ANNEX 1

EU4Health Programme (EU4H)

Description of the action (DoA)

Part A

Part B

DESCRIPTION OF THE ACTION (PART A)

COVER PAGE

Part A of the Description of the Action (DoA) must be completed directly on the Portal Grant Preparation screens.

PROJECT *Grant Preparation (General Information screen) — Enter the info.*	
Project number:	101183284
Project name:	Improvements to the Norwegian surveillance systems for infectious diseases
Project acronym:	NORSURV
Call:	EU4H-2023-DGA-MS3-IBA
Topic:	EU4H-2023-DGA-MS-IBA-01
Type of action:	EU4H-PJG
Service:	HADEA/A/01
Project starting date:	fixed date: 1 October 2024
Project duration:	48 months

TABLE OF CONTENTS

PROJECT SUMMARY

Project summary

Grant Preparation (General Information screen) — Provide an overall description of your project (including context and overall objectives, planned activities and main achievements, and expected results and impacts (on target groups, change procedures, capacities, innovation etc)). This summary should give readers a clear idea of what your project is about.

Use the project summary from your proposal.

Epidemiological surveillance is the continuous and systematic collection, collation, and analysis of data concerning infections, infectious diseases, pathogens, immunity, vaccination, and relevant behaviours, with the presentation of surveillance findings to those who need them for public health purposes. Surveillance is a foundation for infectious disease prevention and control.

The current Norwegian surveillance systems have several weaknesses, including reliance on paper forms sent by mail, no surveillance of severe outcomes, and no use of secondary sources, resulting in inadequate surveillance results for key stakeholders and inability to fulfil ECDC's reporting requirements.

The NORSURV project aims to ameliorate those weaknesses through digitalization, automated processes, and utilization of secondary information sources.

Specifically, the project will:
- develop the technical infrastructure and legal environment for near real-time linkage of case notification data with additional information from other registries, particularly the registry of all hospitalisations, for surveillance purposes and implement this integrated surveillance system,
- further develop and expand the national database of laboratory results from all clinical microbiological laboratories,
- develop the infrastructure for and then pilot an electronic notification pathway from clinicians, and
- develop and implement an epidemic intelligence information system that supports event recording, logging, follow-up, and the production of reports and early warnings nationally and internationally.

Along the way, the legal environment for these changes will be reformed. Capacity and proficiency among staff will be built through trainings sessions and on the job-training.

The NORSURV project is coordinated by the Norwegian Institute of Public Health (NIPH), which is mandated by law to run surveillance systems. NIPH is the ECDC's partner institute in Norway and the focal point for EWRS.

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	NIPH	FOLKEHELSEINSTITUTTET	NO	999478883
1.1	AE	HDIR	HELSEDIREKTORATET	NO	974772304

LIST OF WORK PACKAGES

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
WP1	Management, coordination, administration, and evaluation	1 - NIPH	32.51	1	48	D1.1 – Management structure plan D1.2 – Mid-term evaluation report D1.3 – Evaluation report D1.4 – Action level indicator report
WP2	Integrated surveillance	1 - NIPH	457.14	1	48	D2.1 – Report: integrated surveillance D2.2 – Report: improved MSIS labdatabase D2.3 – Report: electronic notification pathway
WP3	Epidemic intelligence	1 - NIPH	76.20	1	24	D3.1 – Report: outbreak investigation database D3.2 – Report: information system
WP4	Capacity building, dissemination, and sustainability	1 - NIPH	25.15	1	48	D4.1 – Communication and dissemination plan D4.2 – Web site for NORSURV D4.3 – Report: communication and dissemination D4.4 – Report: training D4.5 – Sustainability plan

Work package WP1 – Management, coordination, administration, and evaluation

Work Package Number	WP1	Lead Beneficiary	1 - NIPH
Work Package Name	Management, coordination, administration, and evaluation		
Start Month	1	End Month	48

Objectives
We aim to ensure the effective management, coordination, and administration of the project, adhering to legal and professional standards, optimizing operational efficiency, minimizing costs, and fulfilling all reporting obligations. We aim to manage the entrusted funds for the project according to NIPH's strict policies and guidelines on procurement, financial management, and internal control and within the conditions set in the grant agreement. We aim to monitor the project's progress, culminating in a comprehensive evaluation at the conclusion to assess the project's impact and identify areas for improvement.

Description
T1.1 Project management and coordination: Manage, coordinate, and administrate the project, adhering to legal and professional standards, optimizing operational efficiency, minimizing costs, and fulfilling all reporting obligations. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No T1.2 Project financial management: Manage the entrusted funds for the project according to NIPH's strict policies and guidelines on procurement, financial management, and internal control and within the conditions set in the grant agreement. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No T1.3 Project monitoring and evaluation: Monitor the project's progress, culminating in a comprehensive evaluation at the conclusion to assess the project's impact and identify areas for improvement. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No

Work package WP2 – Integrated surveillance

Work Package Number	WP2	Lead Beneficiary	1 - NIPH
Work Package Name	Integrated surveillance		
Start Month	1	End Month	48

Objectives
We aim to develop the technical infrastructure and legal environment for near real-time linkage of case notification data in the MSIS and SYSVAK with additional information from other registries for surveillance purposes. We aim to pilot and implement integrated surveillance for respiratory infections with epidemic potential, SARI, healthcare-associated infections (HAI), other infectious diseases (zoonotic, vaccine preventable, bloodborne and sexually transmissible infections), and uptake, effectiveness, and adverse events of vaccination. We aim to improve the infrastructure of the NPR and pilot more frequent collection of data from hospitals and facilitate timely linkage with MSIS and other registries. We aim to improve the MSIS LdB infrastructure, structure and standardize the data input, streamline in-house data management, and develop systems for preparing data for surveillance purposes. We aim to develop the infrastructure for and then pilot an electronic notification pathway from clinicians to MSIS, with integration in electronic health records (EHR), eventually to replace paper forms.

We aim to analyse the legal basis for integrated surveillance and identify the needs for changes to regulations to facilitate a) continuous and timely linkage of data from health registries and administrative registries with the surveillance systems, and b) permanent storage of person identifiable information for all laboratory results in MSIS LdB.

Description
T2.1 Integrated Surveillance Core: Develop near real-time linkage of case notification data in the Surveillance System for Communicable Diseases (MSIS) with additional information from other registries. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T2.2 Improving the MSIS Laboratory Database: Improve the MSIS LdB infrastructure, structure and standardize the data input, streamline in-house data management, and develop systems for preparing data for surveillance purposes. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T2.3 Timely updating of the Norwegian Patient Registry: Improve the infrastructure and pilot more frequent collection of data from hospitals to the Norwegian Patient Registry (NPR) to facilitate timely linkage with MSIS and other registries. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: Yes. T2.4 Electronic notification pathway: Develop the infrastructure for and pilot an electronic notification pathway from clinicians to MSIS, integrated in electronic health records (EHR), to eventually replace paper forms. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T2.5 Legal environment: Analyse the legal basis for integrated surveillance and identify the needs for changes to regulations to facilitate a) continuous and timely linkage of data from health registries and administrative registries with the surveillance systems, and b) permanent storage of person identifiable information for all laboratory results in MSIS LdB. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T2.6 Integrated surveillance pilot, respiratory infections: Pilot and implement integrated surveillance for respiratory infections with epidemic potential, and SARI. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T2.7 Integrated surveillance pilot, healthcare-associated infections: Pilot and implement integrated surveillance for healthcare-associated infections (HAI). - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T2.8 Integrated surveillance pilot, other infections, and vaccination: Expand integrated surveillance system to other infectious diseases (zoonotic, vaccine preventable, bloodborne and sexually transmissible infections), and to uptake, effectiveness, and adverse events of vaccination. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No.

Work package WP3 – Epidemic intelligence

Work Package Number	WP3	**Lead Beneficiary**	1 - NIPH
Work Package Name	Epidemic intelligence		
Start Month	1	**End Month**	24

Objectives
We aim to develop and implement at NIPH an epidemic intelligence information system that supports event recording, logging, follow-up, and the production of reports and early warnings nationally and internationally.

We aim to develop and implement an outbreak investigation database template that is ready to be used in outbreak investigations to record patient, disease and exposure information and produce reports.

Description
T3.1 Information system for epidemic intelligence: Develop and implement information system for epidemic intelligence. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T3.2 Outbreak investigation database template: Develop and implement outbreak investigation database template. - Participants: NIPH (COO). In-kind contribution: No. Subcontracting: No.

Work package WP4 – Capacity building, dissemination, and sustainability

Work Package Number	WP4	Lead Beneficiary	1 - NIPH
Work Package Name	Capacity building, dissemination, and sustainability		
Start Month	1	End Month	48

Objectives
We aim to build capacity among NIPH staff and selected healthcare professionals, enhancing their skills and knowledge in surveillance methods and analysis and national and EU legal framework. We aim to communicate and disseminate project plans and results to relevant target groups and stakeholders through a wide range of activities, while ensuring visibility of EU funding. We aim to sustain the achievements from the project, according to the sustainability plan, forging a lasting impact on epidemiological surveillance.

Description
T4.1 Capacity building: Build capacity among NIPH staff and selected health care professionals through trainings sessions, targeted recruitment, on the job training and site visits. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T4.2 Dissemination: Communicate and disseminate project plans and results to relevant target groups and stakeholders through a wide range of activities, while ensuring visibility of EU funding. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No. T4.3 Sustainability: We aim to sustain the achievements from the project, according to the sustainability plan, forging a lasting impact on epidemiological surveillance. - Participants: NIPH (COO), Hdir (AE). In-kind contribution: No. Subcontracting: No.

STAFF EFFORT

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	Total Person-Months
1 - NIPH	26.51	442.14	75.20	19.15	563.00
1.1 - HDIR	6.00	15.00	1.00	6.00	28.00
Total Person-Months	32.51	457.14	76.20	25.15	591.00

LIST OF DELIVERABLES

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

The labels used mean:

Public — fully open (⚠ automatically posted online)
Sensitive — limited under the conditions of the Grant Agreement
EU classified —RESTREINT-UE/EU-RESTRICTED, CONFIDENTIEL-UE/EU-CONFIDENTIAL, SECRET-UE/EU-SECRET under Decision 2015/444

Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	Management structure plan	WP1	1 - NIPH	R — Document, report	PU - Public	3
D1.2	Mid-term evaluation report	WP1	1 - NIPH	R — Document, report	PU - Public	25
D1.3	Evaluation report	WP1	1 - NIPH	R — Document, report	PU - Public	48
D1.4	Action level indicator report	WP1	1 - NIPH	R — Document, report	PU - Public	48
D2.1	Report: integrated surveillance	WP2	1 - NIPH	R — Document, report	PU - Public	48
D2.2	Report: improved MSIS labdatabase	WP2	1 - NIPH	R — Document, report	PU - Public	48
D2.3	Report: electronic notification pathway	WP2	1 - NIPH	R — Document, report	PU - Public	48
D3.1	Report: outbreak investigation database	WP3	1 - NIPH	R — Document, report	PU - Public	24
D3.2	Report: information system	WP3	1 - NIPH	R — Document, report	PU - Public	24
D4.1	Communication and dissemination plan	WP4	1 - NIPH	R — Document, report	PU - Public	2
D4.2	Web site for NORSURV	WP4	1 - NIPH	DEC —Websites, patent filings, videos, etc	PU - Public	3
D4.3	Report: communication and dissemination	WP4	1 - NIPH	R — Document, report	PU - Public	48
D4.4	Report: training	WP4	1 - NIPH	R — Document, report	PU - Public	48
D4.5	Sustainability plan	WP4	1 - NIPH	R — Document, report	PU - Public	48

Deliverable D1.1 – Management structure plan

Deliverable Number	D1.1	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Management structure plan		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	3	**Work Package No**	WP1

Description
Outline of management structure and procedures, including decision making.

Deliverable D1.2 – Mid-term evaluation report

Deliverable Number	D1.2	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Mid-term evaluation report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	25	**Work Package No**	WP1

Description
An report of a mid-term evaluation of the project's progress at mid-term with the purpose of allowing for improving in areas as necessary

Deliverable D1.3 – Evaluation report

Deliverable Number	D1.3	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Evaluation report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP1

Description
A final evaluation of the project’s progress, assessing the project's impact and achievement of aims.

Deliverable D1.4 – Action level indicator report

Deliverable Number	D1.4	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Action level indicator report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP1

Description
We will report on the following indicators: - Number of national surveillance systems with improved timeliness of surveillance data reporting.

- Number of national surveillance systems with an increased sensitivity (defined as the ability of the surveillance system to detect all events under surveillance). - Number of national surveillance systems with increased data quality. - Number of national surveillance systems that comply with the EU surveillance standards. - Number of national surveillance systems able to monitor their country's health care system capacity

Deliverable D2.1 – Report: integrated surveillance

Deliverable Number	D2.1	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Report: integrated surveillance		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP2

Description
Report with description of integrated surveillance and first experiences after implementation, including analysis and solutions to the legal issues

Deliverable D2.2 – Report: improved MSIS labdatabase

Deliverable Number	D2.2	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Report: improved MSIS labdatabase		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP2

Description
Report with description of improved data transfer protocols from microbiological laboratories to the "MSIS lab-database", first experiences of permanent storage of information for all sample results.

Deliverable D2.3 – Report: electronic notification pathway

Deliverable Number	D2.3	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Report: electronic notification pathway		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP2

Description
Report with description of development of infrastructure for new electronic notification pathway and experiences after the pilot, including exploration of possible data collection directly from patients

Deliverable D3.1 – Report: outbreak investigation database

Deliverable Number	D3.1	**Lead Beneficiary**	1 - NIPH
Deliverable Name	Report: outbreak investigation database		

Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP3

Description
Report with description of outbreak investigation database template and first experiences after implementation

Deliverable D3.2 – Report: information system

Deliverable Number	D3.2	Lead Beneficiary	1 - NIPH
Deliverable Name	Report: information system		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	24	Work Package No	WP3

Description
Report with description of information system for epidemic intelligence and first experiences after implementation.

Deliverable D4.1 – Communication and dissemination plan

Deliverable Number	D4.1	Lead Beneficiary	1 - NIPH
Deliverable Name	Communication and dissemination plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	2	Work Package No	WP4

Description
A plan for the communicating and dissemination of project plans and results to relevant target groups and stakeholders through a wide range of activities, while ensuring visibility of EU funding.

Deliverable D4.2 – Web site for NORSURV

Deliverable Number	D4.2	Lead Beneficiary	1 - NIPH
Deliverable Name	Web site for NORSURV		
Type	DEC —Websites, patent filings, videos, etc	Dissemination Level	PU - Public
Due Date (month)	3	Work Package No	WP4

Description
A NORSURV portal will be created at the NIPH's web site www.fhi.no. This portal will be the home for all written products from the project, with an emphasis on maximum transparency (within the boundaries of law). The project coordinator team will have editorial responsibility. A summary about the project will also be published on the web site of HDIR www.helsedirektoratet.no

Deliverable D4.3 – Report: communication and dissemination

Deliverable Number	D4.3	Lead Beneficiary	1 - NIPH
Deliverable Name	Report: communication and dissemination		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	48	Work Package No	WP4

Description
A report of communication and dissemination activities throughout the project.

Deliverable D4.4 – Report: training

Deliverable Number	D4.4	Lead Beneficiary	1 - NIPH
Deliverable Name	Report: training		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	48	Work Package No	WP4

Description
A report of training activities throughout the project.

Deliverable D4.5 – Sustainability plan

Deliverable Number	D4.5	Lead Beneficiary	1 - NIPH
Deliverable Name	Sustainability plan		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	48	Work Package No	WP4

Description
A plan outlining how the achievements from the project may forge lasting impact on epidemiological surveillance in Norway, with delivery of data to EU-wide surveillance.

