sciensano

levenslang gezond

HERA-BE-WGS

Kick-off meeting

11/01/2022

.be

Agenda

1. Summary of HERA-Incubator-WGS results

2. Kick-off of HERA-BE-WGS
    - Project objectives
    - Stakeholders
    - Workplan
    - Milestones and deliverables
    - Contract and budget management
    - Communication strategy
    - Sustainability

SUMMARY OF HERA-INCUBATOR-WGS

sciensano

.be

Objectives of HERA-Incubator-WGS

The project aimed at :

- **enhancing** the national infrastructure for WGS- and other laboratory and epidemiologic results, data exchange and genomic-epidemiological analyses
- in order to **strengthen** the surveillance, public health response in Belgium and the identification of and response to cross-border threats of infectious diseases.

Objective A – COVID-19 response

COVID-19 response

- to sustain the SARS-CoV-2 variant **monitoring and reporting**

Objective B – Preparedness Actions

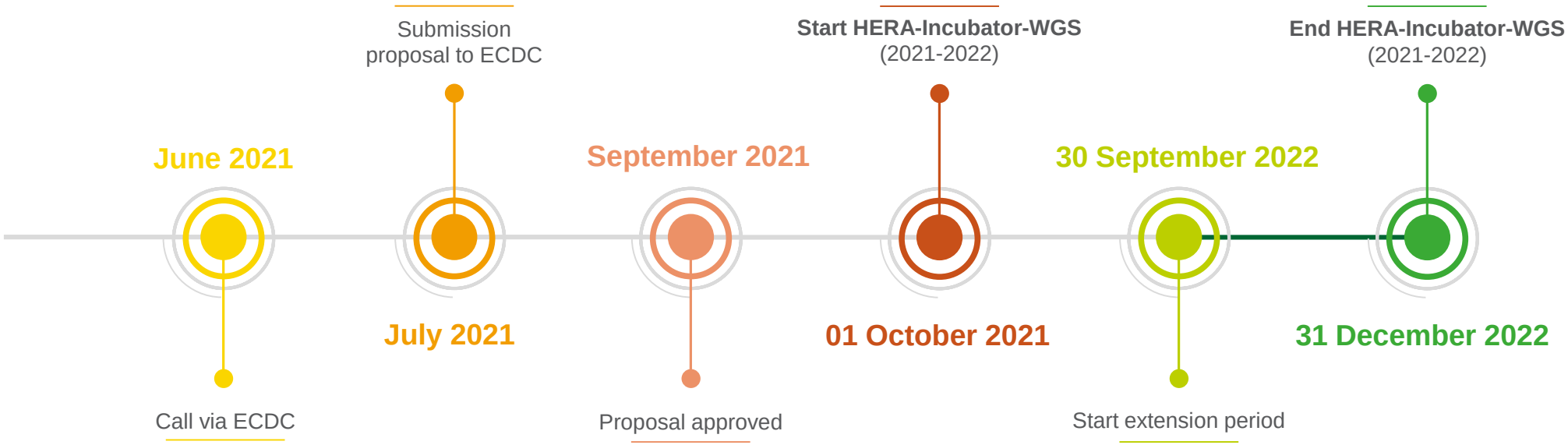
Prepared ness

- Infrastructure for integrated **genomic-epidemiologic analyses**

sciensano

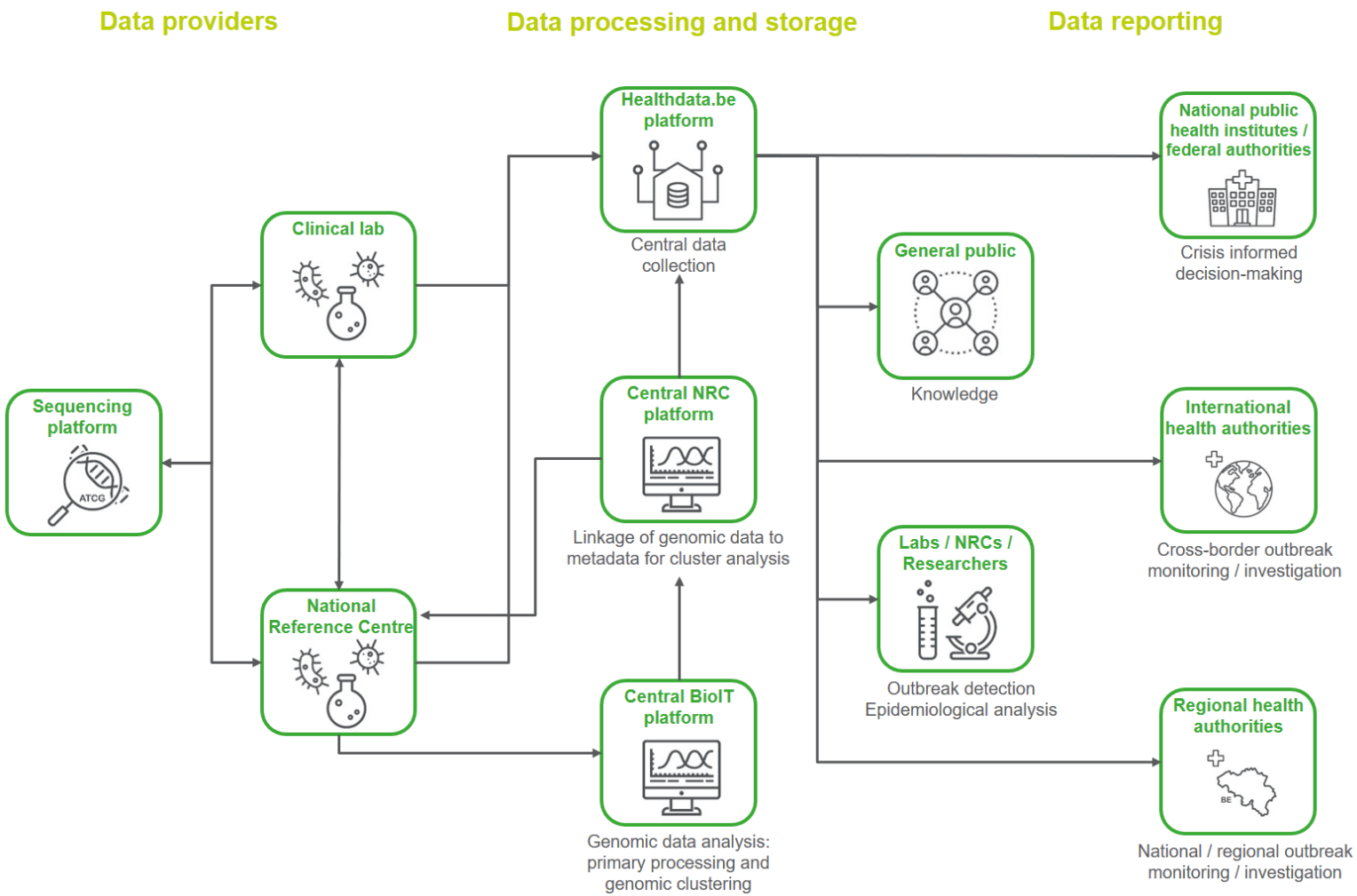
.be

HERA-Incubator-WGS timeline



National infrastructure for genomic-epidemiologic surveillance of infectious diseases

- High level design:



Data collection flows envisioned to make use of Be-HERA infrastructure

- **Overarching** infrastructure to collect and replicate data across stakeholders: **Be-HERA**

Data collection flows envisioned to make use of Be-HERA infrastructure

- **Overarching** infrastructure to collect and replicate data across stakeholders: **Be-HERA**

- Detailed data collection (clinical/epidemiological + genomic) from **National Reference Centres** for human microbiology
  - POC: **5 study case pathogens (NRCs)**


SARS-CoV-2


Influenza


Salmonella


Tuberculosis


Listeria

sciensano

.be

Data collection flows envisioned to make use of Be-HERA infrastructure

- **Overarching** infrastructure to collect and replicate data across stakeholders: **Be-HERA**
- Detailed data collection (clinical/epidemiological + genomic) from **National Reference Centres** for human microbiology
  - POC: **5 study case pathogens (NRCs)**


SARS-CoV-2


Influenza


Salmonella


