- **Broker service**: A broker can forward CDS queries from other systems that it already serves, such as a centralized medical documents repository., In this setup, data from structured documents submitted by practitioners or health structures, is used to generate recommendations, which are then shared as new documents.
- **Distributed applications:** These are systems used by practitioners and health structures.
- **Mobile applications**: Designed for citizens to use on their personal devices.

Each client system will interact with the CDS differently depending on the richness of the data it manages. It may simply pass data through to the CDS or retrieve and integrate a patient's vaccination history and profile.

3.1.3.6 B2 – Creation of basic user interface

To perform the vaccination audit, the CDS needs three sets of information:

- **Basic demographic data**: This includes information like the patient's date of birth, sex, and place of residence.
- **Vaccination History:** A record of the patient's previously administered vaccines.
- **Patient Profile**: This refers to the set of all relevant HALO (Health, Age, Living conditions and Occupation) conditions.

While **basic demographic data** (such as date of birth, sex, and place of residence) and the **vaccination history** of administered vaccines may be automatically retrieved from existing client systems, the **patient profile** presents more complexities. The patient profile, crucial for generating personalized vaccination recommendations, is unlikely to be fully retrieved from a client system without user interaction. This is especially true if the CDS is expected to go beyond providing basic recommendations.

The patient profile consists of HALO conditions, which are numerous (over 200 conditions in the French recommendations alone), and subject to frequent changes with each new release of official

recommendations. These conditions also include factors that are rarely encoded in existing systems for other purposes such as:

- Living with young children or persons with immunodeficiency.
- Exposure to specific environmental factors (e.g., bats).
- Plans to have a child soon.
- Recent or upcoming travels, etc.

Many of these conditions may also become irrelevant over time (e.g., past pregnancies or previous travel plans). As such, retrieving accurate and up-to-date patient profile information requires users to complete a **dynamic questionnaire**. Even if the system prepopulates parts of the questionnaire with existing data, users will still need to review and explicitly validate the information. No matter what client application is used, the presentation of this questionnaire will be necessary. Each **client software editor** must implement an appropriate user interface that includes at least the patient profile questionnaire as part of the CDS integration.

The CDS will provide the dynamic questionnaire (or a series of sequential questionnaires), along with specific instructions on how they should be formatted and presented. These instructions include details such as:

- Structuring questions into a logical hierarchy of domains.
- Providing interpretation helpers for complex questions.
- Emphasizing certain key items that need special attention.

Adhering to these formatting guidelines is essential to prevent any misuse of the CDS, which could potentially lead to harmful recommendations for patients.

At this stage, the dynamic questionnaire is **not prepopulated** with data from the client system. However, depending on the client system's capabilities, the two other information sets - **basic demographic information** and **vaccination history** - can either be manually entered by the user or retrieved from the client system's existing data. Retrieving the vaccination history will require **mapping** the vaccine codes used by the client system to those used by the CDS, as established in Task C.1.

By the end of this phase, all **interactions between the client software and the CDS** should be fully functional. Any further enhancements will focus on improving the local operation of the client software.

The client software editor should also release a **first version of user documentation**, which will be shared with the beta users (Task D1) for testing and feedback.

Interactions between the client software editors and the CDS provider's technical team will be required to:

- Provide **technical credentials** for accessing the CDS.
- Verifying the **correct execution** of interactions between the client software and the CDS.

3.1.3.7 B3 – Prefilling of questionnaire

Once the mapping between the data present in the client system and the conditions required by the CDS has been established (Task C.2), the client system can begin **prefilling questionnaires** with preexisting data. This streamlines the process, allowing users to see relevant data already populated in the questionnaire. However, users will still need to **review, update and validate** the prefilled information to ensure accuracy.

This phase of the implementation is the responsibility of each **client software editor**, who must ensure that their system supports prefilling questionnaires. They may also update the **user documentation** to reflect the newly incorporated automations and any related functionality improvements.

3.1.3.8 C.1 – Mapping of vaccine codes

Each client system selected in Task B1 may use its own encoding for vaccine codes, which may differ from the codification used by the CDS. To accommodate this, the client systems are responsible for **transcribing vaccine codes** into a format compatible with the CDS.

It is recommended to use **NUVA** (a vaccine coding resource) for this purpose. The NUVA resource, which includes alignments with other coding systems, is available as a public good under the Creative Commons CC-BY-ND 4.0 license[6].