LIST OF MILESTONES

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	Management structure plan agreed	WP1	1 - NIPH	Draft available to partners, in English	2
2	Evaluation plan	WP1	1 - NIPH	Plan available to partners, in English	6
3	Complete T2.1 Integrated Surveillance Core	WP2	1 - NIPH	Indicator: The number of registries that have an infrastructure to support daily linkage with MSIS is at least three.	24
4	Complete T2.2 Improving the MSIS Laboratory Database	WP2	1 - NIPH	Indicator: The level of structure and standardization in data input is markedly improved.	24
5	Complete T2.3 Timely updating the Norwegian Patient Registry A	WP2	1 - NIPH	Indicator: Frequency of data collection from hospitals is daily.	24
6	Complete T2.3 Timely updating the Norwegian Patient Registry B	WP2	1 - NIPH	Indicator: Frequency of data distribution to the Analysis Hub is daily	24
7	Complete T2.4 Pilot of electronic notification pathway	WP2	1 - NIPH	Indicator: The proportion of general practitioners who will have the possibility of installing the new pathway in their electronic health records system is 70 percent.	24
8	Complete T2.5 Legal environment	WP2	1 - NIPH	The analysis and request for changes has been submitted to the Ministry of Health	24
9	Draft deliverable D2.1 discussed with major stakeholders	WP2	1 - NIPH	The draft is available to the partners and is reflected in the minutes of the General Assembly	44
10	Draft deliverable D2.2 discussed with major stakeholders	WP2	1 - NIPH	The draft is available to the partners and is reflected in the minutes of the General Assembly	44

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
11	Draft deliverable D2.3 discussed with major stakeholders	WP2	1 - NIPH	The draft is available to the partners and is reflected in the minutes of the General Assembly	44
12	Information system for epidemic intelligence requirements	WP3	1 - NIPH	A report is available to partners and discussed at the General Assembly	12
13	Outbreak investigation database template benchmarking	WP3	1 - NIPH	A report is available to partners and discussed at the General Assembly	12
14	Plan for communication and dissemination	WP4	1 - NIPH	A plan is available to partners and discussed at the General Assembly	2
15	Training plan	WP4	1 - NIPH	A plan is available to partners and discussed at the General Assembly	6

LIST OF CRITICAL RISKS

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
1	Legislative changes foreseen (in task T2.5) may be delayed or not come into effect during the project duration. Likelihood: medium; impact: high.	WP2	We will continue working with the Ministry of Health, already before project start, to prepare the groundwork for the necessary legislative changes. Substantial legal expert resources will go into task T2.5, and, if necessary, this will be supplemented by further institute resources. A Governmental White Paper already points to the need for improving surveillance. A recent interpretation of the current law indicates that linkage of registries is already allowed if the end results is surveillance statistics. This provides a basis for further legal interpretation or changes in the law.

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
2	The frequent data collection from hospitals to the Norwegian Patient Registry (task T2.3) is dependent on the hospitals' ability also. Various reasons outside of our control may delay their contribution. Likelihood: low; impact low.	WP2	We will work with the hospitals to help their compliance. We may still accept data collection with longer intervals while hospitals are working with us to achieve frequent data collection.
3	The electronic notification pathway to MSIS (task 2.4) is a complex undertaking that requires innovative and secure solutions. Various reasons outside of our control may delay the task.	WP2	We will start working on this task in month 1 of the project and map technologies used by other agencies to collect data from clinicians. If need be, we will allocate extra resources from the institute to the task.
4	Loss of key personnel Likelihood: medium; impact: low.	WP4, WP2, WP3, WP1	The NIPH and HDIR have several staff members with the relevant expertise and experience. Replacements and additional staff members can be allocated to the project without significant delay.
5	A large, severe outbreak or another event may affect the prioritization for persons involved in the project, and risk delay the project timeline. Likelihood: low, impact: medium.	WP2, WP3	The NIPH and HDIR have several staff members with the relevant expertise and experience. Replacements and additional staff members can probably be allocated to the project with minor delay.
6	There may be other technical, legal, or other kinds of hurdles or dependencies that delays the project.	WP2, WP3	The coordinator monitors the progress closely at task level. Support and challenge-solving is offered proactively. The NIPH and HDIR have skilled staff that can address the challenges.
7	There may be opposition among the health care services or the public against integrated surveillance for fear of reduced data protection.	WP2, WP3	The NIPH will communicate to the health care personnel and the public about the project's intention and safeguards and facilitate a dialogue on these issues.

IMPORTANT NOTICE

What is the Application Form?

The Application Form is the template for EU grants applications; it must be submitted via the EU Funding & Tenders Portal before the call deadline.

The Form consists of 2 parts:.

- Part A contains structured administrative information
- Part B is a narrative technical description of the project.

Part A is generated by the IT system. It is based on the information which you enter into the Portal Submission System screens.

Part B needs to be uploaded as PDF (+ annexes) in the Submission System. The templates to use are available there.

How to prepare and submit it?

The Application Form must be prepared by the consortium and submitted by a representative. Once submitted, you will receive a confirmation.

Character and **page limits**:

- page limit normally **70** pages (unless otherwise provided in the Call document)
- supporting documents can be provided as an annex and do not count towards the page limit
- minimum font size — Arial 9 points
- page size: A4
- margins (top, bottom, left and right): at least 15 mm (not including headers & footers).

Please abide by the formatting rules. They are NOT a target! Keep your text as concise as possible. Do not use hyperlinks to show information that is an essential part of your application.

⚠ If you attempt to upload an application that exceeds the specified limit, you will receive an automatic warning asking you to shorten and re-upload your application. For applications that are not shortened, the excess pages will be made invisible and thus disregarded by the evaluators.

⚠ **Please do NOT delete any instructions in the document. The overall page limit has been raised to ensure equal treatment of all applicants.**

⚠ This document is tagged. Be careful not to delete the tags; they are needed for the processing.

TECHNICAL DESCRIPTION (PART B)

COVER PAGE

Part B of the Application Form must be downloaded from the Portal Submission System, completed and then assembled and re-uploaded as PDF in the system. Page 1 with the grey IMPORTANT NOTICE box should be deleted before uploading.

***Note:** Please read carefully the conditions set out in the Call document (for open calls: published on the Portal). Pay particular attention to the award criteria; they explain how the application will be evaluated.*

PROJECT	
Project name:	Improvements to the Norwegian surveillance systems for infectious diseases
Project acronym:	NORSURV
Coordinator contact:	Preben Aavitsland, Norwegian Institute of Public Health

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#@APP-FORM-EU4H@#
#@PRJ-SUM-PS@# [This document is tagged. Do not delete the tags; they are needed for the processing.]

PROJECT SUMMARY

Project summary
See Abstract (Application Form Part A).

#§PRJ-SUM-PS§# #@REL-EVA-RE@# #@PRJ-OBJ-PO@#

1. RELEVANCE

1.1 Background and general objectives

Background and general objectives

Describe the background and rationale of the project.

How is the project relevant to the scope of the call? How does the project address the general objectives of the call? What is the project's contribution to the priorities of the call?

Modern surveillance

Epidemiological surveillance entails the continuous and systematic collection, collation, and analysis of data concerning infections, infectious diseases, pathogens, immunity, vaccination, and relevant behaviours, with the subsequent presentation of surveillance findings to those who need them for public health purposes.

Surveillance forms a foundation for infectious disease prevention and control. Surveillance of infections, communicable diseases, and pathogens aims to a) measure incidence and disease severity over time and across geographical and demographic contexts, b) contribute to the detection and investigation of infectious disease outbreaks, and c) garner insights into pathogen characteristics and disease nature.

The surveillance of these outcomes also provides data and results for research, health analysis, infection modelling, and socio-economic analysis relevant to public health.

Traditionally, national surveillance systems focused on counting new cases of designated "notifiable" infectious diseases. However, in recent decades, the science and practice of surveillance have evolved. For many diseases, the focus now encompasses capturing the entire spectrum of illness and disease outcomes, including asymptomatic infections, mild undiagnosed cases, and severe cases leading to hospitalization, intensive care, or death. Such surveillance is essential for measuring the disease burden, which is the combined product of disease incidence and disease severity in individuals. In some situations, measuring infection or disease prevalence may be more appropriate than measuring incidence.

Several diseases require the integration of multiple surveillance methods. Here are just a few illustrative examples:

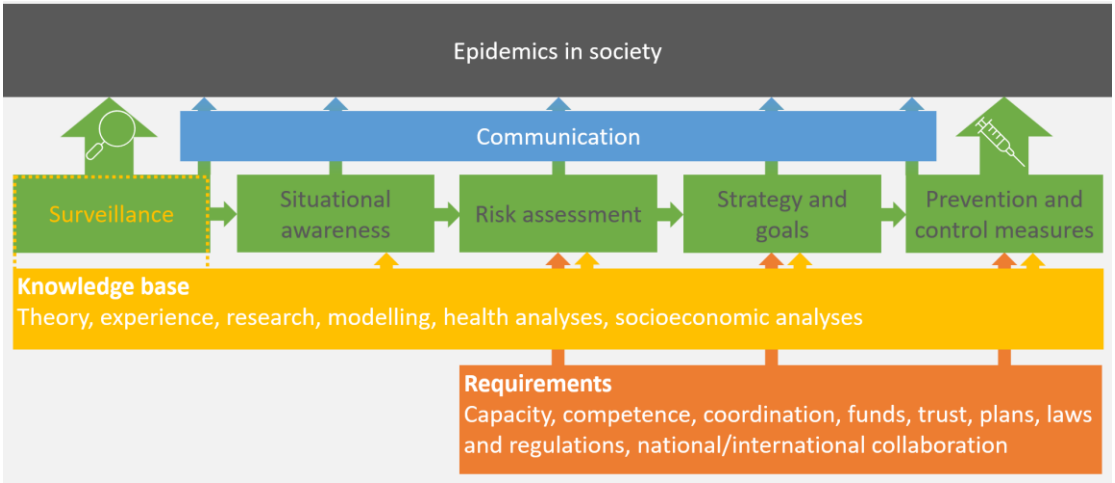
- **Seasonal respiratory infections** such as influenza and Covid-19 exhibit a broad disease pyramid, with a considerable proportion of the population affected each winter season, and new variants may have different disease characteristics. A comprehensive surveillance approach should encompass immunity in the population, virus characteristics, asymptomatic infections, illnesses prompting medical consultation, hospitalizations, and deaths.
- **Hepatitis C virus (HCV)** infection often presents asymptomatically, with some individuals progressing to chronic hepatitis and potentially life-threatening complications over time. Given the asymptomatic nature of HCV infection, notification

data primarily reflect national screening and testing practices, necessitating supplementary data to guide elimination efforts effectively.

- **Healthcare-associated infections (HAIs)** encompasses a range of infections acquired during healthcare delivery within various healthcare settings. HAIs often involve complex transmission dynamics and are influenced by factors such as antimicrobial resistance, invasive medical procedures, and patient comorbidities. Therefore, effective surveillance of HAIs requires a multifaceted approach that addresses various aspects of infection prevention and control, such as tracking the incidence of specific HAIs (such as surgical site infections or bloodstream infections), monitoring the prevalence and antimicrobial resistance patterns of pathogens causing HAIs, and surveillance of patient outcomes, including morbidity, mortality, and length of hospital stay, and surveillance of antimicrobial use.
- **Zoonotic diseases** can pose significant public health threats by spilling over from animals to humans. Integrating data from both human and animal sources is essential for effective surveillance, enabling the identification of emerging and re-emerging zoonotic threats, understanding transmission dynamics, and implementing targeted control measures to mitigate the risk of outbreaks.

The uses of surveillance results

Surveillance, alongside research, knowledge synthesis, infection modelling, theory, experience, and health system capacity monitoring, forms the basis for situational understanding and risk assessment, which, in turn, inform the selection and implementation of infectious disease prevention and control strategies and interventions, including vaccination. Surveillance is also crucial for strategy evaluation and the measurement of the effects of communicable disease prevention and control programmes.



The occurrence of infectious diseases can increase rapidly during outbreaks. Surveillance results must be presented frequently, sometimes daily, or weekly. Rapid, context-specific ad hoc analyses may be necessary to investigate signals uncovered by surveillance.

Surveillance should always provide information for action, as infectious diseases pose unique threats due to their rapid spread, affecting large portions, if not the entire population, requiring preventive measures, including vaccination programmes. Surveillance is necessary for early detection of threats, understand their potential, target interventions, and evaluate response strategies. Therefore, surveillance must be comprehensive and near real-time.

A key intervention against many infectious diseases is immunization. Robust monitoring of immunization programmes is necessary to document their benefits and for authorities to communicate openly and comprehensively about the benefits and risks, including adverse events. Open and transparent communication helps counter the increasing misinformation from vaccine opponents. Surveillance systems can contribute through surveillance of

diseases targeted by vaccination, population immunity, vaccination coverage, vaccination effectiveness, population attitudes towards vaccination, and adverse events. The primary goal of surveillance is to optimize benefits and minimize drawbacks through the proper design and targeting of immunization programmes.

Surveillance is crucial in normal times and during crises. A surveillance system that functions well in normal times is a prerequisite for effective surveillance, possibly with reinforcements, during crises.

The components and attributes of surveillance systems

A surveillance system comprises infrastructure and processes necessary to achieve the system's purpose. The key sequential processes include:

1. data collection or retrieval of data (and biological material),
2. data cleaning and quality control, compilation, management, analysis (including AI), interpretation, and production of surveillance results, and
3. presentation and sharing of surveillance results (and data) with those who need them in public health.

The main attributes of surveillance systems are:

- **Timeliness**, ensuring that surveillance results are available when users need them; sometimes, this means in real-time.
- **Usefulness**, ensuring that surveillance results are of high quality (high completeness, correctness, and representativeness) and are presented in an easily accessible manner; providing the information users need.
- **Effectiveness**, ensuring that surveillance results are produced in a manner that provides good value for users relative to the cost of producing the results.
- **Flexibility**, ensuring that the system can produce other surveillance results, if necessary for new diseases, should users require such results. This includes preparedness for managing other health risks in an all-hazards approach as described in Regulation 2022/2371.
- **Security**, ensuring that personal data are protected from unauthorized access and use.

Each of the following four main improvements can enhance those main attributes:

- **Digitalization** of all parts of surveillance systems, making paper recording and postal communication obsolete.
- **Data integration**, including clinical, laboratory and epidemiological data.
- **Automated processes**, including automated analysis and the use of artificial intelligence (AI) for analysis.
- **Utilization of secondary information sources**, particularly health registries and other registers, through streamlining data retrieval, alleviating clinicians' notification burden, and reducing reliance on manual data entry.

The European perspective

Pathogens may cross borders in humans, animals, food, feed, or other objects. All European countries, as well as the Commission, may benefit from improved national surveillance systems. This advantage may take the form of early warnings from a country that has detected a threat to all other countries through the Early Warning and Response System (EWRS), or through a common system, the European surveillance system (TESSy), as outlined in Regulation 2022/2371, and the HERA IT Platform, providing a better situational overview and better opportunities to generate new knowledge. This represents genuine European added value, as the compilation of surveillance data yields more value than the sum of each country's surveillance results.

All improvements in national surveillance systems should consider this European dimension. The ECDC's Long-term Surveillance Framework 2021–2027 is a critical foundation. It asserts that surveillance of infectious diseases in the European Union/European Economic Area (EU/EEA) builds on national surveillance systems. European surveillance neither merely combines nor merely complements national data collections and analyses but rather enhances them, adding a supranational layer and EU/EEA public health value to what would otherwise be poorly comparable country-specific monitoring activity and statistics.

General objectives

The discussion above forms the background and rationale for this application for a direct grant to the NORSURV project with the overall aim of improving and strengthening the epidemiological surveillance system in Norway that supports the prevention and control of infectious diseases in Norway and the EU/EEA region.