Tuberculosis


Listeria

- **Alignment with other data collections** such as sentinel laboratory network for minimal data collection and linkage of repositories

sciensano

.be

Design characteristics of Be-HERA infrastructure and processes

- **Real-time / near real-time** input from the moment of clinical/medical validation

- **Clinical/Epidemiological** data submission hierarchy:
  1. System 2 system: HD4DP v2.0 (preferred)
  2. CSV upload (back-up solution)
  3. Web browser (back-up solution)

- **Genomic data submission** hierarchy:
  1. Raw sequencing data (FASTQ files)
  2. Consensus sequencing data (FASTA files)
  3. Genomic indicator data (e.g. interpretation results, lineage)

- Standardized variable **nomenclature and processes**

Data collection: which, how and from where?

Which?

- Information modelling: where possible defined in the **Data Collection Definitions**
  - Patient clinical and epidemiological information collected from clinical biology labs
  - Sample/specimen information and test results
  - Genomic data

How?

- Data codification: Information collected by Be-HERA needs to be codified where possible using a **common terminology**
  - Laboratory tests and methods: LOINC (ReTaM subset)
  - Clinical and epidemiological concepts: SNOMED CT

Where?

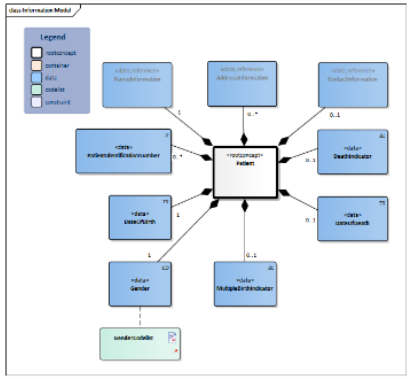
- **L**aboratory **I**nformation **M**anagement **S**ystems (LIMS)
- Sequencing platforms (via NRCs)

Internal LIMS data collection developments

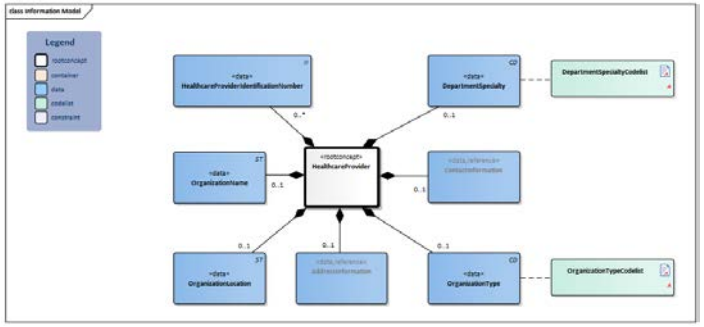
- Before exportation, the codes used by the NRC should be **converted to SNOMED CT and LOINC codes**
  - This requires new reference tables and mapping applications to be added in the NRC LIMS software
  - These reference tables and mapping applications may already be present in some NRC and Clinical Biology lab software and not in other, **development and configuration effort can vary**
- The use of international terminology is also required for other **eHealth projects** (FHIR Lab Results), this is not specific to Be-HERA
- **New applications** were developed in Sciensano LIMS to:
  - Import the DCD specifications (Excel file)
  - Map the DCD fields to the internal LIMS fields

