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Document overview

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1. Introduction

The **European Vaccines Hub (EVH)** project contributes to the development of an agreed set of pandemic-prototype vaccines and scalable technologies through a consortium including leading EU organisations directly involved in vaccine development and in charge of pandemic preparedness in their own countries, ensuring effective coordination of national vaccine research programs. EVH aligns with the current international consensus on pandemic-vaccine development, leveraging insights from existing prototypes to enable the rapid selection and deployment of the most suitable vaccine candidates in an emerging pandemic.

From prototype design to clinical applications, the EVH drives innovation, enhances clinical evaluation capacities, and coordinate efforts with manufacturers while optimizing the digitalization of vaccine design and distribution processes. EVH aims thus not only to create a reactive R&D system and knowledge hub linking powerful leading research institutions, but also initiate vaccine-development projects, refining relevant processes and procedures within its framework. The current focus is on a select group of pathogens deemed critical for pandemic preparedness.

To assess the effectiveness and impact of the EVH, the outreach and coverage of the project's activities are monitored and verified through a customized analysis. This approach utilizes specific action-level indicators for reporting purposes and a quantitative approach to provide a measurable overview of the project's achievements, enabling an objective assessment of outputs and the timely delivery of results. This systematic verification process facilitates real-time monitoring, ensuring that operational progress remains strictly aligned with the program's predefined strategic requirements.

2. Summary of the deliverable D1.8 on “Specific action-level indicators for reporting purposes”

This report presents the specific action-level indicators established for reporting purposes within the EVH project. It corresponds to Deliverable 1.8 – Specific action-level indicators for reporting purposes, which provides an overview of the indicators implemented and monitored during the first 12 months of the project (1 March 2025 to 28 March 2026). This deliverable is part of Work Package 1 (WP1) – Coordination, management, impact assessment, which oversees the overall governance and operational framework of the project. WP1 runs from Month 1 to Month 48 and is responsible for ensuring efficient coordination, timely reporting, consistent monitoring of progress, and assessment of the project's impact across its full duration.

This deliverable defines the **quantitative action-level indicators** used for monitoring and reporting progress within the EVH project. All indicators follow principles of measurability, clarity, and alignment with the

project work plan. Baseline values and targets are established according to the call requirements (Baseline: 0; Target: 100% on schedule).

The indicators cover technical and scientific progress, operational readiness of the ever-warm system, digitalisation of processes, contractual and administrative achievements, training, knowledge sharing, and laboratory-level technological adoption.

3. Specific Action-Level Indicators and Quantitative Metrics

To provide a clear and structured evaluation framework, the project's monitoring approach for EVH is based on specific action-level indicators, which allow progress to be assessed directly in relation to the activities carried out. This quantitative approach uses measurable and verifiable data, ensuring an objective evaluation of overall project progress. By standardizing how results are measured and compared, this method enables consistent monitoring throughout the project lifecycle and supports transparent reporting to HERA as well as to all relevant stakeholders.

Quantitative indicators include specific, measurable units such as the number of deliverables completed on time, baseline values, and target values, as indicated in the HERA Call for Proposals EU4H-2024-PJ-01 (Baseline: 0, Target: 100% on schedule).

The specific action-level indicators are organized into four main categories:

- **Operational Implementation:** focuses on the effective execution of planned activities;
- **Scientific Advancement:** measures progress in research outputs and innovation;
- **Capacity Building and Technical Optimization:** reflects improvements in skills, tools, and processes;
- **Knowledge Transfer and Advisory:** refers to the delivery of training courses and advisory support.
- **Project progress and planned activities:** refers to activities conducted according the action and work plan

The associated action-level indicators of these categories are reported in Table 1 and offer a comprehensive and transparent view of the project's development and impact.

Table 1. Specific action-level indicators

Category	Action-Level Indicator
Operational Implementation	Number of plans and implementation according to work plan, delivered on time
	Number of written agreements and contracts developed and signed to facilitate the activities of the hub
	Number of contractual agreements developed
Scientific Advancement	Number of vaccine prototypes or candidates subject to studies and trials
	Number of improved clinical and preclinical evaluations
	Number of laboratories implementing the system for standardized and innovative assays
Capacity Building and Technical Optimization	Number of optimally digitalized processes
	Number of "ever-warm" capacities after auditing and testing
	Number of stress tests carried out
	Number of technology platforms developed, optimised or adapted
Knowledge Transfer and Advisory	Number of trainings delivered and number of participants
	Satisfaction and efficiency of trainings tested
	Number of users of the centre of shared knowledge
	Number of pieces of advice provided
Project progress and planned activities	Number of deliverables completed
	Number of milestones completed

The specific action-level indicators include the number of plans and their implementation according to the work plan, delivered on time. The number of written agreements and contracts developed and signed to facilitate the activities of the hub will also be tracked. The number of contractual agreements developed will be tracked to ensure all necessary documents are in place.

Additionally, the number of vaccine prototypes or candidates subject to studies and trials will be monitored, ensuring that all planned prototypes or candidates are being studied (Baseline: 0, Target: 2 prototypes). Improved clinical and preclinical evaluations will be tracked by counting the number of evaluations that have been enhanced. The number of laboratories implementing the system for standardised and innovative assays will be tracked to ensure all targeted facilities adopt the new protocol.

The number of optimally digitalized processes will be measured to ensure that all processes are digitalized as planned. The number of ever-warm capacities after auditing and testing will be monitored to ensure all capacities are maintained as required. The number of stress tests carried out will be recorded to verify that all planned simulations are conducted. Furthermore, the number of technology platforms developed, optimised, or adapted will be monitored to ensure all planned platforms are in place.

The number of training courses delivered, and the number of participants trained will be recorded to ensure

that all planned training courses are conducted and attended. The number of users of the centre of shared knowledge will be tracked to measure the reach and utilization of the Hub's resources.. Finally, the number of advisory services provided will be monitored to ensure that all planned outputs are delivered.

By using the monitoring strategy with the selected specific action-level indicators , EVH ensures full transparency and consistent tracking of project progress and activities.

These metrics will be tracked throughout the project lifecycle to provide continuous oversight, serving as the essential data source for the preparation of a comprehensive periodic report and for the impact assessment of the EVH project.

4. Conclusions

The report on **“Specific action-level indicators for reporting purposes”** has been prepared by SVA in full compliance with the requirements specified in the **EU4H-2024-PJ-01-1 (CP-g-24-10)** Call for Proposals for the **European Hub for Vaccine Development (HERA)**.

The indicators defined in this report provide a comprehensive and measurable framework to track project progress at action level. They ensure transparency, accountability, and structured reporting across all major dimensions of the EVH project. These indicators will be used throughout the project lifecycle to assess performance against baseline values, targets, milestones, and expected outcomes, supporting effective implementation and governance. The framework of action-level indicators is conceived as a dynamic tool; while the metrics remain aligned with HERA requirements, their status and results will be continuously updated to reflect the actual progression of the project.

The Deliverable 1.8 “Specific action-level indicators for reporting purposes” is fully achieved with the submission to HaDEA of the present report.

Document review / approval (the coordinator)

Name	Role	Action (review / approval)	Date
Donata Medaglini	Scientific Project Coordinator	Review and approval	12/03/26