Two scenarios are possible:

- **Standard Codification:** If the client system uses a standardized coding system within the Member State (such as pharmaceutical codes), the **NUVA team** will handle the mapping. This process is based on code lists provided by the MS project manager and will be integrated into the globally available NUVA resource.
- **Proprietary Codification**: If the client system uses a proprietary coding system, the responsibility lies with the **client software editor** to establish and maintain the alignments between their proprietary codes and the NUVA system. These private alignments will not be included in the NUVA resource.

This task represents the **initial mapping** of vaccine codes, but a **continuous update process** will be required during the Run phase to account for newly introduced vaccines.

3.1.3.9 C.2 – Mapping of conditions

Each client system selected in Task B.1 may hold patient data that could be reused to prefill the CDS questionnaires. This process requires a thorough inspection of all **conditions** potentially queried by the CDS to determine whether they correspond to existing data in the patient's medical record.

The **CDS provider** can assist in this process by providing mappings with standard clinical or biological codification systems, such as **ICD-11**, **SNOMED-CT**, **LOINC**, and **ICPC**. However, the **client software editor** holds the ultimate responsibility for completing and maintaining these mappings within their system.

The CDS provider will deliver the **database of clinical cases** in a structured document format, which the client software editor can use to generate corresponding patient records in their system.

The list of conditions is dynamic, constantly evolving with updates to official recommendations. New conditions may be added, some of which can also be **pre-filled** in the questionnaires. Like the vaccine mapping, this task involves the **initial mapping** of conditions, with a **continuous update process** required during the Run phase to stay current with evolving medical guidelines.

3.1.3.10 D.1 – Beta testing

Beta testing can begin as soon as the **basic user interface** (described in Task B2) has been developed and documented. However, **structured beta testing** requires the validation of the ruleset, along with the integration of appropriate justifications (Task A4) and the implementation of assistance for filling out questionnaires (Task B3).

During the beta testing phase, **beta users** will be trained and then access the CDS through the selected client systems. Feedback from beta users should be routed through the **software editors notification infrastructure**. The software editors are then responsible for triaging the feedback, assigning issues either to their own development team or to the CDS provider, and maintaining an active dialogue with the beta users until the issues are resolved.

[6] https://creativecommons.org/licenses/by-nd/4.0/legalcode.en

3.1.3.11 D.2 – Training and communication

Based upon the feedback gathered during beta testing, the **client software editor** will finalize the user documentation and prepare educational materials for end users. This material may include **online help**, **webinars**, and other training resources, in line with the software editor's usual practices.

3.1.4 Typical planning

The overall planning could thus be as follows:

Task	M1	M2	M3	M4	M5	M6
A – CDS Server						
A.1 – Setup of bland CDS server and frontend						
A.2 – Capture of rules and reference document						
A.3 – Elaborate first ruleset						
A.4 – Validate the ruleset and tune the justifications						
B – Client applications						
B.1 – Selection of client systems						
B.2 – Creation of basic user interface						
B.3 – Prefilling of questionnaire						
C – Semantic mapping						
C.1 – Mapping of vaccines codes						
C.2 – Mapping of conditions						
D - Delivery						
D.1 – Beta testing						
D.2 – Training and communication for users						

3.1.5 Build resources

Tool specifications

Although this implementation plan is not tied to any particular CDS tool, the pilot projects were executed using the CDS implemented by SYADEM, which has been deployed both in France (under the brand MesVaccins.net, serving both citizens and professional users) and in Luxembourg (as part of the national health data platform under the CVE - Carnet de Vaccination Electronique) - for citizens and professionals).

This specific CDS tool offers several key features:

- **Delivered as a Service**: It provides a comprehensive solution, including the recommendation engine, its presentation as a web service, and the medical expertise required to formalize the decision support rules.
- **Stateless Architecture**: It uses REST (Representational State Transfer) architecture, meaning no data is stored on CDS servers. All data is processed without retaining any information between sessions.

For this project, the legacy **application programming interface (API)** used for querying the CDS was replaced with a **FHIR-compliant interface**. This FHIR interface was also shared with the Immunization Focus Group within the HL7 Public Health and Emergency Response (PHER) workgroup to promote further standardization in the field.