The NORSURV project has three general objectives that correspond to the general objectives of the call and directly contribute to the priorities of the call:

- **Infrastructure development:** We aim to improve the surveillance infrastructure in Norway, enabling more timely, useful, effective, flexible, and secure collection, collation, and analysis of data in order to produce surveillance results that can be shared with those who need them in Norway and in the EU to improve prevention and control of infectious diseases. A main improvement will be the integration of data from health registries and other secondary data sources which facilitates the expansion of surveillance objectives to larger parts of the disease pyramid.
- **Capacity building:** We aim to enhance our surveillance capacity by developing skilled personnel proficient in IT systems, epidemic intelligence, surveillance data analysis, and legal frameworks, through training existing staff and targeted recruitment, complemented by ECDC's Train the Trainers Course and national training sessions. In this way we will ensure sustainable capacity building to support implementation of innovative surveillance functions and infrastructure development.
- **Piloting, implementation, and uptake according to our priority needs:** We aim to pilot and implement an improved integrated surveillance system, and a modern digital infrastructure for epidemic intelligence, enhancing functionality, interoperability, and compliance with EU regulations. This system will improve outbreak detection, reducing burdens on healthcare workers and ensuring timely, high-quality surveillance results for risk assessment, situational awareness, and informed decision-making for public health interventions.

List of abbreviations

In this application, we use these abbreviations:

- AI – Artificial intelligence
- BIVAK – Registry for adverse events following immunisation
- ECDC – European Centre for Disease Prevention and Control, an EU agency
- EEA – European Economic Area, consisting of EU, Norway, Iceland, and Lichtenstein
- EU – The European Union
- EWRS – Early Warning and Response System, the EU Commission's digital system for early warnings between health authorities about health threats
- HAI – Healthcare-associated infection
- IHR – International Health Regulations, and agreement between WHO's member states
- KUHR – The Control and Payment of Health Refunds
- MSIS – Norwegian Surveillance System for Communicable Diseases
- MSIS LdB – Norwegian Surveillance System for Communicable Diseases, Laboratory database

- NIPH – The Norwegian Institute of Public Health (Folkehelseinstituttet, FHI)
- HDIR – The Norwegian Directorate of Health (Helsedirektoratet)
- NORSURV – This project: "Improvements to the Norwegian surveillance systems for infectious diseases
- NPR – Norwegian Patient Registry (with information from specialist health care)
- SARI – Severe Acute Respiratory Infections
- SYSVAK – Norwegian Immunisation Registry
- TESSy – The European Surveillance System, based at ECDC
- WHO – World Health Organization

1.2 Needs analysis and specific objectives

Needs analysis and specific objectives

Describe how the objectives of the project are based on a sound needs analysis in line with the specific objectives of the call. What issue/challenge/gap does the project aim to address?

The objectives should be clear, measureable, realistic and achievable within the duration of the project. For each objective, define appropriate indicators for measuring achievement (including a unit of measurement, baseline value and target value).

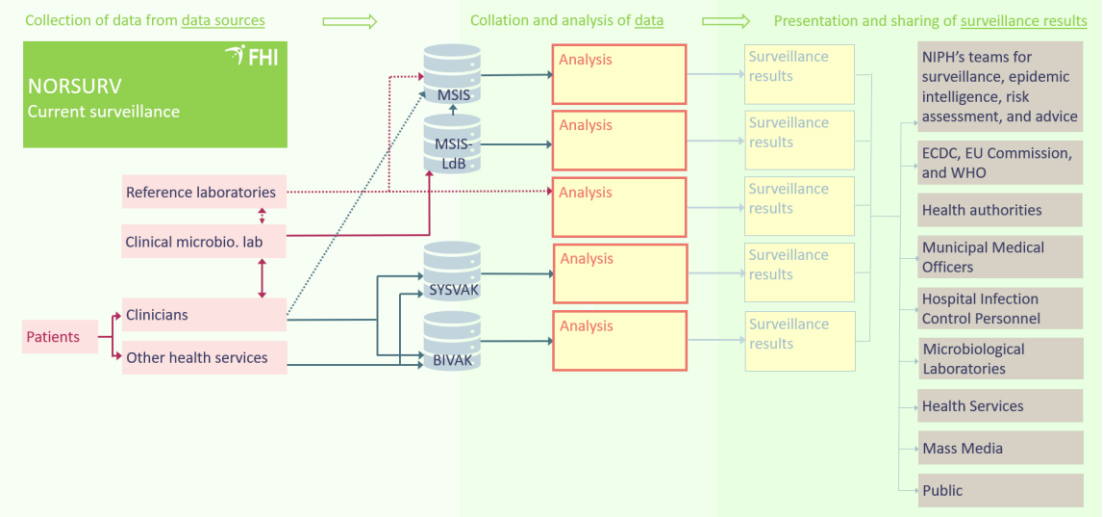
The discussion below is the analysis of shortcomings and weaknesses of the epidemiological surveillance system in Norway. This analysis is the basis for the needs in infrastructure, capacity building and implementation of improved epidemiological surveillance systems that supports the prevention and control of infectious diseases in Norway and the EU/EEA region.

Shortcomings of current surveillance in Norway

In preparation for this application, we have assessed the digitalization and integration level of Norway's current infectious disease surveillance systems, including our capacity to provide data to ECDC's TESSy and other EU systems as per Regulation 2022/2371. We have also taken account of our experiences curing the Covid-19 pandemic.

Today's surveillance primarily relies on:

- **MSIS**, which receives paper notifications and web portal notifications from clinicians and electronic copies of lab reports from microbiological laboratories regarding cases of notifiable diseases.
- **MSIS Laboratory Database (MSIS LdB)**, which receives digital copies of lab reports, linked to MSIS notifications via personal ID numbers, with negative lab results or other disease-indicating results anonymized post-registration.
- **SYSVAK**, which receives digital notifications of all vaccinations, with personal ID numbers.
- **BIVAK**, which receives digital notifications (through a secure web site) from patients and health care providers about suspected or confirmed adverse events following immunization, with personal ID.



This surveillance has several limitations for optimal infectious disease prevention and control:

- Key stakeholders, notably municipal medical officers, lack timely and adequate surveillance results to support their public health duties.
- Those responsible for vaccination programs, especially NIPH and the Norwegian Medical Products Agency, lack timely and adequate surveillance results (on uptake, efficacy, and adverse events) to support their responsibilities.
- Physicians endure unnecessary reporting burdens, being mainly reliant on paper notifications sent by post, posing privacy risks.
- Valuable existing data remains underutilized, including data from electronic health records in general practice and hospitals.
- For several important indicators, we are unable to report data to EU surveillance systems.

These problems escalated with the start of the Covid-19 pandemic, resulting in inadequate situational awareness, incomplete risk assessment, and possibly erroneous strategic choices. Consequently, there was a risk of implementing incorrect measures at the wrong time, in the wrong place, for the wrong group, and of incorrect duration. The most important compensatory measure was to establish the emergency preparedness register "Prepared-C19" (authorized under the Health Emergency Preparedness Act § 2-4), which proved highly useful. However, it is a temporary registry linked to the management of the Covid-19 pandemic.

The main weaknesses of the current surveillance setup in Norway include:

- When a patient presents with symptoms of an infectious disease, the physician can send a sample to a medical microbiological laboratory for analysis. The test result informs the physician whether it indicates a notifiable disease, and a copy is included in the MSIS LdB. Additionally, the physician must complete an MSIS notification form on paper and send it to MSIS at NIPH or fill in the form on a dedicated web site after secure login. This process is slow, costly, has low uptake (only about 50% of forms are submitted without NIPH reminders), and potentially compromises privacy as paper forms are sent by mail.
- Some infectious diseases are diagnosed without laboratory tests, such as through point-of-care testing or clinical diagnosis. Such cases can be identified using diagnosis codes in the Norwegian Patient Registry (NPR) or the Control and Payment of Health Refunds (KUHR) system, but there is currently no search for such cases for inclusion in MSIS.
- MSIS provides information on the number of cases but not complete information on severe outcomes, such as hospitalization or death.

- The MSIS LdB collects all test results from the medical microbiological laboratories but must delete personal identification (and thus the possibility of linking to other data) for all results except those positive for notifiable diseases. This means valuable information that could strengthen surveillance is missed.
- In infectious disease control, there is sometimes a need for quite detailed information about which groups are particularly affected by a disease or are less likely to accept vaccination offers. This information is readily available through linking MSIS and SYSVAK with other data sources, such as the Population Registry, other health registries, and administrative registries. However, ongoing linkage for surveillance purposes is not allowed.
- Surveillance also includes an outbreak and event alert system nationally and internationally, where rapid response may be necessary. NIPH is the core of this system. Several of the processes are manual.
- With the introduction of new vaccines or other major changes to vaccination programs, it is not possible to actively and timely monitor signals of possible side effects by searching for changes in the incidence of diseases that may be associated with vaccination (typically Guillain-Barré syndrome).

The need for integrated surveillance (i.e., the basis for WP2)

Background

The Covid-19 pandemic underscored the critical need for rapidly accessible, almost real-time information derived from integrated surveillance, as evaluated by the NIPH (https://www.fhi.no/nyheter/2023/erfaringsgjennomgang-fra-pandemiarbeidet-i-fhi/). Integrated surveillance involves surveillance that draws on information from diverse sources, moving beyond traditional stand-alone notification systems. This need is essential for managing seasonal epidemics of respiratory infections and for enhancing preparedness for future epidemics and pandemics.

The lack of integrated surveillance

Integrated surveillance using data from different registries and sources is a promising approach that enables the generation of knowledge crucial for improved situational awareness, risk assessment, and strategic interventions against community-acquired or healthcare-associated infections.

Integrated surveillance is necessary for all infectious diseases under monitoring, not only epidemic-prone diseases but also endemic diseases, antimicrobial resistance, and healthcare-associated infections.

Without integrated surveillance, we have limited oversight of the entire disease pyramid, limited background information about patients (such as previous chronic illnesses, medication usage, vaccination history, and immigrant status), and surveillance remains labour-intensive and, at least for some diseases, non-existent. Consequently, national, and local authorities have an inadequate basis for the prevention and control of infectious diseases, and NIPH can only provide insufficient data to ECDC's European surveillance. For instance, NIPH is currently unable to report cases of Severe Acute Respiratory Infections (SARI) and associated deaths to TESSy at ECDC.

Integrated surveillance not only addresses existing needs but also presents novel opportunities, demonstrated by Joint Action United4Surveillance, where the integration of clinical information on hospitalized patients with microbiological data is being piloted.

In the ESURE project, coordinated by ECDC, improved surveillance of healthcare-associated infections and antimicrobial resistance is being piloting by linking the NPR and the MSIS LdB. The current system for surveillance of healthcare-associated infections relies on manual chart review, data entry, coding, and data submission to the NIPH. For this reason, NPR is

currently unable to report cases e.g. on health care associated bloodstream infections to TESSy at ECDC.

The current system for monitoring vaccination programmes (coverage, effectiveness, and adverse events) lacks the linkage of information from the Norwegian Immunisation Registry (SYSVAK) with other health registries and administrative registries.

Compliance with Regulation (EU) 2022/2371 further underscores the necessity of integrated surveillance within the EU and associated countries. Additionally, it has the potential to alleviate the notification workload on frontline healthcare workers. Automation of information retrieval, including vaccination status and immigrant status and origin, from various registers streamlines case reporting to NIPH, enhancing efficiency and accuracy, and improving quality and timeliness of reporting to ECDC.

Specific objective 1: We aim to develop the technical infrastructure and legal environment for near real-time linkage of case notification data in the MSIS and SYSVAK with additional information from other registries for surveillance purposes.

Indicator: The number of registries that have an infrastructure to support daily linkage with MSIS. Currently: zero. Target: three.

Specific objective 2: We aim to pilot and implement integrated surveillance for respiratory infections with epidemic potential, SARI, healthcare-associated infections (HAI), other infectious diseases (zoonotic, vaccine preventable, bloodborne and sexually transmissible infections), and uptake, effectiveness, and adverse events of vaccination.

Indicator: Number of surveillance reports per quarter where integrated surveillance data have been used, and compliance with ECDC requirements. Currently: zero and some non-compliance. Target: five and no non-compliance.

Shortcomings of the MSIS Laboratory Database (MSIS LdB)

The MSIS LdB stores a copy of all test results for microbiological tests reported to the clinician. Currently the legal framework allows the permanent storage of directly identifiable information only for samples positive for a notifiable disease. There is a need for the permanent storage of directly identifiable information for all sample results, irrespective of the disease or analysis outcome. This will alleviate several shortcomings in the surveillance. This is a non-exhaustive list of examples of use and utility of permanent storage of directly identifiable information for all test results:

- Test results indicating a disease (e.g., rhinovirus infection) not notifiable to MSIS, are valuable for interpreting the trends for diseases that are notifiable (e.g., Covid-19). For instance, an increase in respiratory symptoms in the population, as seen in September and October 2023, may be attributed to a Covid-19 wave. However, further investigations reveal that a rhinovirus wave largely explains the situation.
- Negative test results, along with positive ones, determine the total testing activity. By having personal IDs on all test results, linkage with other data sources can elucidate testing activity in subgroups of the population. This can assist NIPH and municipal doctors in understanding if testing reaches everyone or is sufficiently targeted.
- The proportion positive in the population and among subgroups may be an important indicator for some diseases.
- Negative test results followed by a positive one from the same person contribute significantly to assessing when the patient was infected. For chronic diseases like hepatitis B in immigrants, this can help determine if the patient was infected before or after immigrating to Norway.
- Negative test results in a case may exclude some diagnoses.
- Healthcare-associated infections and outbreaks in healthcare settings can be caused by a wide variety of pathogens. By retaining all test results with personal IDs, linkage

with the NPR can identify healthcare-associated infections and outbreaks in healthcare institutions. This information and opportunities are lacking in today's MSIS.
- Recent national outbreaks of severe infections in hospitals with implications for primary care were caused by pathogens (Pseudomonas and Serratia) not notifiable to MSIS. The outbreaks could have been detected faster, and investigation would have been easier if we could fully harness the potential of the MSIS LdB.

This enhancement aligns with findings from United4Surveillance WP2, highlighting the importance of improving the standardisation and structure of data input from microbiological laboratories to the MSIS LdB. The in-house management and cleaning processes of data also needs to be streamlined and automated as much as possible. Furthermore, systems and algorithms need to be developed to translate data to a format that is suitable for surveillance. A more structured MSIS LdB will provide new opportunities for real-time surveillance and quicker access to laboratory data.

Specific objective 3: We aim to improve the MSIS LdB infrastructure, structure and standardize the data input, streamline in-house data management, and develop systems for preparing data for surveillance purposes.

Indicator: The level of structure and standardization in data input is markedly improved. (A unit of measurement will be developed.)

Infrequent updating of the Norwegian Patient Registry (NPR)

The NPR is a registry of upmost importance which through linking to MSIS may enhance surveillance. NPR has administrative and ICD-10 codes on every encounter (ambulatory or admission) with specialised health services, including all public hospitals. However, reporting from the health services to NPR is not timely, jeopardising the needs for near real-time surveillance. Furthermore, the infrastructure is partly outdated and cannot support efficient supply of data for infectious disease surveillance.

There is a need for an improved infrastructure that can provide an automated daily flow of health data from health services to NPR and from NPR to the Analysis Hub for surveillance.

Specific objective 4: We aim to improve the infrastructure of the NPR and pilot more frequent collection of data from hospitals and facilitate timely linkage with MSIS and other registries.

Indicator: Frequency of data collection from hospitals. Currently: monthly: Target: daily.

Indicator: Frequency of data distribution from NPR to the Analysis Hub. Currently: none. Target: daily.

Slow and incomplete paper notifications

Both clinical microbiological laboratories and clinicians has a duty to report notifiable cases to MSIS. When the analysis in a clinical microbiological laboratory indicate that the patient is infected by a notifiable disease, the laboratory prompts the patient's clinician to notify the case to MSIS. The laboratory also notifies MSIS directly, but this notification does not include much relevant epidemiological information about the case.