Generic LaboratoryTestResults DCD composed of CBBs

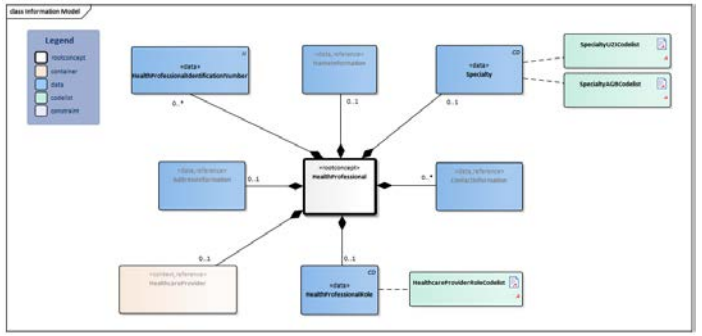
Patient



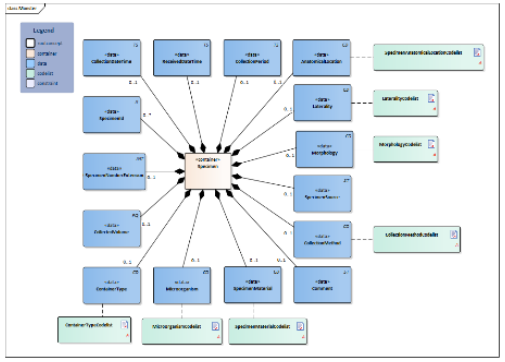
HealthcareProvider



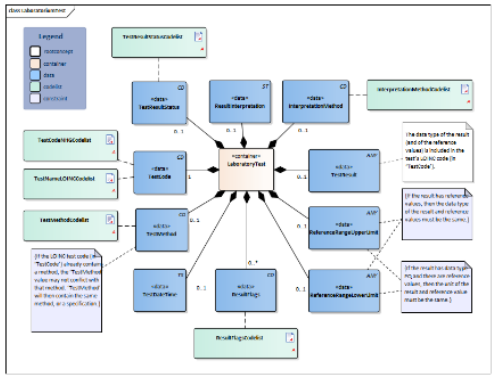
HealthProfessional



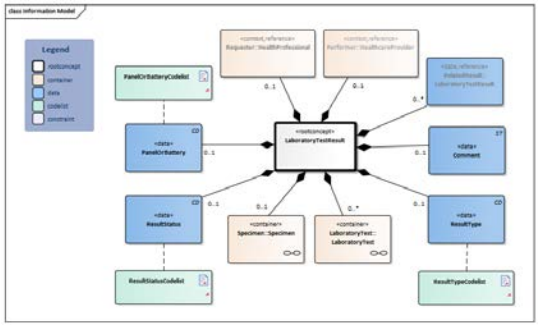
LaboratoryTestResult: Specimen



LaboratoryTestResult: LaboratoryTest



LaboratoryTestResult: LaboratoryTestResult



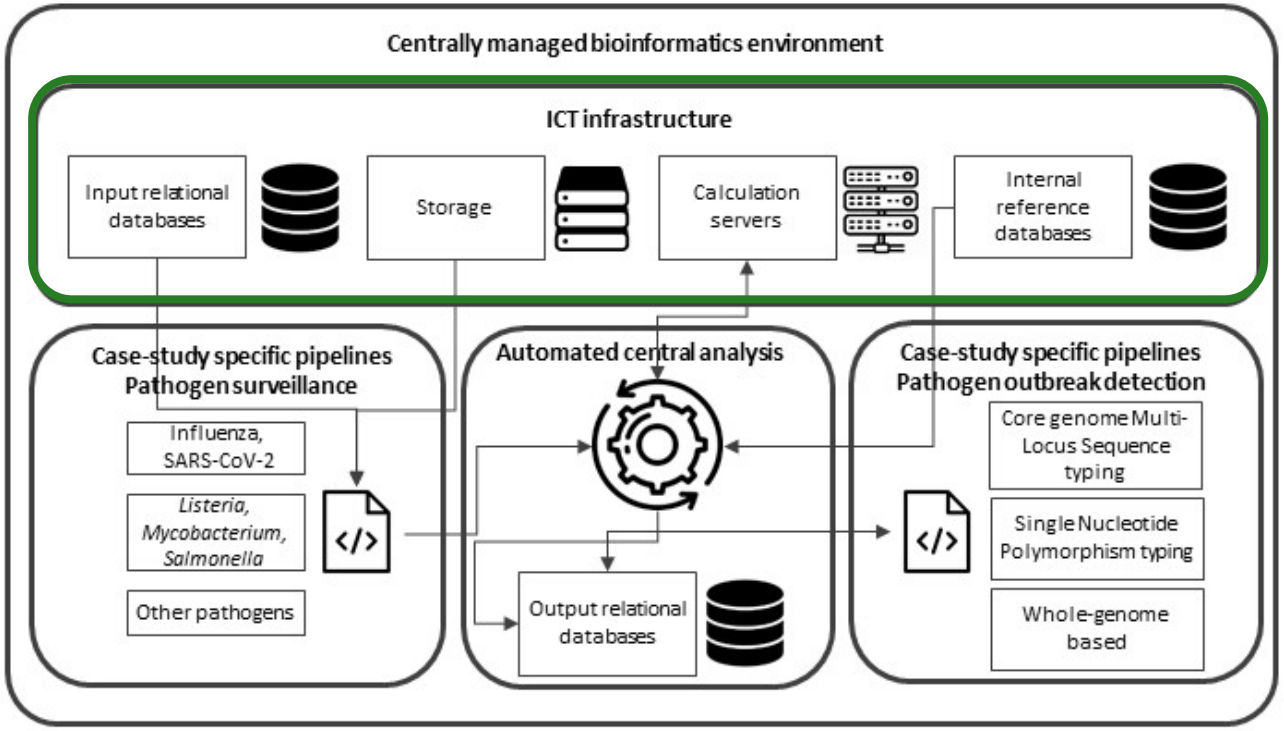
Available at: https://simplifier.net/guide/hdbe-r4-laboratorytestresult?version=current

Technical onboarding and deployment laboratories

- Status deployment all **recognized laboratories for clinical biology**:

	Deployed and tested	Deployed, not tested	Infra info received	No Infra info received
Sciensano	1/1			
External NRCs	11/13	1/13	1/13	
Clinical	91/117	3/117	6/117	17/117