- The specification for this **FHIR-compliant API** can be accessed at https://build.fhir.org/ig/EUVABECO/VCDS/

The **decision support rules** are developed by SYADEM medical experts, following a rigorous knowledge management procedure. Further details of this procedure are available at https://euvabeco.eu/cds-knowledge-management-procedure/

Additionally, a template for conducting a **Privacy Impact Assessment**, built using a tool from the French GDPR authority, is available at https://euvabeco.eu/cds-pia/

3.1.6 Verification

Verification of the ruleset (Tasks A3, A4) is conducted by the **MS immunization experts**, who compare the **CDS responses** for clinical cases with the expected results. This comparison is facilitated through execution reports provided by the CDS provider.

Verification of codifications (Tasks C1, C2) and their implementation (Task B3) is the responsibility of the **client software editors** through the following process:

- **Patient Records Creation:** Patient records are generated by processing the **exported clinical cases** provided by the CDS provider (Task C2).
- **Request Comparison:** The CDS queries sent for these patient records are compared with **reference requests** provided by the CDS provider for the same patients. Any discrepancy between the actual and reference requests indicates issues in the mapping or its implementation, requiring correction.

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

A continuous update process is needed to ensure the CDS remains aligned with evolving vaccination recommendations and newly available vaccines. Key governance actions include:

- **NUVA Updates:** Updating the **NUVA** coding system is beyond the scope of this project. If an alternative terminology is used, the responsibility for its maintenance lies with the **MS Health authority**.
  Rules and Conditions Updates: Updates to the CDS rules and conditions requires a structured collaboration between the NITAG, the Health authority and the CDS provider medical team. The process involves:
  - **Preparation:** Collaborating during the recommendation development phase to prepare the rules and test cases. The digitization of the rules at this stage enhances their quality by identifying and addressing ambiguous scenarios.
  - **Validation:** Ensuring that the updated ruleset and justifications are validated before the new recommendations become officially applicable.
  - **Synchronization:** Coordinating the release of the updated ruleset with the official implementation of the new recommendations.

This collaboration is event-driven, initiated by the NITAG when new recommendations are being considered. Additionally, regular management meetings (typically every six months) monitor progress and execution.

In addition to medical governance, technical management is necessary to maintain the availability and performance of the CDS. Two scenarios can occur:

- **Centralized CDS Service:** If the CDS is offered as a service by the MS health authority to multiple software editors, the MS will organize technical management to maintain the services availability and performance.
- **Single Client Subscription:** If a single client software editor subscribes directly to the CDS, technical management becomes the responsibility of that editor.

These two cases can overlap when the MS e-Health national operator is the sole client software editor.

A quarterly technical management meeting involving the project's technical team, client software editors, and the CDS provider will ensure proper system management. Operational meetings may be scheduled as needed to address short-term technical issues.

An incident management procedure should also be established to handle situations where the CDS becomes unavailable or outdated.

3.2.2 Monitoring

Monitoring of the CDS service is crucial to ensure optimal performance and user satisfaction. Key technical monitoring indicators include:

- **CDS Service Availability:** The target availability should be defined by project management, but could typically be 99.9% per calendar month, excluding planned maintenance periods.
- **Response Time:** For interactive queries, the CDS should respond in less than 2 seconds per request. In batch processing mode (e.g., for entire populations), stricter performance targets may be necessary.
- **Request Load:** Monitoring the average and peak flow of requests will help assess the system's capacity and inform decisions about scaling the infrastructure.

A quality-of-service monitoring could also be implemented. However, delays in updating rules and conditions could stem from multiple stakeholders, including the CDS provider, MS immunization experts, the communication team, or the Health Authority.

3.2.3 Communication

The communication strategy for the tool will vary depending on how it is introduced. If integrated into preexisting workflows - such as updating patient records in existing medical software - the communication effort may be minimal. However, if the tool is introduced as a new service for health professionals or the general population, a more substantial communication effort will be required. In this case, the tool can complement existing initiatives like targeted vaccination campaigns or World Immunization Week.

Regardless of the context, specific training should be offered to health professionals, based upon the material developed in Task D.2 of the Build phase. The method of delivery will depend on how the tool is exposed to users. For a standalone interface, online video courses may suffice. However, if the tool is integrated with existing medical software, training should be delivered by the software editor, in line with the usual practices for introducing new features.

In day-to-day operations, the justifications accompanying each recommendation are also a key communication tool. These justifications should be carefully tailored for each audience - whether health professionals or the general population.

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