Upon receiving notification prompts, clinicians are required to fill out a notification form, either on paper or digitally via a dedicated secure web portal, providing essential information such as patient identification, profession, time and place of infection, indication for testing, transmission route, signs and symptoms, and other pertinent details. (Clinicians are also obligated to send a paper copy to the municipal medical officer.)

However, the existing system faces significant challenges. For only some 60 percent of laboratory-notified cases, the notifications are sent by clinicians to NIPH before reminders, and even fewer to municipal medical officers. This incomplete reporting results in a lack of

vital information leading to poor quality in the local and national surveillance. Furthermore, about 50 percent of clinicians' reports are submitted on paper, sent via traditional mail.

The current weaknesses became particularly evident during the Covid-19 pandemic:

1. The notification process is slow, time-consuming, and incomplete, with only a fraction of cases being reported by clinicians.
2. The system incurs significant expenses, requiring thousands of reminders to clinicians annually from NIPH, and manual data entry at NIPH.
3. The existing system is antiquated and inflexible with one standard form to be used for almost all notifiable diseases, with few possibilities for customized fields for the different diseases. This was exacerbated by the challenges faced during the Covid-19 pandemic.
4. Paper forms transmitted through mail pose data security issues.
5. Paper forms that must be manually entered in the MSIS database, opens for manual errors and is impractical during epidemics when the volume of reports explodes.

It is imperative to overhaul the notification process, addressing its inefficiencies and shortcomings.

Specific objective 5: We aim to develop the infrastructure for and then pilot an electronic notification pathway from clinicians to MSIS, with integration in electronic health records, eventually to replace paper forms.

Indicator: Proportion of general practitioners who will have the possibility of installing the new pathway in their electronic health records system. Currently: zero. Target: 70 percent.

Legal environment

There are several legal barriers in the national legislation for the improving the surveillance systems. The prerequisite for an integrated surveillance system is the permanent legal grounds for storage of directly person-identifiable information for all laboratory results in MSIS LdB, regardless of infectious agent and analysis result. Another main hurdle is that other registries are prohibited from sharing data for surveillance purposes. An analysis of these barriers is ongoing. There seems to be a clear need to propose changes to several regulations.

Specific objective 6: We aim to analyse the legal basis for integrated surveillance and identify the needs for changes to regulations to facilitate a) continuous and timely linkage of data from health registries and administrative registries with the surveillance systems, and b) permanent storage of person identifiable information for all laboratory results in MSIS LdB.

Indicator: Number of regulations where the necessary changes have been approved. Currently: zero. Target: five.

The need for improved epidemic intelligence (i.e., the basis for WP3)

Two main weaknesses impact the efficiency of the epidemic intelligence activities at NIPH.

Epidemic intelligence

NIPH plays a crucial role in epidemic intelligence by compiling signals and alerts from different sources and conducting risk assessments on the potential public health impacts. NIPH is the national focal point for both IHR and EWRS and the main collaborator in Norway with ECDC.

Information on outbreaks and other events can originate from both national and international alert systems, including those run by the WHO (IHR Event Information Site), the EU member

states and the Commission (EWRS), ECDC (EpiPulse and Threat Reports), NIPH (Vesuv), as well as from national and international animal, food, and water authorities.

Relevant signals are also monitored through the indicator-based surveillance system MSIS. The national reference laboratories, most of which are run by NIPH, are also important sources of information about possible outbreaks. Additionally, NIPH actively scans mass media for potential indicators of significant events.

The information collected through epidemic intelligence activities is necessary to fulfil NIPH's obligation to provide early notifications of events with potential public health impact to national, EU, and global health authorities. NIPH also produces a weekly summary report for dissemination to health authorities of all signals detected through epidemic intelligence activities.

However, the processing and analysis of information from a range of sources are minimally supported by digital tools. The current system is based on numerous manual procedures. The lack of a digital information and logging system for new information during event follow-up poses a challenge.

There is a compelling need for the development and implementation of a digital information system that can serve as the centralized repository for recording event details and follow-up information. By becoming the primary source for NIPH's early warnings and regular reports to various health authorities, the digital tool aims to streamline and enhance the efficiency of the epidemic intelligence process.

Specific objective 7: We aim to develop and implement at NIPH an epidemic intelligence information system that supports event recording, logging, follow-up, and the production of reports and early warnings nationally and internationally.

Indicator: Number of events recorded, and number of early warnings produced using the system. Currently: zero and zero. Target: 30 and three, respectively.

Outbreak investigations

When NIPH launches a formal outbreak investigation, usually with partners from other national and local authorities, the work is supported by an outbreak investigation database that stores exposure and outcome information about cases (and sometimes unexposed or disease-free controls). Such a database is currently made from scratch for each outbreak.

There is a need for an adaptable outbreak investigation database template. This template should be versatile enough to cater to the diverse nature of outbreaks that NIPH investigates, promoting efficiency and consistency in outbreak response efforts.

Specific objective 8: We aim to develop and implement an outbreak investigation database template that is ready to be used in outbreak investigations to record patient, disease and exposure information and produce reports.

Indicator: Number of outbreak investigations where the template has been used. Currently: zero. Target: five.

The need for capacity building (i.e., part of the basis for WP4)

The successful development of new infrastructure and the implementation of innovative surveillance functions hinge on the capabilities of skilled personnel. Specifically, proficiency in four key areas is paramount:

- Development and Maintenance of IT Systems: Competent individuals are essential for the creation, upkeep, and use of robust IT systems.
- Epidemic Intelligence Competencies: Expertise in epidemic intelligence, encompassing the evaluation of event information and risk assessment, is crucial.

- Analysis of Surveillance Data: Skilled professionals capable of utilizing tools like R-statistics for the comprehensive analysis of surveillance data, generating actionable results.
- Legal Background Knowledge: A solid understanding of legal contexts in both the Norwegian and EU settings (Regulation 2022/2317 and 2016/679) is necessary for adherence to regulatory frameworks.

NIPH has many highly qualified staff with varied and comprehensive skills. Strengthened surveillance and the new integrated approach will, however, require that more personnel upgrade their competencies. This will also contribute to sustainability of the improved surveillance capacities.

Specific objective 9: We aim to build capacity among NIPH staff and selected healthcare professionals, enhancing their skills and knowledge in surveillance methods and analysis and national and EU legal framework.

Indicator: Number of training sessions at for NIPH staff and for health care professionals. Currently: zero and zero. Target: six and 10.

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1.3 Complementarity with other actions and innovation — European added value

Complementarity with other actions and innovation

Explain how the project builds on the results of past activities carried out in the field and describe its innovative aspects. Explain how the activities are complementary to other activities carried out by other organisations.

Illustrate the European dimension of the activities: trans-national dimension of the project; impact/interest for a number of EU countries; possibility to use the results in other countries, potential to develop mutual trust/cross-border cooperation among EU countries, etc.

Which countries will benefit from the project (directly and indirectly)? Where will the activities take place?

The NORSURV project builds on several other European projects and collaborations. NIPH has been and is engaged in many Joint Actions, EU research projects and other collaborations where surveillance and surveillance systems are components, and where experience and knowledge gained from these are highly relevant to what we want to achieve with this application and improve our ability to report relevant data to ECDC and other EU agencies in a timely manner and in close collaboration with EU Member States.

The premise for many of these projects is that pathogens may cross borders in humans, animals, food, feed, or other objects. All European countries, as well as the Commission, may benefit from improved national surveillance systems. This advantage may take the form of early warnings from a country that has detected a threat to all other countries through the Early Warning and Response System (EWRS), or through a common European surveillance system, as outlined in Regulation 2022/2371, and the HERA IT Platform, providing a better situational overview and better opportunities to generate new knowledge. This represents genuine European added value, as the compilation of surveillance data yields more value than the sum of each country's surveillance results.

The NORSURV will add to this list of important projects and collaborations where NIPH participates, in some cases also with HDIR:

UNITED4Surveillance
The Joint Action UNITED4Surveillance aims to strengthen infectious disease surveillance systems at the national level, and improve integration, interoperability, and digitalization of data sources. The project runs from 2023 to 2025 and includes three technical work packages (WPs) focusing on outbreak detection (WP2), hospital surveillance (WP3), and One Health surveillance (WP4). NIPH participates in these technical work packages through e.g., national stakeholder mapping, gaps and needs analysis and piloting of promising approaches. The experiences and knowledge generated from our national pilots will be shared with member states to support integration of national health surveillance systems and to contribute to the development of interoperable, reliable, and comprehensive health systems

across Europe. The NORSURV project will directly build upon the experiences and results gained through the pilots in UNITED4Surveillance.

EU HIP *– EU interoperability with HERA's IT platform*
The NIPH is participating in the project on behalf of Norway where the purpose is to strengthen the national reporting systems in EU member states and associated countries with a view to establishing interoperability with the centralized IT platform of HERA (Health Emergency Preparedness and Response Authority). HERA's IT platform (recently named ATHINA) will bring together public health surveillance and medical countermeasures (MCM) information to support threat assessment and crisis management across Europe.

EJP One Health
This Horizon 2020 programme (2018-2023) consisted of 44 partner institutions and a range of different projects; from pure research projects within the domains food safety, AMR, and emerging infections to more collaborative projects which all aimed to building a network of experts on One Health and improve the quality and degree of existing collaboration both national and international and thus facilitate a better understanding of what One Health implies. NIPH participated in the projects, and this programme improved the collaboration nationally and internationally, and provided us with a large European network of researchers in this field (published results can be found on the OHEJP website). The results from EJP One Health have improved our knowledge of One Health Surveillance which will be utilised in the NORSURV project.

OH4Surveillance
The Direct Grant OH4Surveillance (EU4H-2022-DGA-MS-IBA3) is 3-year project starting up in 2024. NIPH (BEN) participates together with Norwegian Veterinary Institute (AE) in a consortium of 11 countries led by SSI (Denmark). The overall aim of the project is to facilitate improvement of existing surveillance and establishment of One Health surveillance that will provide animal and environmental health information to reduce the risk and harm of zoonotic diseases. The project focuses on human health and the protection of public health through the early detection of emerging and re-emerging zoonotic pathogens in animals and environment. The setting up and scaling up of surveillance activities will be done in closed collaboration with EFSA and ECDC, as well as other related projects (UNITED4Surveillance) to avoid duplication and achieve synergies. The results from OH4Surveillance (Improved One-health surveillance, collaboration human, animal and environmental health, and capacity building) will provide input to NORSURV on zoonotic diseases (selected priority pathogens, e.g. Highly Pathogenic Avian Influenza).

JA SHARP
The Joint Action SHARP (Strengthened International HeAlth Regulation and Preparedness in the EU) aimed to strengthen preparedness in the EU against serious cross-border health threats and to support the implementation of the International Health Regulations (IHR) (2005) and Decision 1082/2013/EU. NIPH was affiliated partner in JA SHARP and contributed to several WPs, including IHR core capacity strengthening and laboratory preparedness. NIPH supported developing and implementing a workshop in public health surveillance and detection of emergencies, based on the experiences of Covid-19. Outcomes highlighted the importance of dynamic and integrated approach to surveillance, and good quality data to improve detection, assessment, and response to health threats. The JA SHARP concluded that the common ability of the EU Member States and SHARP partners to prevent, detect and respond to biological outbreaks, chemical contamination and environmental and unknown threats to human health was strengthened. Many of the experiences of JA SHARP will be taken forward in NORSURV to improve surveillance and epidemic intelligence.

EU-JAMRAI-2
EU-JAMRAI-2 (the second EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections) gathers 30 countries (27 EU Member States plus Iceland, Norway, and the Ukraine) with the intention to assist countries to develop and implement their national action plans on AMR. With €50 million in financing from the European Commission, it is anticipated that EU-JAMRAI-2 will provide direct and sizable support to help MS in the core areas of AMR – surveillance, IPC, stewardship, and access to antibiotics and other AMR-related technologies. Regarding surveillance, EU-JAMRAI-2 aims to support countries to progress towards an integrated One Health surveillance of AMR, and thereby be directly relevant and create synergies with NORSURV. Participation in the EU-JAMRAI-2's surveillance work package provides Norway with a network for exchanging experiences and best practices, while also offering a strategic roadmap towards the implementation of a unified approach to surveillance across Europe.

ECDC
NIPH has had a close collaboration with ECDC since it was established. There is extensive professional collaboration between NIPH, other national public health institutes in Europe and ECDC in surveillance,

risk assessment, advice, and training. NIPH supplies ECDC's surveillance system TESSy with Norwegian data from our surveillance systems and participates in exchange of signals and information through EpiPulse. We provide input to ECDC's risk assessments and guidance documents, participate in ECDC's training programs EPIET and EUPHEM, and are involved in many disease-specific or subject-specific networks with the sister institutes, coordinated by ECDC. Each network has appointed contact persons from NIPH. NIPH is represented in ECDC's Advisory Forum, is appointed to be the designated Coordinating Competent Body for Norway and is the National Coordinator for contact with ECDC. NORSURV will directly build on our long-standing collaborations with ECDC and will enable us to provide data and other information to ECDC faster and of better quality.

Be Ready
NIPH is an active member of Be Ready which is an EU Coordination and Support Action (CSA) with a main aim to develop a Strategic Research and Innovation Agenda (SRIA) for pandemic preparedness. We propose to include research on improving surveillance systems into the SRIA, and when improving and strengthening our national surveillance systems, we will keep in mind how to improve data availability for researchers both nationally and through international collaborations.

PHIRI
PHIRI is the roll-out of the research infrastructure on population health information that aims to facilitate and generate the best available evidence for research on health and well-being of populations as impacted by Covid-19. PHIRI allows for better coordinated European efforts across national and European stakeholders to generate the best Covid-19 population health knowledge. In doing so, PHIRI is laying the foundation to build a Research Infrastructure on Population Health to be used to overcome future crisis and ensure the sustainability of the project. The intent is to support research across Europe through the identification, access, assessment and reuse of population health and non-health data to underpin public health policy decisions. This is achieved through a close collaboration with 41 partners across 30 countries over a period of 36 months (November 2020 - November 2023). PHIRI builds on the achievements of the BRIDGE Health and the Joint Action on Health Information (InfAct) projects. NIPH has mostly contributed with building up the European Health Information Portal: Homepage | European Health Information Portal that is an important tool giving access to population health information relevant both for surveillance and research.

E-SURE ECDC EHR-surveillance
The NIPH is an active member in the ECDC project "Design and implementation of multinational surveillance systems using routinely collected electronic health records (EHR) in EU/EEA", coordinated by Epiconcept. The project works towards designing country-specific SARI (severe acute respiratory infections) and BSI/AMR (bloodstream infections and BSI-antimicrobial resistance) surveillance systems by activities as developing a surveillance protocol and annual reports. The SARI part of E-SURE project also aims to further develop pre-existing systems and assist countries in setting up new systems by conducting evaluations of specified parts of the surveillance systems, such as case definitions used. In the BSI/AMR part of the E-SURE project algorithms for automated identification of HA (healthcare-associated) BSIs in hospitals will be established. In the algorithms data from MSIS LdB and The NPR will be linked by national identity numbers. Furthermore, incidence rates of HA BSIs per 100 000 patient days will be calculated. The algorithms and incidence rates may be integrated in the future integrated surveillance system. All results from this project will directly feed into the work on the NORSURV project.

EU-WISH
The general objective of EU-WISH (Wastewater Integrated Surveillance for Public Health) is to support the participating countries to enhance, extend and consolidate wastewater surveillance for public health. NIPH represents Norway as Competent Authority leading EU-WISH WP4 for Sustainability and Capacity Building, which based on the general objective described above, is the cornerstone of the action ensuring the implementation of wastewater surveillance for public health in the long term. EU-WISH is part of HERA's vision of a centralized IT platform (ATHINA), therefore complementary and connected with EU-HIP, EU-JAMRAI-2, HERA-WGS, DURABLE (NIPH is not member) and many other international initiatives and institutions. Wastewater surveillance development is not part of the new Direct grant, but the results from EU-WISH will complement the new surveillance hub being developed.