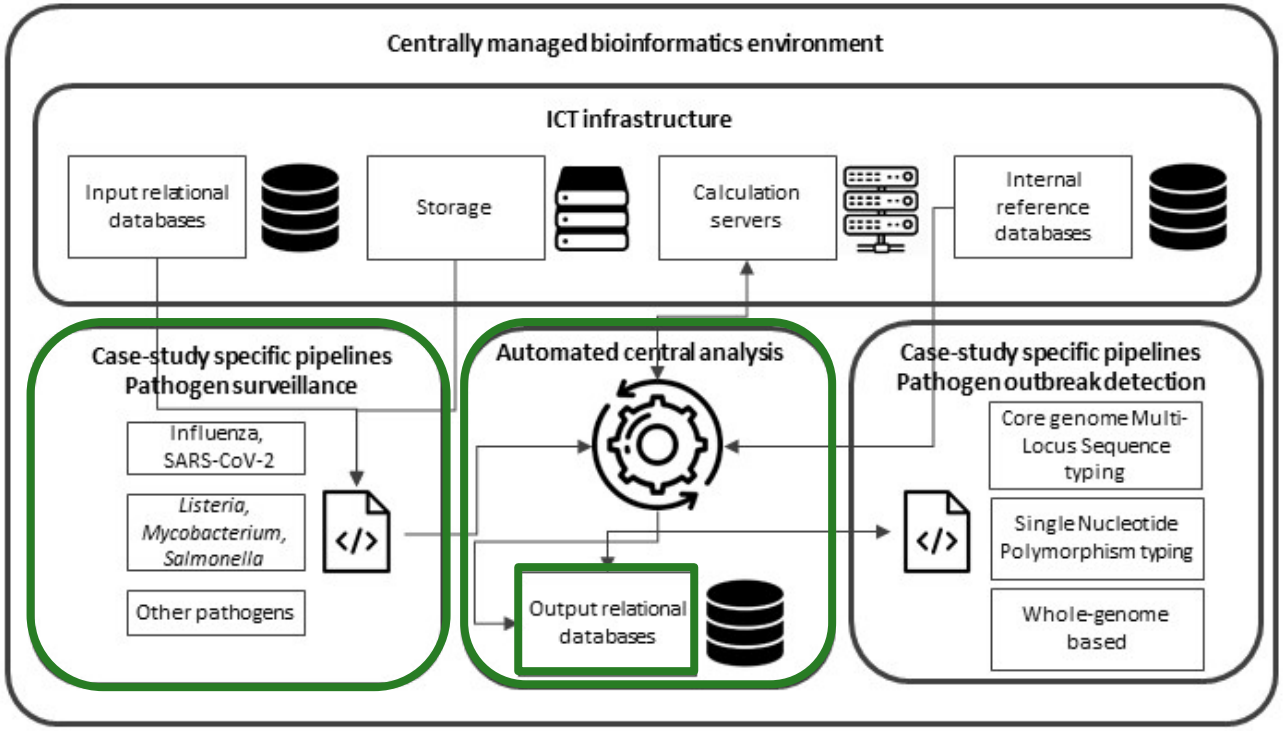
Central BioIT platform



ICT infrastructure

- Automated ‘real-time’ solution
- Public-cloud based solution using Microsoft Azure (scalability, high volume of data) in collaboration with subcontractor Arxus
- Migration currently existing solutions + newly developed POCs to cloud architecture during HERA-BE-WGS

Central BioIT platform



POCs operational for all missing planned phase 1 components @Sciensano

- All scheduled pipelines (*Salmonella*, *Mycobacterium tuberculosis, Listeria monocytogenes,* influenza, human read scrubbing – for Illumina sequencing)
- Automated reanalysis when underlying reference databases change
- Database for genomic indicators using MongoDB

sciensano

.be

Central NRC platform

- Need for a central environment where **genomic data can be linked to clinical/epidemiological data**
    - *E.g.* Genomic cluster analysis
- Due to governance rules (nominative + genomic data) a seperate, **central environment** needs to be set-up
- Development included as a **proof-of-concept** in the follow-up project (HERA-BE-WGS)

Authorization for data collection flows and governance

- Information Security Committee (ISC)

ISC request for **Be-HERA architecture** to collect and process nominative data by HD for other infectious diseases	✓ **Approved (Deliberation number 22/268 from 12 september 2022)**
ISC request for **HERA study cases** (NRCs)	✓ Submission: Request form end of September 2022 + **Deliberation form mid November (in the meantime: approved in February 2023)**

- Draft data management plan: continuously updated

Data retention policy

Type of data	Data retention
Clinical data	**15* years** after registration
Epidemiological data	**15* years** after registration
FASTQ files	Several options under discussion: Data is kept for **2 years** or predetermine it for **5 years**
FASTA files	**Indefinite**
Genomic indicators (= results)	**Indefinite**

* Adapted since the kick-off meeting

Data sharing policy

F A I R

« As open as possible, as closed as necessary »