JA Terror
Joint Action TERROR, running to the end of 2024, aims to strengthen health care response to terrorist attacks with chemical and biological agents. Cross-sectoral cooperation is an integrated part of the project. NIPH leads the JA TERROR WP for sustainability and implementation in national strategies, thus gaining experience in developing deliverables and project outcomes ready for further implementation.

2. QUALITY

2.1 Concept and methodology

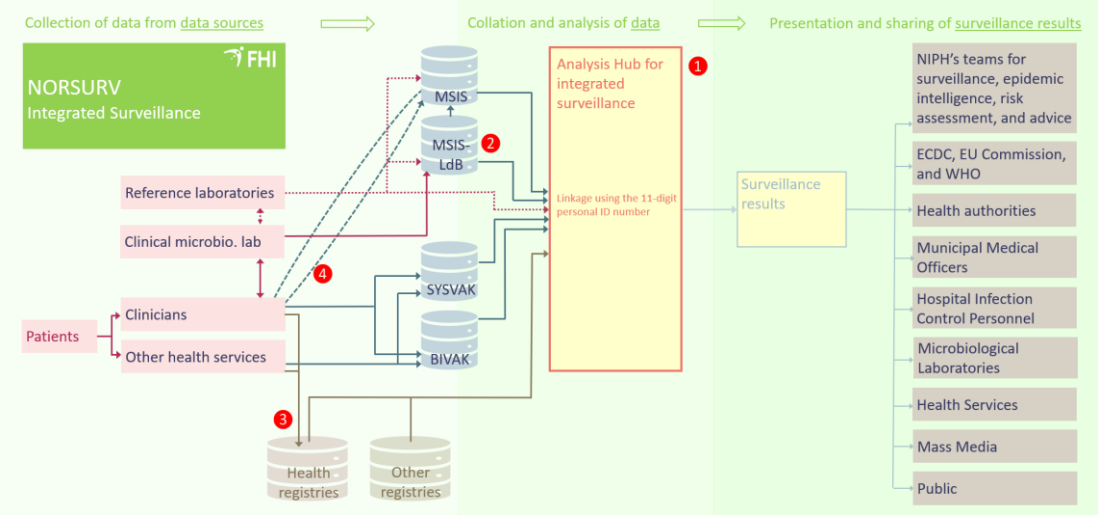
Concept and methodology

Outline the approach and methodology behind the project. Explain why they are the most suitable for achieving the project's objectives.

Integrated surveillance

In Work Package 2, we will develop and implement an advanced scalable and integrated surveillance system that enhances the timeliness, usefulness, effectiveness, flexibility and data security of infectious disease surveillance and vaccination monitoring, addressing the limitations highlighted during the Covid-19 pandemic, and ensuring compliance with EU Regulation (EU) 2022/2371, reducing the burden on frontline health care workers, and providing timely, complete, and accurate information for outbreak detection, situational awareness, risk assessment and public health interventions.

To achieve this, we will make four improvements to the current surveillance system to facilitate integrated surveillance.



1. Integrated Surveillance Core

The core concept of integrated surveillance is to gather information about the same case of an infectious disease from multiple sources in addition to case notifications in MSIS. In Norway, such linkage is possible using the patient's unique 11-digit personal ID number. The sources include the Population Register, the NPR (covering all government-funded health care for all patients in specialized health care, using ICD codes), the Norwegian Registry for Primary Health Care, the Norwegian Immunization Registry (SYSVAK), the Cause of Death Registry, the Medical Birth Registry of Norway, the Cancer Registry of Norway, the Norwegian Prescribed Drug Registry, and various healthcare quality and administrative registries. The health registries are based at NIPH.

We will leverage the Analysis Hub, NIPH's infrastructure (currently under development) for health registry data linkage (followed by de-identification) for research purposes for internal and external researchers.

Through planned and automated linkage of multiple registries, we can produce regular surveillance reports for users who need the information for infectious disease prevention and control. This includes our internal epidemic intelligence team who rely also on indicator-based surveillance to pick up signals of potential outbreaks. Regular, automated analyses that compare recent notification rates to historical baselines can be fed into the new Epidemic

Intelligence Information System (see letter A below), allowing our team to scan the overall situation rapidly. Any signal can be triangulated against other epidemic intelligence information and, if necessary, investigated further. Confirmed events will form the basis of early warnings, as appropriate, including through the EWRS. Additionally, we can create ad hoc reports as needed.

Linking allows us to supplement routine surveillance data with the following additional information:

- The patient's health status and healthcare utilization prior to the current illness, which can help define risk groups.
- The patient's health status and healthcare utilization (including use of antimicrobials) during the current illness, which can help measure the severity of the disease, such as hospitalization or death.
- The patient's health status and healthcare utilization after the current illness, which can help measure the sequelae of the disease.
- The patient's vaccination status, which can help measure vaccination effectiveness.
- Other information about the patient, such as occupation, household size, and country of origin/immigrant status, which can help define risk groups.

This strengthens the knowledge base for infection control, providing comprehensive information for targeted action. Furthermore, we will improve our ability to comply with the reporting requirements in Regulation 2022/2371.

The plan builds on groundwork performed in Joint Action United4Surveillance WP3. There will be a need for streamlining technical and legal procedures.

Additionally, the plan builds on experiences during the pandemic with the Emergency Preparedness Registry for Covid-19 (Prepared-C19), which was established under the Norwegian Health Preparedness Act § 2-4. Prepared-C19 collected information from all the above-mentioned registries in addition to other public registries, enabling rapid analyses to manage the Covid-19 pandemic. Prepared-C19 is a temporary registry, but its use provided important experiences on the potential benefits of a more permanent system of analysis based on linking information from different registries. Planning and establishing an improved equivalent of Prepared-C19 will provide a better foundation for building sustainable and reliable solutions with adequate functionality.

2. Improved MSIS Laboratory Database (MSIS LdB)

The database collects copies of all results of microbiological analyses reported to the clinicians and provides the main input to the MSIS registry of notifiable disease cases. We will enhance the database by permanently storing all test results with personal ID numbers. This will significantly enhance the usefulness for surveillance.

Building on experiences in United4Surveillance WP2, we will improve standardization and the structure of input from laboratories. Furthermore, we will automate our data cleaning and collation processes. We will also develop algorithms to translate incoming data into a format suitable for surveillance analysis.

3. Timely updating of the Norwegian Patient Registry (NPR)

The NPR is the most important of the other health registries that we plan to link with the surveillance systems. The NPR contains administrative and ICD-10 codes for every encounter (ambulatory or admission) with specialized health services, including all public hospitals. With linkage to MSIS and MSIS LdB we can determine which of the infected patients that ended up in hospital and their length of stay and other information. With linkage to SYSVAK we can look for any unusual patterns of admissions following vaccinations.

However, reporting from the health services to NPR is not timely, jeopardizing real-time surveillance. Furthermore, the infrastructure is partly outdated and cannot support efficient supply of data for infectious disease surveillance.

Therefore, we will improve the infrastructure and pilot more timely reporting from hospitals and other health services to the NPR at NIPH. This way, we can obtain more timely surveillance results on, for example, the incidence of hospitalization for influenza, Covid-19, SARI, or a future pandemic disease.

This includes development of the ways and formats of reporting to NPR, the treatment of received health data records, and the distribution of data. NIPH needs to work in companion with the reporting units (e.g., hospitals and health care trusts), the specialist health care sector and the various users of the data. The creation of new and patient-oriented trajectories for activities in the specialized health care needs to be given special attention.

4. Electronic notification pathway:

We will develop and pilot a new infrastructure for an integrated and electronic notification data flow. This will eventually replace the current paper forms sent from doctors in general practice and hospitals to NIPH, where the information needs to be manually coded and entered into the MSIS database. Electronic notifications will also replace manual notifications entered into the MSIS form. We will strive to achieve a notification tailored to each disease group and, if possible, extract data directly from the electronic health records. In this regard, we may also explore the possibility of collecting some of the necessary information directly from patients, rather than relying solely on their healthcare provider.

Legal issues

Improvements number 1 and 2 above will require changes in national regulations:

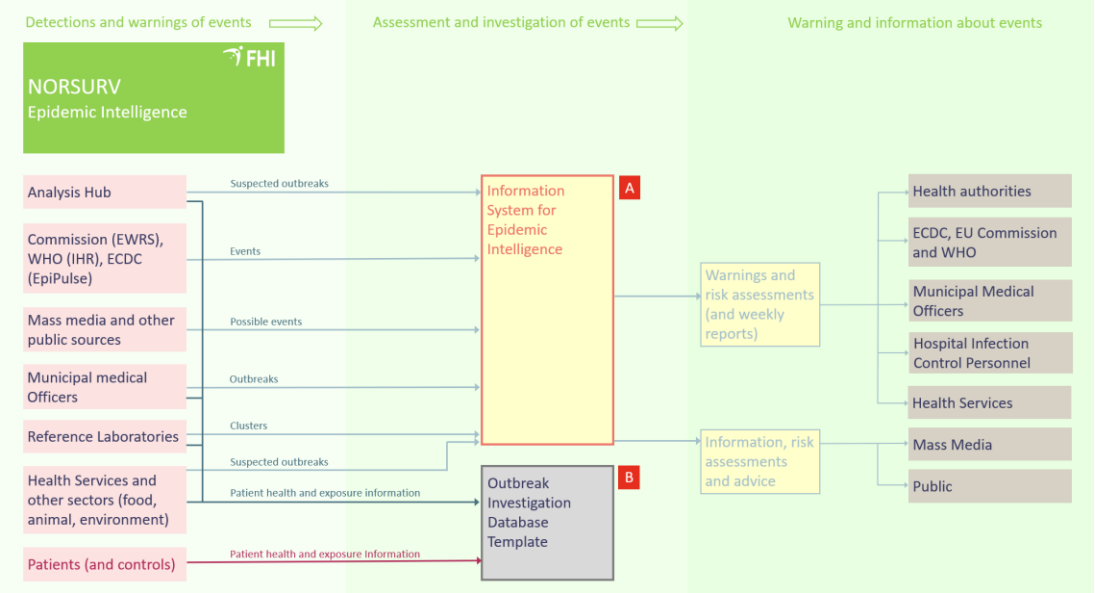
- Linkage of registries for surveillance purposes is currently not allowed.
- Currently, the legal framework only allows the storage in the MSIS LdB of directly identifiable information for samples that are positive for a notifiable disease, not for all the other negative and positive samples.

We will work with the Ministry of Health to achieve the necessary changes in the regulations.

Epidemic intelligence

In Work Package 3, we will develop a modern, robust, and efficient digital infrastructure for epidemic intelligence at NIPH, ensuring timely and effective surveillance and management of infectious disease events, and potentially also for other events in the future, and facilitating event recording, logging, follow-up, outbreak investigations, and the production of reports and early warnings.

To achieve this, we will develop and implement two tools to support epidemic intelligence.



A. Information System for Epidemic Intelligence:

An "event" of interest for NIPH's epidemic intelligence may include a suspected or confirmed outbreak of an infectious disease, a suspected or confirmed individual case of an infectious disease subjected to immediate notification to NIPH, a mass media report about a potential outbreak, a natural event (such as flooding) that could lead to outbreaks, or any other situation requiring NIPH's infectious disease expertise, assessment, and potential further management and notification.

Sources of information about events include alerts from Norway (as described above), alerts from abroad through the EU's EWRS or WHO's IHR system, and surveillance results from indicator-based monitoring (through the Analysis Hub as seen in the figure above) and reference laboratories.

NIPH already has procedures in place to detect, assess and report such events as part of epidemic intelligence. NIPH immediately notifies some events to other authorities in accordance with current national and international regulations (Regulation 2022/2371 and IHR), while other events are summarized in a weekly report to the authorities.

Since this work is currently done manually and documented only in word processing files, we will develop, deploy, and implement a centralized information system for epidemic intelligence at NIPH. The system must allow registration of each event (without identifying patient information) with further documentation of risk assessment, management, and automated notification if necessary to other national or international bodies, as well as automatic extraction for the weekly report.

The information system will be a simple database with a few fields and an interface that makes it easy to enter information and produce warnings and reports, as well as log our assessment and management of the event and produce statistics on the events we have managed.

We will consult with some other public health institutions and ECDC in designing the information system to ensure harmonization and potential sharing of the concept with other institutions in Europe where possible.

We expect that this information system will achieve a measurable reduction in manual procedures associated with event logging and follow-up, ensure a comprehensive and standardized approach to recording and reporting epidemic intelligence information, ensure documentation and reduce the time taken to produce reports.

B. Outbreak Investigation Database Template:

In certain outbreaks, NIPH initiates and coordinates an outbreak investigation. Examples include outbreaks where food items are a possible source of infection, in which case the investigation is conducted in collaboration with the relevant Reference Laboratory, the Norwegian Food Safety Authority, the Norwegian Veterinary Institute, and municipal doctors, and outbreaks of healthcare-associated infections, in which case the investigation is conducted in collaboration with the relevant Reference Laboratory, infection control physicians at the relevant healthcare institutions, municipal doctors, and the relevant Regional Competence Centres for Infection Control in Healthcare.

During investigations, we record detailed information about individual patients (with personal ID number) who are part of the outbreak, such as the patients' time and place of infection, mode of transmission, and exposures to potential sources of infection. This enables us to produce line lists. Some of the information may come from interviews with the patients themselves. The information collected is necessary for the investigation and management of the outbreak. The information can be recorded under the Health Emergency Preparedness Act § 2-4.

In some outbreaks we will also record information about persons who have not been exposed to suspected sources of infection (unexposed persons in a cohort study) or persons who have not been ill (control persons in a case-control study).

For each outbreak, such a database is created from scratch, often only in a spreadsheet. We will now create a template for such an outbreak database. The template should be easy to use for future outbreaks to be investigated, possibly after some tailoring to the outbreak in question. The template must therefore allow for some flexibility. The database must comply with national regulations and GDPR for data protection, ensure access control, and provide simple solutions for data entry, analysis, and reporting.

We expect that this will achieve a measurable reduction in manual procedures associated with outbreak investigations and support a standardized approach to outbreak investigations.

Capacity building

In Work Package 4, we will build capacity among NIPH staff and selected healthcare professionals, enhancing their skills and knowledge in surveillance methods and analysis and national and EU legal framework.

To achieve this, we will implement the following activities:

- Trainings sessions: We will participate in the ECDC and Commission's Train-the-trainers-course and follow up these with national webinars for our own staff and relevant personnel in other agencies and health care services.
- Targeted recruitment of additional personnel.
- On the job training and internal training sessions for NIPH staff, including in analysis of surveillance data using R.
- Site visits to relevant sister institutes.

Capacity building initiatives play a pivotal role not only in enhancing project-specific skills but also in supporting the dissemination and sustainability of project outcomes for lasting public health benefits.

2.2 Consortium set-up

Consortium cooperation and division of roles (if applicable)

Describe the participants (Beneficiaries, Affiliated Entities and Associated Partners, if any) and explain how they will work together to implement the project. How will they bring together the necessary expertise? How will they complement each other?

In what way does each of the participants contribute to the project? Show that each has a valid role and adequate resources to fulfil that role.

***Note:** When building your consortium you should think of organisations that can help you reach objectives and solve problems.*

The NORSURV consortium has two participants:

Norwegian Institute of Public Health (NIPH)

The Norwegian Institute of Public Health (NIPH) is the coordinator, main beneficiary, and competent authority of the NORSURV project.

About the NIPH

NIPH's mission is to produce, summarise and disseminate knowledge to support good public health efforts and healthcare services. NIPH has 1250 employees. The three core tasks of the NIPH are:

- Knowledge: more, better, and faster knowledge for health and sustainable services
- Preparedness: new solutions and knowledge to protect life and health
- Infrastructure: health data, laboratories, and services for the future

NIPH is the Norwegian government's expert institute for infectious disease prevention and control. It is mandated by laws and regulations to perform surveillance, health analysis, and research, to run the national vaccination programmes and to give advice to national and local health authorities and the health services.

NIPH is the Norwegian partner institute of ECDC and participates in ECDC's disease and laboratory networks and the ECDC Advisory Forum.

NIPH-assets that are especially relevant for the NORSURV project include:

- The surveillance systems for community acquired and healthcare-associated infections and vaccinations.
- The epidemic intelligence functions, including national focal point for the EU Commission's EWRS and WHO's IHR warning system, and the national field epidemiology team.
- Most of the national reference laboratories, including those for respiratory pathogens with pandemic potential, such as influenza virus and SARS-CoV-2.
- Infrastructure of the National Vaccination Programmes
- All national health registries and related infrastructure.
- Research cohorts and biobanks.
- Centre for Epidemic Interventions Research (CEIR)
- Active networks with the municipal medical officers (the municipal public health doctors), the clinical microbiological laboratories, the hospital infection control personnel, and the municipal public health and vaccination nurses.
- Close collaboration with the national health authorities: the Directorate of Health, the Norwegian Food Safety Authority, the Norwegian Medical Products Agency, and the Ministry of Health
- Close collaboration with our sister institute in the fields of animal health, fish health, and food safety, the Norwegian Veterinary Institute

The NIPH has competence in epidemiology, microbiology and virology, immunology and vaccinology, entomology, statistics, modelling, bioinformatics, microbiology, immunology, health psychology, health economics, evidence-based medicine, IT, and digitalisation.

Contributions from NIPH to NORSURV

NIPH will lead the project and all work packages and perform most of the work, involving mainly experts in surveillance, epidemic intelligence and IT architecture and infrastructure.

The NORSURV is a joint project including two of NIPH's divisions:

- **Division of Infection Control.** The division gives advice based on insight and scientific understanding that is generated from research, systematic research reviews and reports. The division has responsibility for preparedness related to risk, prevention, detection, and investigation of outbreaks of infectious diseases. This applies both to ongoing preparedness for minor outbreaks and for major incidents. We monitor the epidemiological situation nationally and participate in monitoring the international epidemiological situation. Our field epidemiology team helps the municipal health and care service with investigation, clarification, and measures to stop outbreaks of infection. The division has a national preparedness laboratory for highly pathogenic agents and agents that can be used in bioterror, with 24-hour preparedness. We have three on-call duty officers who are also part of the preparedness. The division has the ambition to digitise and automate several of our processes and be at the forefront when it comes to adopting new technology at the right time, both among the agencies and partners in Norway and the public health institutes in Europe. This applies, among other things, to data collection, data quality assurance, monitoring, analysis, modelling, presentation and availability of health data and statistics, compilation of knowledge, preparation of reports and advice. AI will play a key role in this.
- **Division of Health Data and Digitalization.** The division has expertise in health registries, population-based health surveys and biobanking, together with IT/digitalisation knowledge. One of the division's most important tasks is the modernisation and comprehensive development of the NIPH's infrastructure for health registries and health studies. The division is also responsible for receiving, collecting, and managing health data and biological material. This includes both handling data responsibly on behalf of NIPH as register administrator and working with quality assurance. The division also conducts its own research based on health registries and health studies, including the use of genetic data.

Other parts of the institute will contribute at a minor level. The project is based in NIPH's main Oslo campus with some input from offices in Bergen, Trondheim and Tynset.

Norwegian Directorate of Health (HDIR)

The Norwegian Directorate of Health is the affiliated entity in the NORSURV project.

About the HDIR

The HDIR reports to the Ministry of Health and Care Services. The HDIR is a government authority with expanded responsibility for analysis and advice in relation to public health in Norway's care services, and for digitalisation in the health services.

The HDIR implement government policies and have other responsibilities that are delegated by the ministry, including the authority to apply and interpret laws and regulations about public health and the health and care sector, including laws and regulations concerning infectious disease prevention and control.

In implementing policy, HDIR carry out work on behalf of the government and parliament. This may involve, for example, executing action plans and campaigns, or awarding grants in line with the objectives set by parliament.

HDIR's mission is to contribute to more people being in good health, to reducing health inequalities between people and to good and safe treatment in the health and care services. The directorate also helps to ensure that the services that patients and users receive are coordinated. In addition to this, the directorate facilitates improved community safety and preparedness.

HDIR has 850 employees at offices in Oslo, Trondheim and Ålesund.

Contributions from the HDIR to NORSURV

HDIR will assist the project with expertise in health registry and personal data protection law in Norway and the EU, with advice on relevant standards in digitalisation of the health sector, and advice on the health authorities' needs for surveillance results and early warnings.

2.3 Project teams, staff and experts

Project teams and staff

Describe the project teams and how they will work together to implement the project.

List the staff included in the project budget (budget category A) by function/profile (e.g. project manager, senior expert/, junior expert, trainers/teachers, technical personnel, administrative personnel etc. — use the same profiles as in the detailed budget table, if any (n/a for prefixed Lump Sum Grants)) and describe briefly their tasks. Provide CVs of all key actors (if required).

Name and function	Organisation	Role/tasks/professional profile and expertise
Preben Aavitsland	NIPH	Project Leader. WP1 and WP Lead.
Trine Orten Groven	NIPH	Project Co-Leader.
Bjørn Iversen	NIPH	Overall planning, supervision, and coordination. WP4 Lead.
Karin Nygård	NIPH	Overall planning, supervision, and coordination.
Hanne-Merete Eriksen Volle	NIPH	WP 2, Task 2.7 Task lead, planning, coordinating, developing new integrated surveillance for healthcare-associated infections (HAI)
Umaer Naseer	NIPH	WP 2 Participate in planning, coordinating, developing new integrated surveillance for various diseases. WP 3 Lead. Develop and implement information system for epidemic intelligence and outbreak investigation database template
Trude Lyngstad	NIPH	WP 2, Task 2.8 Planning, coordinating, developing new integrated surveillance for zoonotic and food-borne diseases
Solveig Jore	NIPH	WP 2, Task 2.8 Planning, coordinating, developing new integrated surveillance for zoonotic and food-borne diseases
Hilde Kløvstad	NIPH	Overall planning, supervision, and coordination
Trine Paulsen	NIPH	WP2, Task 2.6 Planning, coordinating, developing new integrated surveillance for respiratory infections
Richard White	NIPH	WP 2 infrastructure, automated surveillance analyses and reporting
Beatrice Valcarcel	NIPH	WP 2 infrastructure, automated surveillance analyses and reporting
Hinta Meijerink	NIPH	WP 2 Taks 2.6/ 2.8 developing system for integrated surveillance of vaccine effect and vaccine coverage, including data cleaning, analyses, and reporting

Robert Whittaker	NIPH	WP 2 Task 2.6 and task 2.8 developing integrated surveillance for HIV, STIs and viral hepatitis- including data cleaning, analyses, and reporting
Jesper Dahl	NIPH	WP2 Task 2.6 and 2.8 developing system for integrated surveillance of respiratory infections, vaccine effect, vaccine coverage and side-effects, including data cleaning, analyses, and reporting
Håkon Bøås	NIPH	WP2 Taks 2.6 developing system for integrated surveillance of vaccine effect and vaccine coverage, including data cleaning, analyses, and reporting
Elina Seppälä	NIPH	WP2 Task 2.6 developing system for integrated surveillance of respiratory infections including data cleaning, analyses, and reporting
NN	NIPH	Database manager, tasks 2.1, 2,2, 2.6, 2.7, 2.8, and 3.1
Anne Marte Bakken Kran	NIPH	WP 2, tasks 2.2, 2.4, and 2.5. Develop infrastructure for and pilot an electronic notification pathway from clinicians to MSIS. Participate in analysing the legal basis for integrated surveillance and identify the needs for changes to regulations. Improve the MSIS LdB infrastructure, structure and standardize the data input, streamline in-house data management, and develop systems for preparing data for surveillance purposes.
Astrid Løvlie	NIPH	WP 2, tasks 2.4 and 2.5. Develop infrastructure for and pilot an electronic notification pathway from clinicians to MSIS. Participate in analysing the legal basis for integrated surveillance and identify the needs for changes to regulations to facilitate. WP 3, task 3.1 and 3.2. Develop and implement information system for epidemic intelligence and outbreak investigation database template.
Nina Aasand	NIPH	WP 2, tasks 2.2 and 2.5. Improve the MSIS LdB infrastructure, structure and standardize the data input, streamline in-house data management, and develop systems for preparing data for surveillance purposes. Participate in analysing the legal basis for integrated surveillance and identify the needs for changes to regulations to facilitate permanent storage of person identifiable information for all laboratory results in MSIS LdB
Rossa O'Donnell	NIPH	Co-lead WP 3, Programme / Project Management with extensive healthcare experience
Elisabeth Hagen	NIPH	Co-lead WP 2, Programme / Project Management with extensive healthcare experience
Eyvind Helland	NIPH	Task 2.3, Data distribution
Geir Ivar Andreassen	NIPH	Task 2.3, Lead
Marianne Solheim Salvesen	NIPH	Legal advisor
Kjell Rune Skaaraas	NIPH	Task 2.3, Developer
Kjell Vågenes	NIPH	Task 2.3, Developer
Gülfem Aytekin	NIPH	Task 2.3, Developer

Stein Olav Hamland Gystad	NIPH	Task 2.3, Data quality
Ragnhild Bremnes	NIPH	Task 2.3, Data quality
Bente Urfjell	NIPH	Task 2.3, Data quality
Wenche Langfjord	NIPH	Task 2.3, Data quality
Research Administrative coordinator	NIPH	Research administrative coordination on all WPs, mainly WP1
NN	NIPH	Epidemiologist, surveillance specialist, WP2 and WP3
NN	NIPH	Legal advisor
Anders Skyrud Danielsen	NIPH	WP 2, Task 2.7 Planning, coordinating, developing new integrated surveillance for healthcare-associated infections (HAI)
Torunn Alberg	NIPH	WP 2, Task 2.7 Planning, coordinating, developing new integrated surveillance for healthcare-associated infections (HAI)
Petter Langlete	NIPH	WP 2, Task 2.7 Planning, coordinating, developing new integrated surveillance for healthcare-associated infections (HAI)
Heidi Lange	NIPH	WP3. Develop and implement information system for epidemic intelligence and outbreak investigation database template
Thale Berg	NIPH	WP3. Develop and implement information system for epidemic intelligence and outbreak investigation database template
Petter Heradstveit	NIPH	WP3. Develop and implement information system for epidemic intelligence and outbreak investigation database template
Alexander Josef Theo Wetzel	NIPH	WP2, Business Architect
Øistein Klevhus	NIPH	Task 2.4, Developer
Ståle Haugenes	NIPH	Task 2.4, Developer
Beate Margrethe Huseby	HDIR	Senior advisor, analytics director, Analytics, preparedness
Geir Kristian Hansen	HDIR	Senior advisor, Architecture, infrastructure, digitalization
Idunn Løvseth Kavlie	HDIR	Senior advisor, National e-health strategy, digitalization
Mirela Slomic	HDIR	Senior advisor, Infection prevention and control, preparedness
NN	HDIR	Senior advisor, Automatization, digitalization
NN	HDIR	Senior advisor, Legal expertise

NN	HDIR	Senior advisor, Health care personnel, end-user expertise
NN	HDIR	Senior advisor, Preparedness, crisis management
NN	HDIR	Senior advisor, Preparedness, crisis management
Norunn Elin Saure	HDIR	Department director, coordination, Coordination, digitalization
Ragnhild Angell Holst	HDIR	Senior advisor, Legal expertise
Sevala Malkic	HDIR	Senior advisor, Coordination, strategic management
Tricia Larose	HDIR	Senior advisor, Analytics

Outside resources (subcontracting, seconded staff, etc)

If you do not have all skills/resources in-house, describe how you intend to get them (contributions of members, partner organisations, subcontracting, etc.).

If there is subcontracting, please also complete the table in section 4.

For the tasks within WP2, it is vital to use the subcontractor that operates the technical infrastructure of the NIPH is within their servers. As this contractor is a national service provider of e-health solutions, NIPH is obliged to use them in accordance with internal procurement procedures as a consequence of administrative decision by the Ministry of Health for the Norwegian health sector. NIPH will enter into a specific contract with the subcontractor for this project.

Experts (if applicable)

*Explain if **national** and/or **international experts** will be nominated by national authorities to support the project implementation. Describe the specific professional and technical expertise and experience of each proposed expert and their contribution to the project implementation. Provide CVs (if required).*

Minimum requirements:

- *Qualification: A level of education which corresponds to a Bachelor's degree.*
- *Professional experience: At least 4 years of proven experience as set out in the Call document*
- *Other skills: ability to work in English (minimum B2 level)*

NIPH has for many years had broad and multi-faceted collaborations on surveillance and surveillance systems with colleagues and institutions in Norway, in the Nordic countries, other European countries and globally, with several EU agencies, including ECDC, and with international organisations like WHO and IANPHI.

NIPH has been and is engaged in many Joint Actions, EU research projects and other collaborations where surveillance and surveillance systems are components. Through these collaborations, we have established a large network of national and international experts whom we can contact and discuss challenges that may occur during the implementation of the NORSURV Project. We believe it would narrow the range and limit us, if we were to name one or a few experts to consult for this grant.

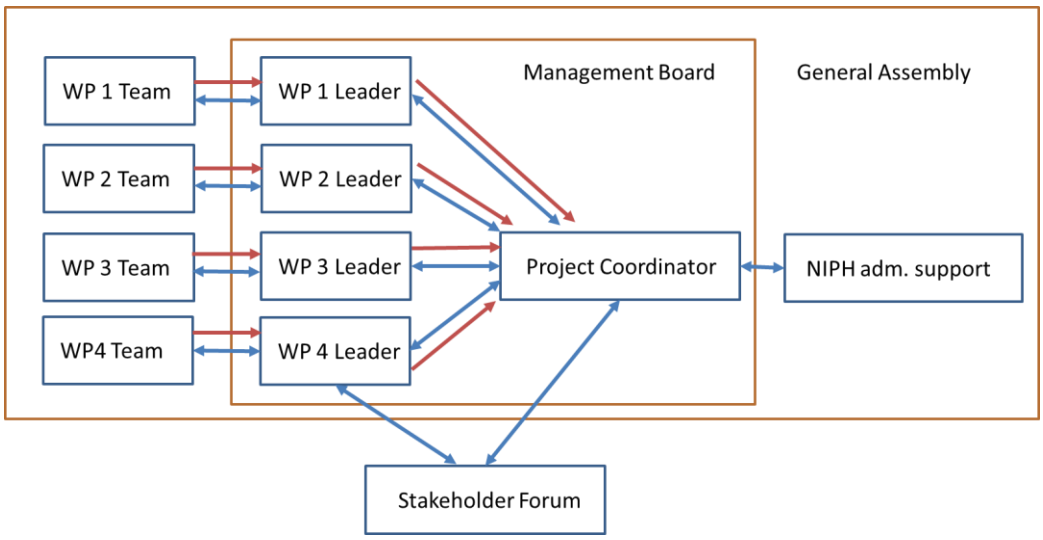
2.4 Consortium management and decision-making

Consortium management and decision-making (if applicable)

Explain the management structures and decision-making mechanisms within the consortium. Describe how decisions will be taken and how regular and effective communication will be ensured. Describe methods to ensure planning and control.

***Note:** The concept (including organisational structure and decision-making mechanisms) must be adapted to the complexity and scale of the project.*

The management structure is shown schematically in the figure below, with the flow of communication (blue) and responsibility (red) shown with the direction of arrows.