sciensano

.be

DISSEMINATION

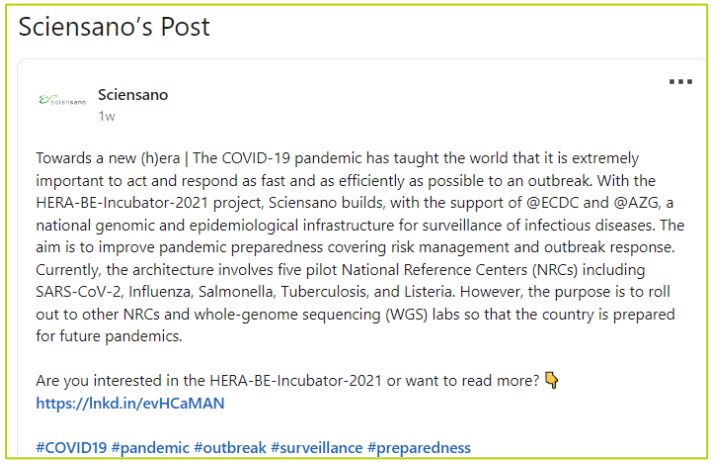
sciensano

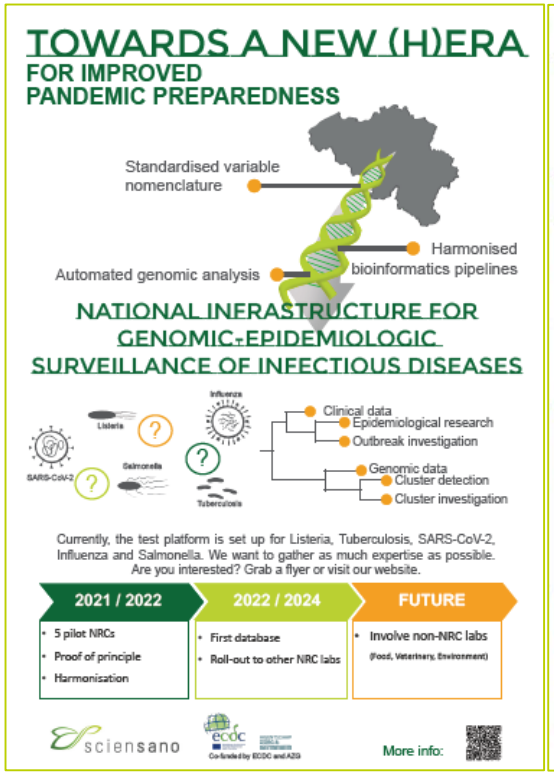
.be

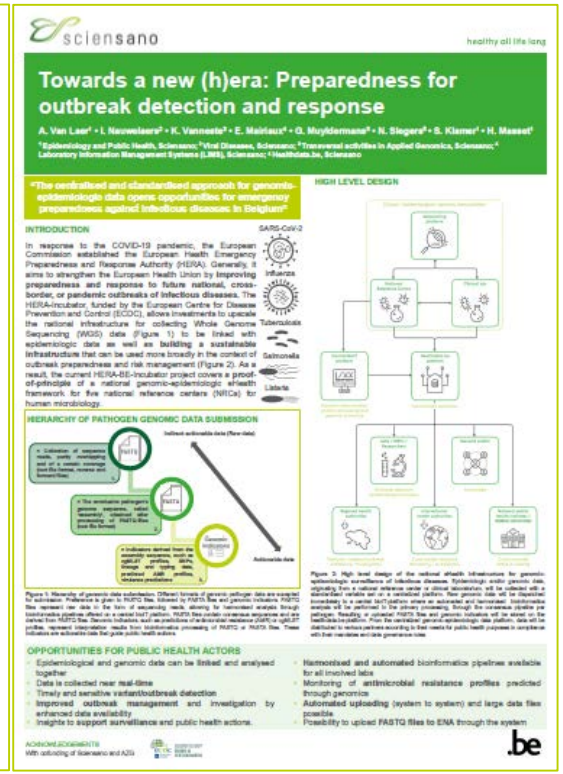
Communication and dissemination

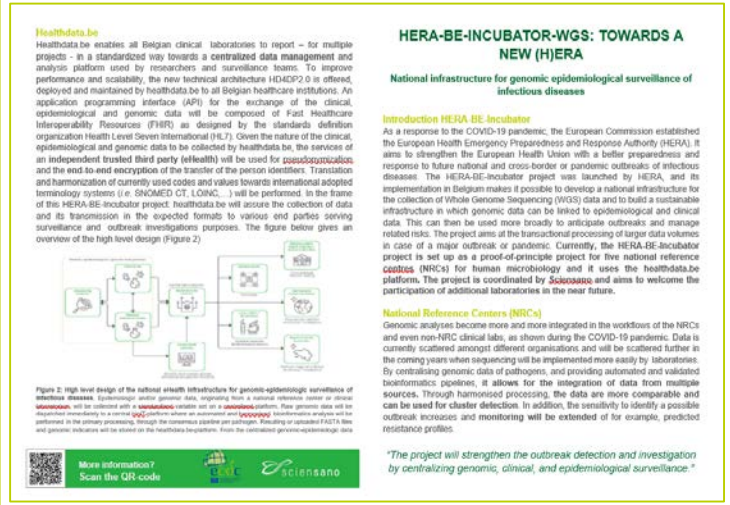
- **Webpage** was created
- **LinkedIn** post to introduce the HERA-Incubator-WGS project to the broader public
- **SsID** 11th of May 2023
  - Flyers
  - Scientific poster
  - Information poster

Communication and dissemination









sciensano

.be

INTRODUCTION HERA-BE-WGS

sciensano

.be

Objectives of HERA-BE-WGS

The project is:

- a **consolidation** and a **direct follow-up** of the HERA-Incubator-WGS activities implemented from October 2021 until December 2022

The project aims at:

- building further on the foundation of an **overarching national public health information infrastructure**
- developing **genomic expertise** within the NRC network
- improve reporting of genomic results in order to allow **integrated genomic-epidemiological analysis**

Specific objectives of HERA-BE-WGS

- **Data collection resulting from genomics-based infectious disease outbreak investigation capacities at national level for a number of pathogens** by allowing genomic analysis for samples from multiple sources (e.g. sequencing laboratories in university hospitals that work together with National Reference Centres (NRC))