The project will have regular **General Assembly** meetings (1-2 per year) for control of advancement of the project. The Project Coordinator chairs the meetings. Both partners have a role in these meetings and both partners are responsible for the progress. Based on the milestones, STOP/GO decisions will be prepared by the Project Coordinator when necessary and will be further discussed and settled at Management Board meetings.

The **Management Board** will have the general responsibility for the project's organisation, development, and planning. The Board will be established at the NIPH and be composed of the Project Coordinator and Work Package Leaders and Co-leaders. The Project Coordinator shall chair all meetings of the Management Board. Minutes of Management Board meetings shall be sent by the Project Coordinator to the General Assembly Members for information. During these meetings progress and (potential) bottlenecks will be discussed with the goal to deal with or eliminate any barriers that can develop during the project and might hinder overall progress.

An **Administrative Management Support Team** will be established with the Project Coordinator and a designated project manager to support the consortium and serve as a contact point for external contacts. The management team will ensure that all project participants have the necessary knowledge of the Consortium Agreement and the Grant Agreement. Coordination will include organizing a project kick-off-meeting, General Assembly meetings and Project Management Board meetings. A management structure plan will be drawn up.

The Project Coordinator is an intermediary between the European Commission and the NORSURV project, as well as other European initiatives that align with NORSURV. The Project Coordinator is overseeing the day-to-day management and administration of the project, through tasks described in WP1.

Work Package Leaders are responsible for the progress of their WP and alignment with other WPs. They partake in Management Boards meetings, where they report regularly on the progress of their WP. WP Leaders lead and organize the Work Package Teams consisting of the other key WP-investigators.

Work Package Teams perform Tasks described in the WP description and report regularly to the WP Leaders. WP team members will stay in touch via email, telephone, or video conference – or in the case of a shared working location, in person.

Stakeholder Forum is comprised of experts and representatives of relevant stakeholders (see chapter 3.1) with leading and unique competence in areas that are crucial for NORSURV. Among these are representatives of national health authorities, municipal medical officers, clinical microbiological laboratories and hospital infection control personnel. We will leverage our on regular ongoing webinars and other meetings wit these groups to recruit members to the Stakeholder Forum. Through at least biannual meetings, the Forum members will be updated about plans and progress and invited to provide relevant input, feedback, and recommendations to the project.

Communication across the project is crucial to achieve effective work processes, address dependencies and mitigate risks. In this regard, it is an advantage that the project involves only two partners, NIPH and HDIR. These two agencies work closely together in several areas already, including in EU funded Joint Actions, and many of the staff members have previously worked in the other agency. In the NIPH, almost all the work will be performed by two organisational domains. The involved personnel from these domains already know each other and work together. This facilitates the day-to-day communication. In addition to the Management Board meetings, there will be other, less formal regular and ad hoc meetings as needed, between WP teams. Furthermore, an internal newsletter edited by the project coordinator will be available to everyone who is involved in the project.

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2.5 Project management, quality assurance and monitoring and evaluation strategy

Project management, quality assurance and monitoring and evaluation strategy

Describe the measures planned to ensure that the project implementation is of high quality and completed in time.

Describe the methods to ensure good quality, monitoring, planning and control.

Describe the evaluation methods and indicators (quantitative and qualitative) to monitor and verify the outreach and coverage of the activities and results (including unit of measurement, baseline and target values). The indicators proposed to measure progress should be relevant, realistic and measurable.

The partners are responsible for the management of their own tasks and work and the communication with NIPH. NIPH is responsible for the overall management and coordination of the project and communication with the European Commission.

Collaborative tools will be established for the communication within NORSURV including library for documents (protocols, articles, minutes of meetings, reports), calendar of events, mailing lists and tools to follow up routines for good operating practices. This will ensure good monitoring possibility for the Management Board of projects' progress.

Project Coordinator will be able to take decisions required to ensure the smooth progress of the project as long as they are not critical for the delivery of the project objectives. When necessary, the Coordinator and WP Leaders will interact with the Administrative Management Support Team to identify the most appropriate decisions. The Project Coordinator will need to inform or consult with the Management Board on significant issues, especially in case where the achievement of the project milestones is in doubt.

The Management Board will be the project's formal decision-making body at the overall project level. Any significant changes to the research programme will have to be approved by it. Where such changes may have an impact on the contractual obligations of the project, the European Commission Project Officer in charge will be consulted. In case of disputes on a specific (minor) issue, the Project Coordinator will have the authority to intervene to try and solve the dispute amicably. If this effort fails, the dispute will be settled by the Management Board, always ensuring that any decisions made are in line with the European Commission requirements.

Quality assurance and contingency planning will be implemented proactively in NORSURV, which maximizes the probability of reaching the key project objectives. In general, risks will be analysed by probability of occurrence (H/M/L) and impact on the project deliverables (H/M/L) to give an overall Risk Level. Any potential risks are identified and listed in the Table 2.7. The likelihood and impact of each risk will be prioritized according to importance using the risk table, followed by a plan for the management of each potential risk. The Project Coordinator will act as the overall responsible for continuously carrying out risk management in the project, including recommendations to the MB on the implementation of effective procedures for risk identification and mitigation, to minimize any potential negative effects. The table will be updated throughout the lifespan of the project as new risks are identified and existing risks

are addressed. It will be presented and reviewed yearly in the Management Board and General Assembly meetings.

Nearing the completion of the project, an end-evaluation process will be carried out, following NIPH's usual procedures for evaluation of externally funded projects. The Project Coordinator will compose two summary reports (one for the consortium and one for internal evaluation purposes). These reports will follow, and be based on, an end-review project meeting where aspects like the functioning of the project organisation and information flow between the governance bodies; the degree in which the objectives were met and the performance of each WP and tasks against their own objectives and quality standards, as well as measure the impact of the project grant at both, EU level and nationally, will be discussed with the General Assembly.

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2.6 Cost effectiveness and financial management

Cost effectiveness and financial management *(n/a for prefixed Lump Sum Grants)*

Describe the measures adopted to ensure that the proposed results and objectives will be achieved in the most cost-effective way.

Indicate the arrangements adopted for the financial management of the project and, in particular, how the financial resources will be allocated and managed within the consortium.

⚠ *Do NOT compare and justify the costs of each work package, but summarize briefly why your budget is cost effective.*

NIPH will manage the entrusted funds for the project according to NIPH's strict policies and guidelines on procurement, fiscal management, and internal control and within the conditions set in the grant agreement.

NIPH's policies on procurement and fiscal management follows the strict regulations for the public sector in Norway. NIPH's fiscal management is approved and controlled by the Office of the Auditor General of Norway.

Goods and services are solicited through a competitive process. The procurement protocol for goods and services at NIPH ensures best value for money, fairness, integrity, transparency, and verifiability. To ensure value for money, costs will be optimized to meet the quality necessary to for requirements of the project, while considering the potential risk factors.

The project leader will ensure that the funds are utilized in accordance with the grant agreement and in compliance with the financial regulations.

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2.7 Risk management

Critical risks and risk management strategy

Describe critical risks, uncertainties or difficulties related to the implementation of your project, and your measures/strategy for addressing them.

Indicate for each risk (in the description) the impact and the likelihood that the risk will materialise (high, medium, low), even after taking into account the mitigating measures.

***Note:** Uncertainties and unexpected events occur in all organisations, even if very well-run. The risk analysis will help you to predict issues that could delay or hinder project activities. A good risk management strategy is essential for good project management.*

Risk No	Description	Work package No	Proposed risk-mitigation measures
1	Legislative changes foreseen (in task T2.5) may be delayed or not come into effect during the project duration. Likelihood: medium; impact: high.	WP2	We will continue working with the Ministry of Health, already before project start, to prepare the groundwork for the necessary legislative changes. Substantial legal expert resources will go into task T2.5, and, if necessary, this

			will be supplemented by further institute resources. A Governmental White Paper already points to the need for improving surveillance. A recent interpretation of the current law indicates that linkage of registries is already allowed if the end results is surveillance statistics. This provides a basis for further legal interpretation or changes in the law.
2	The frequent data collection from hospitals to the Norwegian Patient Registry (task T2.3) is dependent on the hospitals' ability also. Various reasons outside of our control may delay their contribution. Likelihood: low; impact low.	WP2	We will work with the hospitals to help their compliance. We may still accept data collection with longer intervals while hospitals are working with us to achieve frequent data collection.
3	The electronic notification pathway to MSIS (task 2.4) is a complex undertaking that requires innovative and secure solutions. Various reasons outside of our control may delay the task.	WP2	We will start working on this task in month 1 of the project and map technologies used by other agencies to collect data from clinicians. If need be, we will allocate extra resources from the institute to the task.
4	Loss of key personnel Likelihood: medium; impact: low.	All WPs	The NIPH and HDIR have several staff members with the relevant expertise and experience. Replacements and additional staff members can be allocated to the project without significant delay.
5	A large, severe outbreak or another event may affect the prioritization for persons involved in the project, and risk delay the project timeline. Likelihood: low, impact: medium.	WP2 and WP3	The NIPH and HDIR have several staff members with the relevant expertise and experience. Replacements and additional staff members can probably be allocated to the project with minor delay.
6	There may be other technical, legal, or other kinds of hurdles or dependencies that delays the project.	WP2 and WP3	The coordinator monitors the progress closely at task level. Support and challenge-solving is offered proactively. The NIPH and HDIR have skilled staff that can address the challenges.
7	There may be opposition among the health care services or the public against integrated surveillance for fear of reduced data protection.	WP2 and WP3	The NIPH will communicate to the health care personnel and the public about the project's intention and safeguards and facilitate a dialogue on these issues.

#§RSK-MGT-RM§# #§QUA-LIT-QL§# #@IMP-ACT-IA@#

3. IMPACT

3.1 Impact and ambition

Impact and ambition — Progress beyond the state-of-the-art

Define the short, medium, and long-term effects of the project.

Who are the target groups? How will the target groups benefit concretely from the project and what would change for them?

Does the project aim to trigger change/innovation? If so, describe them and the degree of ambition (progress beyond the status quo/state-of-the-art).

Effects of the project

We expect the following main effects of the project in the short-term (during the project), in the medium term (during and shortly after the project) and long-term (after the project):

- Improved and modernised surveillance systems and epidemic intelligence infrastructure. Short-term.
- Reduction of manual and paper-based surveillance and epidemic intelligence tasks, and consequently saved time and better **effectiveness** for healthcare personnel and NIPH staff. Short-term.
- Increased use of automated and AI-supported processes and analysis, creating more effective surveillance. Medium-term.
- Improved data **security**. Short-term.
- Surveillance data and surveillance results available much more **timely**; almost real-time. Medium term.
- More comprehensive and **useful** data, including information about cases' risk factors and health outcomes. Medium term.
- Improved reporting to European surveillance, including TESSy and EWRS, as per Regulation 2022/2317. Medium term.
- Improved capacity among NIPH staff and other personnel with responsibilities in disease prevention and control. Medium-term.
- Improved knowledge basis for NIPH and national and local health authorities for situational awareness, risk assessment, strategy development, choice of measures and evaluation of strategy and measures. Long term.
- Improved infectious disease prevention and control. Long-term.
- Reduced infectious disease burden in the population. Long-term.
- Improved preparedness for outbreaks, epidemics, and pandemics through more **flexible** surveillance. Medium-term.

In conclusion, we will strive to make this project result in increased **timeliness, usefulness, effectiveness, flexibility, and security** of epidemiological surveillance in Norway. To achieve this, we will improve the surveillance infrastructure, build capacity in personnel, and implement integrated surveillance and new epidemic intelligence infrastructure. The main methods are digitalization, automated processes, and utilization of secondary information sources.

An important and prioritised outcome is to make NIPH able to fulfil all requirements laid down in Regulation 2022/2317, article 13, paragraph 3.

Furthermore, we believe that many of the concepts and infrastructures we are developing will be of interest to our European sister institutes.

- The Analysis Hub (WP2) with linkage of information from several registries may be of interest to other countries where inhabitants have a personal ID number that can be used for linkage. In this regard, we have already collaborated in some projects with our Nordic sister institutes on utilising information linked from several registries, and have started planning with Denmark, Sweden and Finland on how to develop this further.
- The Epidemic Intelligence Information system (WP3) will probably also be of interest to sister institutes. We will align our work with ECDC's plan for extension of its EpiPulse system.
- The Outbreak Investigation Database Template (WP3) is generic and thus can be of interest to several sister institutes (after translation).

NORSURV reports will be shared on the website, and we will also share experiences in ESCAIDE and in annual meetings for ECDC networks.

Target groups and their benefits and changes

We expect that the project's target groups will experience the following benefits and changes:

- **NIPH's infrastructure team** will benefit from a more modern and secure surveillance infrastructure.
- **NIPH's surveillance team** will have better and more data to work with, more assistance from automated processes and AI so that they can produce more useful surveillance results, and more training to build capacity.
- **NIPH's epidemic intelligence team** and field epidemiologists will have better tools to perform their tasks and benefit from less need for paper-based work.
- **NIPHs risk assessors**, modellers and advisors will receive more useful and timely surveillance results so that they can produce better situational awareness reports, better models, and better risk assessments so that they can give high quality advice on strategy and measures.
- **ECDC, EU Commission and WHO** will receive improved and more timely surveillance results and early warnings.
- **National and local health authorities** will receive more timely and useful surveillance results and better risk assessments and advice.
- **Municipal medical officers** will receive more timely and useful surveillance results adapted to their municipality so that they can perform their local surveillance and advisory roles better, and they will benefit from better assistance in outbreak investigations.
- **Hospital infection control personnel** will receive more timely and useful surveillance results adapted to their municipality so that they can perform their local surveillance and advisory roles better, and they will benefit from better assistance in outbreak investigations.
- **Clinical microbiological laboratories** and reference laboratories will benefit from improved reporting routines to the MSIS LdB and receive more timely and useful surveillance results.
- **The health services** will benefit from an easier notification process, more useful and timely surveillance results, and possibly less burden from infectious diseases.
- **The mass media** will receive more timely and more comprehensive surveillance results.
- **The public** will be better informed about the epidemiology of infectious diseases and have the benefit of better prevention and control and possibly less burden from infectious diseases.

Innovation

The main innovative part of this project is the integrated surveillance. Data from several other health registries (based at NIPH) and administrative registries will through linkage (using the unique 11-digit personal ID number) augment the MSIS and SYSVAK registries, creating a wealth of new possibilities for producing more useful surveillance results. In the new Analysis Hub, we will be able to produce regular surveillance reports for users who need the information for infectious disease prevention and control. Additionally, we can create ad hoc reports as needed.

The Analysis Hub facilitates the automation of analysis of surveillance data in a secure environment. We will explore the use of AI for this purpose.

#§IMP-ACT-IA§# #@COM-DIS-VIS-CDV@#

3.2 Communication, dissemination and visibility

Communication, dissemination and visibility of funding

Describe the communication and dissemination activities which are planned in order to promote the activities/results and maximise the impact (to whom, which format, how many, etc.). Clarify how you will reach the target groups, relevant stakeholders, policymakers and the general public and explain the choice of the dissemination channels.

Describe how the visibility of EU funding will be ensured.

Communication and dissemination activities

We plan the following communication and dissemination activities:

- **Web site:** A NORSURV portal will be created at the NIPH's web site www.fhi.no. This portal will be the home for all written products from the project, with an emphasis on maximum transparency (within the boundaries of law). The project coordinator team will have editorial responsibility. A summary about the project will also be published on the web site of HDIR www.helsedirektoratet.no

- **Webinars:** NIPH holds regular webinars for several groups of stakeholders, including municipal medical officers, hospital infection control personnel, public health nurses and others who manages the local part of the vaccination programmes, and clinical microbiological laboratories and reference laboratories. Updates about NORSURV will be on the agenda in many of these webinars. The webinars include two way-communication and are excellent ways of receiving input from key stakeholders.
- **Reports** will be produced as scheduled deliverables. Other reports, in Norwegian, may also be produced.
- **Surveillance results** using the improved systems will be produced and reference will then be given to the project.
- **Articles** in scientific journals may be produced. We can report both on the development, structure, and evaluation of the system as well as surveillance results from the system.
- **Conferences and meetings**, such as ESCAIDE and annual meetings in ECDC networks, offer an opportunity for presenting updates on the development of NORSURV.
- **Stakeholder forum.** Representatives of key stakeholder groups will be invited for more in-depth updates and discussion throughout the project period.
- **News items** on the NIPH web site will be published around a few important milestones and hopefully followed up by mass media interviews.
- **Mail** to relevant stakeholders will be sent when there are changes in the surveillance system that directly affects them.