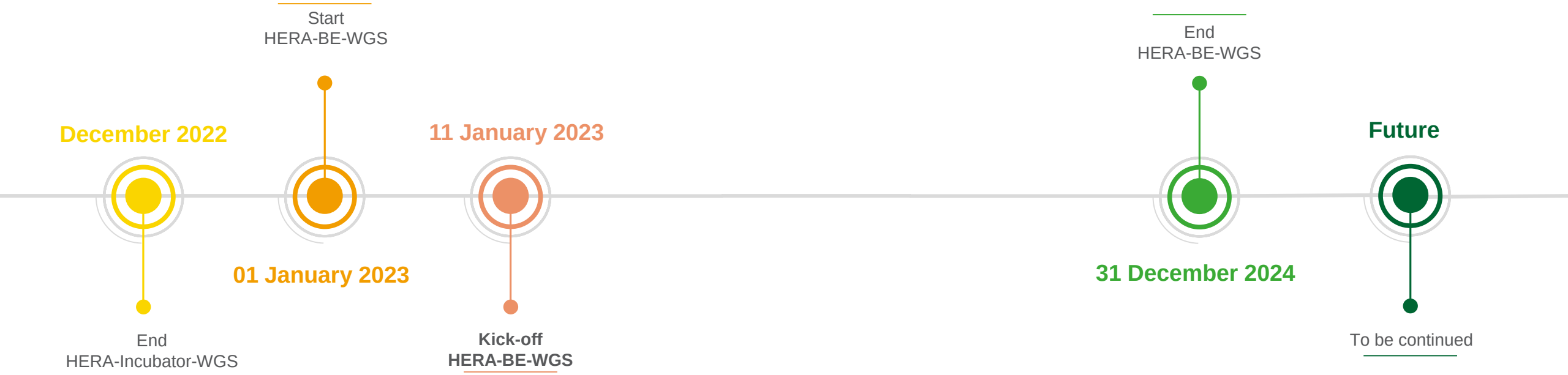
- **Building a secure, national platform that provides tools for (genomic) cluster analysis and visualisation combined with metadata under strict regulations**

- **Setting up a pseudonymized database that is automatically updated after scientific validation** to ensure up-to-date availability of data for epidemiological research of both genomic and non-identifying epidemiological or clinical data

Key performance indicators

Key Performance Indicator	Baseline value	Target value	Related Specific Work Packages (WPs)
BioIT platform: The platform functions as a genomics processing unit for genomic data and technical metadata. Automated, study case specific pipelines are made available.	Currently, a centralized BioIT platform doesn't exist. Study case specific pipelines are in development.	Existing centralized BioIT platform. Central genomics database will consist for at least four study case specific pipelines, i.e. Salmonella, M. Tuberculosis, Influenza, Listeria.	WP 7: National molecular database and genomic tools
NRC platform: The platform can be used for validation of data and linkage of genomic data to metadata for cluster analysis.	Currently, a NRC platform doesn't exist.	Existing. We foresee a demonstrator that works for four pathogens, i.e. Salmonella, M. Tuberculosis, Influenza, Listeria.	WP 5: Extension of infrastructure use to other participants WP 7: Central BioIT- and NRC platform
Combined genomic and clinical /epidemiological analyses for epidemiologists	Structures and processes currently in development	Linking of genomic –and clinical/epidemiological data in a centralized data platform for four pathogens, i.e. Salmonella, M. Tuberculosis, Influenza, Listeria.	WP 6: Enhancement of base functionalities
Communication and dissemination towards stakeholders and the general public	Not applicable	At least 10 social media posts, #HERABEWGS used at least 50 times.	WP 2: Communication and Dissemination