Communication with target groups and stakeholders

We will reach the target groups, relevant stakeholders, policymakers, and the public by these means:

- **The EU Commission** will be informed through the project's deliverables and the NORSURV web portal.
- **ECDC** will be informed through meetings and other contacts, and indirectly through improved surveillance results.
- **National and local health authorities** will be informed through meetings and other contacts.
- **Municipal medical officers** will be continuously updated about NORSURV through our regular monthly webinars with this group as well us through the project website and reports posted there. They will receive mail when there are changes to the system that directly affects them.
- **Hospital infection control personnel** will be continuously updated about NORSURV through our regular webinars as well us through the project website and reports posted there. They will receive mail when there are changes to the system that directly affects them.
- **Clinical microbiological laboratories** and reference laboratories will be continuously updated about NORSURV through our regular webinars as well us through the project website and reports posted there. They will receive mail when there are changes to the system that directly affects them.
- **The health services** will be informed through news items at NIPH's web site and the NORSURV web portal.
- **The mass media** will be informed through news items at NIPH's web site and the NORSURV web portal.
- **The public** will be updated through news items at NIPH's web site and follow up interviews in the mass media.

Visibility of EU funding

Funding from the EU programme EU4Health will be acknowledged in reports, articles, the NORSURV web portal, news items on the web site, and presentation materials (PowerPoint).

We will follow the FAIR principle: NORSURV aims to improve the Findability, Accessibility, Interoperability, and Reuse of digital assets.

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3.3 Sustainability and continuation

Sustainability, long-term impact and continuation

Describe the follow-up of the project after the EU funding ends. How will the project impact be ensured and sustained?

What will need to be done? Which parts of the project should be continued or maintained? How will this be achieved? Which resources will be necessary to continue the project? How will the results be used?

Are there any possible synergies/complementarities with other (EU funded) activities that can build on the project results?

We aim to sustain all the achievements from WP2 (tasks 1 through 4) and WP3 (tasks 1 and 2) if they are successfully developed and implemented, depending on positive evaluation:

- **Integrated Surveillance Core (T2.1)** is the core of the modernised surveillance system. There will be a cost of operating this after the project period. This is, however, a modernisation that is prioritised by all involved stakeholders, given the experience during the pandemic. We are in contact with the Ministry of Health to ensure financing after the project period. The NIPH can decide on this implementation when the legal conditions have been clarified.
- **Improving the MSIS Laboratory Database (T2.2)** will substantially improve the basis for integrated surveillance. We will improve the infrastructure and streamline in-house data management and thus achieve cost savings in the future. The Ministry of Health will decide on permanent storage of person identifiable information for all results, ref. task 2.5.
- **Timely updating of the Norwegian Patient Registry (T2.3)** will ensure daily updates of new hospital admissions from all hospitals, which is a basis for integrated surveillance of severe outcomes of infectious diseases. The initial investments are substantial, but when established, the costs are not much higher than today. The NIPH can decide on this implementation.
- **Electronic notification pathway (T2.4)** will replace clinicians' paper notifications of cases of notifiable diseases. The potential for cost savings for clinicians and NIPH (making manual handling obsolete) is large. If successfully piloted, we will ask the Ministry of Health to decide on the implementation.
- **Information system for epidemic intelligence (T3.1)** will replace the current manual procedures and thus save resources. After the project ends it will form the core tool of our epidemic intelligence activities and be aligned with ECDC's EpiPulse and provide input to EpiPulse and EWRS. The NIPH can decide on this implementation.
- **Outbreak investigation database template (T3.2)** will be used for relevant outbreaks in the coming years. It will replace the need to create a new database for every outbreak investigation and thus save resources. The NIPH can decide on this implementation.

For this to happen, it is crucial that we:

- Adhere to standards in Norway for architecture, information management, coding systems, and terminology, and make sure that we can supply data to the EU digital health infrastructure, including TESSy and ATHINA.
- Address the needs for surveillance results of national health authorities, especially the Norwegian Directorate of Health, the Norwegian Medical Products Agency, and the Ministry of Health and Care Services, and make sure that surveillance results can feed into other national information systems that supports overall health preparedness.
- Consider the legal barriers at the national level and work towards sustainable solutions, including necessary changes in laws and regulations.
- Ensure capacity building among key personnel.

Through strategic dissemination and broad involvement of stakeholders, the project aims to forge a lasting impact on epidemiological surveillance. In WP4 we will develop a sustainability plan.

We will keep our owner, the Ministry of Health, informed about NORSURV and any extra financial needs for the improved surveillance after 2028.

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4. WORKPLAN, WORK PACKAGES, ACTIVITIES, RESOURCES AND TIMING

4.1 Work plan

Work plan

Provide a brief description of the overall structure of the work plan (list of work packages or graphical presentation (Pert chart or similar)).

The list shows work packages, leaders of work packages, and tasks and their dependencies, if any.

NORSURV project (Project Coordinator: Preben Aavitsland, NIPH. Co-coordinator: Trine Groven, NIPH)

WP1, WP2 and WP3 each have a leadership duo where both the NIPH's Division of Health Data and Digitalization and Division of Infection Control are represented**.**

Work Package 1: Management, coordination, administration, and evaluation (Leader: Preben Aavitsland, NIPH. Co-leader: Trine Groven, NIPH.)

- T1.1 Project management and coordination
- T1.2 Project financial management
- T1.3 Project monitoring and evaluation

Work package 2: Integrated surveillance (Leader: Preben Aavitsland, NIPH. Co-leader: Elisabeth Hagen, NIPH)

- T2.1 Integrated Surveillance Core - dependent on T2.5
- T2.2 Improving the MSIS Laboratory Database – dependent on T2.5
- T2.3 Timely updating of the Norwegian Patient Registry
- T2.4 Electronic notification pathway
- T2.5 Legal environment
- T2.6 Integrated surveillance pilot, respiratory infections - dependent on T2.1, T2.3 and T2.5
- T2.7 Integrated surveillance pilot, healthcare-associated infections - dependent on T2.1, T2.2, T2.3 and T2.5
- T2.8 Integrated surveillance pilot, other infections, and vaccination - dependent on T2.1. T2.3 and T2.5

Work package 3: Epidemic intelligence (Leader: Emily MacDonald, NIPH. Co-leader: Rossa O'Donnell, NIPH)

- T3.1 Information system for epidemic intelligence
- T3.2 Outbreak investigation database template

Work package 4: Capacity building, dissemination, and sustainability (Leader: Bjørn Iversen, NIPH)

- T4.1 Capacity building

- T4.2 Dissemination
- T4.3 Sustainability

Coordination between activities is facilitated through the management board. Almost all activities will take place in two divisions of the NIPH where there is already close collaboration between members of the teams for each WP and task.

Subcontracting (n/a for prefixed Lump Sum Grants)

Subcontracting

Give details on subcontracted project tasks (if any) and explain the reasons why (as opposed to direct implementation by the Beneficiaries/Affiliated Entities).

Subcontracting — Subcontracting means the implementation of 'action tasks', i.e. specific tasks which are part of the EU grant and are described in Annex 1 of the Grant Agreement.

***Note:** Subcontracting concerns the outsourcing of a part of the project to a party outside the consortium. It is not simply about purchasing goods or services. We normally expect that the participants have sufficient operational capacity to implement the project activities themselves. Subcontracting should therefore be exceptional.*

Include only subcontracts that comply with the rules (i.e. best value for money and no conflict of interest; no subcontracting of coordinator tasks).

Work Package No	Subcontract No (continuous numbering linked to WP)	Subcontract Name (subcontracted action tasks)	Description (including task number and BEN/AE to which it is linked)	Estimated Costs (EUR)	Justification (why is subcontracting necessary?)	Best-Value-for-Money (how do you intend to ensure it?)
WP2	S2.1	Timely updating of the Norwegian Patient Registry	Task 2.3 - Timely updating of the Norwegian Patient Registry (on behalf of the NIPH)	900 000 EUR	As the technical infrastructure of the NIPH is operated within the subcontractor's servers, it is vital that they are engaged as an ICT provider of national digital services for the health sector.	The subcontractor is one that NIPH is obliged to use in accordance with internal procurement procedures as a consequence of administrative decision for the Norwegian health sector.

Other issues: *If subcontracting for the project goes beyond 30% of the total eligible costs, give specific reasons.*	Insert text

Timetable

Timetable (projects of more than 2 years)

Fill in cells in beige to show the duration of activities. Repeat lines/columns as necessary.

Note: *Use actual calendar years and quarters. In the timeline you should indicate the timing of each activity per WP. You may add additional columns if your project is longer than 6 years.*

ACTIVITY	YEAR 1				YEAR 2				YEAR 3				YEAR 4				YEAR 5				YEAR 6			
	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Task 1.1 - Project management and coordination																								
Task 1.2 - Project financial management																								
Task 1.3 - Project monitoring and evaluation																								
Task 2.1 - Integrated Surveillance Core																								
Task 2.2 - Improving the MSIS Laboratory Database																								
Task 2.3 - Timely updating of the Norwegian Patient Registry																								
Task 2.4 - Electronic notification pathway																								
Task 2.5 - Legal environment																								
Task 2.6 - Integrated surveillance pilot, respiratory infections																								

Task 2.7 Integrated surveillance pilot, healthcare-associated infections																								
Task 2.8 - Integrated surveillance pilot, other infections, and vaccination																								
Task 3.1 - Information system for epidemic intelligence																								
Task 3.2 - Outbreak investigation database template																								
Task 4.1 - Capacity building																								
Task 4.2 - Dissemination																								
Task 4.3 - Sustainability																								

#§WRK-PLA-WP§#

#@ETH-ICS-EI@#

5. OTHER

5.1 Ethics

Ethics *If the Call document contains a section on ethics, describe ethics issues that may arise during the project implementation and the measures you intend to take to solve/avoid them.*
Ethical aspects will be discussed regularly during the project lifetime. Surveillance is exempted from the requirement to have approval from an ethical review board. However, if such approval is needed for some of the pilot studies, we will apply for such approval. Data will be managed according to the rules and regulations for the registries in question, and in full compliance with relevant national and EU laws and regulations. All the work will be done in compliance with GDPR legislation.

#§ETH-ICS-EI§# #@SEC-URI-SU@#

5.2 Security

Security *If the Call document contains a section on security, describe security issues that may arise during the project implementation and the measures you intend to take to solve/avoid them.* *Indicate if there is need for EU classification of information (Decision 2015/444) or any other specific security measures.*
Not relevant.

#§SEC-URI-SU§# #@DEC-LAR-DL@#

6. DECLARATIONS

Higher funding rate (if applicable)	**YES/NO**
Do you fulfil the conditions set out in the Call document for a higher funding rate? If YES, explain and provide details.	**No**
Not applicable.	

Double funding	
Information concerning other EU grants for this project ⚠ *Please note that there is a strict prohibition of double funding from the EU budget (except under EU Synergies actions).*	**YES/NO**
We confirm that to our best knowledge neither the project as a whole nor any parts of it have benefitted from any other EU grant *(including EU funding managed by authorities in EU Member States or other funding bodies, e.g. EU Regional Funds, EU Agricultural Funds, etc)*. If NO, explain and provide details.	Yes

We confirm that to our best knowledge neither the project as a whole nor any parts of it are (nor will be) submitted for any other EU grant *(including EU funding managed by authorities in EU Member States or other funding bodies, e.g. EU Regional Funds, EU Agricultural Funds, etc)*. If NO, explain and provide details.	Yes

Financial support to third parties (if applicable) *If in your project the maximum amount per third party will be more than the threshold amount set in the Call document, justify and explain why the higher amount is necessary in order to fulfil your project's objectives.*
Not applicable

#§DEC-LAR-DL§#

HISTORY OF CHANGES

Version	Publication date	Change
1.0		Initial version submitted as the proposal
1.1	28.06.2024	(1) ESR: NORSURV has limited transferability potential as it aims at improving the national surveillance system with a well-tailored approach. It could have been better developed how the results of the proposal could have been shared with other EU countries. NO response: We have addressed this point by expanding the text in chapter 3.1 under the heading *Effects of the project*.
-	-	(2) ESR: The methodology does not provide sufficient details on how data collected through different data sources will be analysed to inform epidemic intelligence and improve early warning capacity. This is a shortcoming. NO response: We have addressed this shortcoming by expanding the text in chapter 2.1 under the heading *Integrated surveillance* and under the heading *Epidemic Intelligence*.
-	-	(3) ESR: Risk analysis addresses significant possible risks and appropriate mitigation measures however, work package-specific risks are only partly considered. The needed political support to modify legal issues is not sufficiently addressed. NO response: We have addressed these points by expanding the text in the table in chapter 2.7.
-	-	(4) ESR: The project involves a large number of staff members. Time allocation is largely concentrated on WP2, totaling more than 400 persons/month raising concerns about cost-effectiveness. NO response: The NORSURV project amounts to a complete overhaul and a much-needed substantial modernization of the surveillance system. Most of this work is based in WP2, which we believe is the most efficient way of organising the work to secure close coordination of the various tasks (in contrast to splitting the tasks in more WPs). They include IT development, legal work, and epidemiological expertise and results in three pilot studies.

Version	Publication date	Change
		For these reasons, a large number of experts with various background needs to be involved at various stages throughout the four years.
-	-	(5) ESR: Proposed NIPH and HDIR team members demonstrate complementary competencies covering not only technical areas of expertise but also project management, administration and communication. However, their respective contribution is not always sufficiently described. This is a minor shortcoming. NO response: We have addressed this shortcoming in the table in chapter 2.3 and in the budget file.
-	-	(6) ESR: A stakeholder forum is of added value, however details on its functioning could have been better explained. NO response: We have addressed this point by expanding the text in chapter 2.4.
-	-	(7) ESR: Communication and collaboration between WPs are not detailed. This is a minor shortcoming. NO response: We have addressed this shortcoming by expanding the text in chapter 2.4.
-	-	(8) ESR: Sustainability is addressed but there are certain limitations which are mentioned but not discussed in detail. This is a shortcoming. NO response: We have addressed this shortcoming by expanding the text in chapter 3.3.
-	-	(9) HaDEA: There is a requirement for a report on action level indicators. NO response: We have added an Action level indicator report as deliverable D1.4 at month 48.
-	-	(10) HaDEA: There is a requirement for a Communication and dissemination plan early in the project. NO response: We have added a Communication and dissemination plan as deliverable D4.1 at month 2. (This affects numbering of other deliverables in WP4.)
-	-	(11) HaDEA: There is a need for a mid-term evaluation report halfway through the project. NO response: We have added a mid-term evaluation report as deliverable D1.2 at month 25.
-	-	(12) NO justification: Some employees have quit or been transferred to the Ministry or to other parts of the NIPH, and some new employees have arrived.

Version	Publication date	Change
		NO change: We have adjusted the table in chapter 2.3 accordingly. The level of competence available to the project remains the same.
-	-	(13) NO justification: Our ambition for the timeliness of the Norwegian Patient Registry was mis-stated in the application. We aim for *daily*, not *weekly*, updates. No change: We have for the sake of consistency adjusted the text for the indicators to specific objective 4, in chapter 1.2 and for the Milestones MS5 and new MS6. (This also affects the *numbering* of subsequent milestones.)