HERA-BE-WGS timeline



sciensano

.be

Stakeholders

Internal actors

HERA-BE-WGS

TAG
Transveral activities in Applied Genomics

Healthdata.be

NRCs
National Reference Centers for human microbiology

LIMS
Laboratory Information Management System

EID
Epidemiology of Infectious Diseases

sciensano

.be

External actors

RIZIV/INAMI

Regional HA

AViQ, COCOM, AZG, DGOV

Federal HA

ECDC/HaDEA

All involved actors

RIZIV/INAMI

Regional HA

AViQ, COCOM, AZG, DGOV

Federal HA

ECDC/HaDEA

TAG

Transveral activities in Applied Genomics

Healthdata.be

NRCs

National Reference Centers for human microbiology

LIMS

Laboratory Information Management System

EID

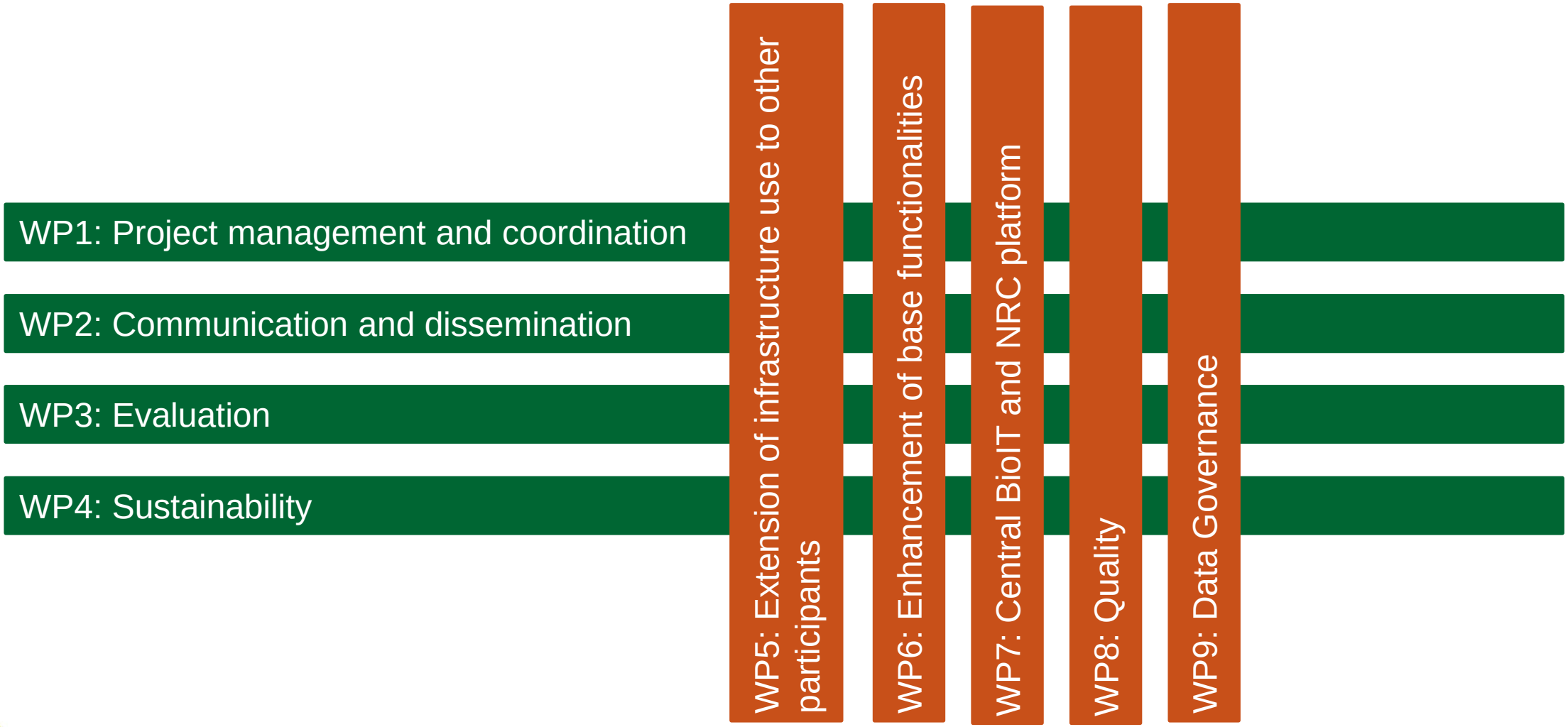
Epidemiology of Infectious Diseases

sciensano

.be

Workplan

Outline of the workplan



sciensano

.be

Introduction of Work Packages 1-9

List of work packages (WP):

WP1: Project management and coordination

WP2: Communication and dissemination

WP3: Evaluation

WP4: Sustainability

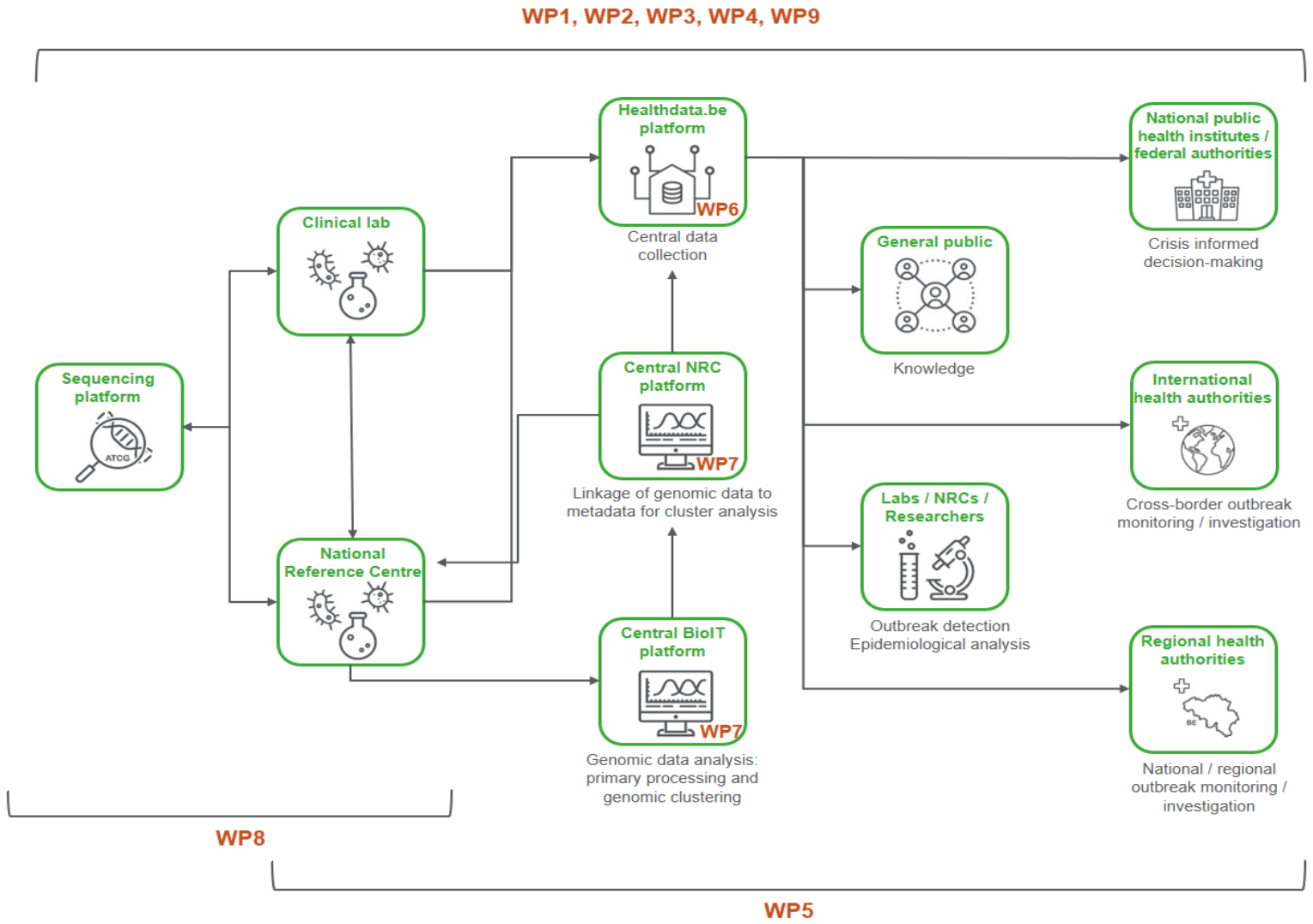
WP5: Extension of infrastructure use to other participants

WP6: Enhancement of base functionalities

WP7: Central BioIT and NRC platform

WP8: Quality

WP9: Data Governance



WP1: Project management and coordination

WP-lead: Heleen Masset, service Epidemiology of Infectious Diseases

Tasks:

- Drafting project management plan, detailed action plan + Gantt chart
- Chairing and preparation of meetings (*see communication strategy*)
- Tracking of milestones and reporting on progress
- Communication throughout multiple levels: project team, WP leaders, Scientific Directors and Direction Board of Sciensano
- Reporting the mandatory deliverables/reports and data reporting to HaDEA/ECDC

WP2: Communication and dissemination

WP-lead: Amber Van Laer, service Epidemiology of Infectious Diseases

Tasks:

- Defining a communication strategy (*see later*) @ kick-off meeting
- Providing publicity via social media, design new webpage, flyers, information meetings, hands-on trainings/workshops
- Dissemination report
- Communication plan

WP3: Evaluation

WP-lead: Amber Van Laer, service Epidemiology of Infectious Diseases

Tasks:

- Set-up of an evaluation committee
- Defining an evaluation plan
- Gathering input for the evaluation report

WP4: Sustainability

WP-lead: Heleen Masset, service Epidemiology of Infectious Diseases

Tasks:

- Ensuring financial sustainability of the national public health infrastructure
- Aligning with legal frameworks already in place on a national level for monitoring infectious diseases
- Defining a framework for expanding the infrastructure for other infectious diseases

Laboratory Information Management System developments – Eric Mairiaux

WP5: Extension of infrastructure use to other participants

- Ensure functional connectivity for onboarding of Sciensano NRCs

WP6: Enhancement of base functionalities

- Design HL7FHIR compatibility for Sciensano LIMS

Transversal activities in Applied Genomics developments – Kevin Vanneste

WP7: Central BioIT and NRC-platform

- Consolidation and enhancement of previously developed pipelines for case studies
- Development of new bioinformatics pipelines for new case studies
- Development of central BioIT platform
- Development and deployment of cluster detection algorithms and methods for selected case studies
- Development of a central NRC platform

National Reference Center developments – Jolein Laumen

WP5: Extension of infrastructure use to other participants

- Validation of data flows and processes of the infrastructure

- Facilitate onboarding of POC and additional NRCs, i.e. *Salmonella*, *Listeria Monocytogenes*, *Mycobacterium Tuberculosis*, Influenza, SARS-CoV-2, *Neisseria Meningitidis,* in collaboration with the service Epidemiology of Infectious diseases (Amber Van Laer)

- List the requirements and needs of the case studies for the NRC-platform

Healthdata.be developments – Marijke Pauwels

WP6: Enhancement of base functionalities

- Provide infrastructure maintenance and enhancements
- Ensure technical connectivity for case studies
- Facilitate onboarding of additonal case studies
- Implement HL7FHIR communication

sciensano

.be

WP8: Quality

WP-lead: Sigrid De Keersmaecker, service Transversal activities in Applied Genomics

Tasks:

- Strengthen the quality assurance of the diagnostic genomic analyses of bacterial and viral pathogens
- Ensure the quality of the data collection
- Ensure upscaled sequencing capacity within national public health institute

WP9: Data governance

WP-lead: Heleen Masset, service Epidemiology of Infectious Diseases

Tasks:

- Update data management plan
- Align with Data Protection Office
- Draft/update data sharing policy

Milestones and deliverables

Milestones HERA-BE-WGS

Milestone	WP
Topics hands-on training/workshop	2: Communication and dissemination
Intermediate dissemination report	2: Communication and dissemination
Intermediate internal evaluation reports (internal and external)	3: Evaluation
Intermediate check of the functionalities	6: Enhancement of base functionalities
Central bioinformatics environment	7: Central BioIT and NRC platform
Developing and fine-tuning the case-study specific pipelines	7: Central BioIT and NRC platform
Develop and deploy cluster detection	7: Central BioIT and NRC platform
Central NRC platform	7: Central BioIT and NRC platform
Intermediate data management plan	9: Data management

Deliverables HERA-BE-WGS

Deliverable number	Deliverable name	Related work package
D1.1	Kick-off meeting conclusions	WP1
D2.1	Promoting HERA-BE-WGS (webpage, social media posts)	WP2
D2.2	Promoting HERA-BE-WGS (webpage, social media posts)- continued	WP2
D2.3	Communication plan	WP2
D2.4	Hands-on training/workshop	WP2
D2.5	Final dissemination report	WP2
D3.1	Evaluation plan	WP3
D3.2	Evaluation report	WP3
D4.1	Sustainability plan	WP4
D4.2	Sustainability report	WP4
D4.3	Extension of the infrastructure report	WP4
D5.1	Setting requirements and needs for the NRC platform	WP5
D5.2	Technical and functional connectivity (=NRC onboarding) report	WP5
D6.1	Functionalities report	WP6
D7.1	Technical sequencing data report	WP7
D8.1	Updated quality guidelines report	WP8
D8.2	Report on actions related to upscaling sequencing capacity in quality system	WP8
D9.1	Data management plan	WP9
D9.2	Data governance report	WP9

Contract and budget management

Contract and budget management

Contact persons: Carol Morillo Lopez, Mathieu Brabant, Nouhaila Aouda

- Current contractual status: Grant Agreement Preparation
- Retroactivity granted: start date of the Grant Agreement should be 01/01/2023

- Budget status: total of €3M
  - €1.8M funded via HaDEA/EU4Health
  - €1.2M own contribution
  - Most costs represented by staff efforts, additional investments for IT hardware on NRC-platform and consumables for sequencing

- Monthly timesheets for measuring contributions to project

Communication strategy

Key principles

- HERA-BE-WGS is **transversal**
- Communication on different **layers**
- Complies with the GDPR rules
- Following four key principles

Key principles

- HERA-BE-WGS is **transversal**
- Communication on different **layers**
- Complies with the GDPR rules
- Following four key principles:

Concise

Transparent

Intelligible

Easily accessible

Goals

- Create **visibility** for HERA-BE-WGS
- **Promote** the activities/results
- Maximise the **impact**

Goals

- Create **visibility** for HERA-BE-WGS
- **Promote** the activities/results
- Maximise the **impact**

Internal vs. External

Communication strategy

WHO

Who will be involved?

WHAT/WHEN

Planning and meetings?

HOW

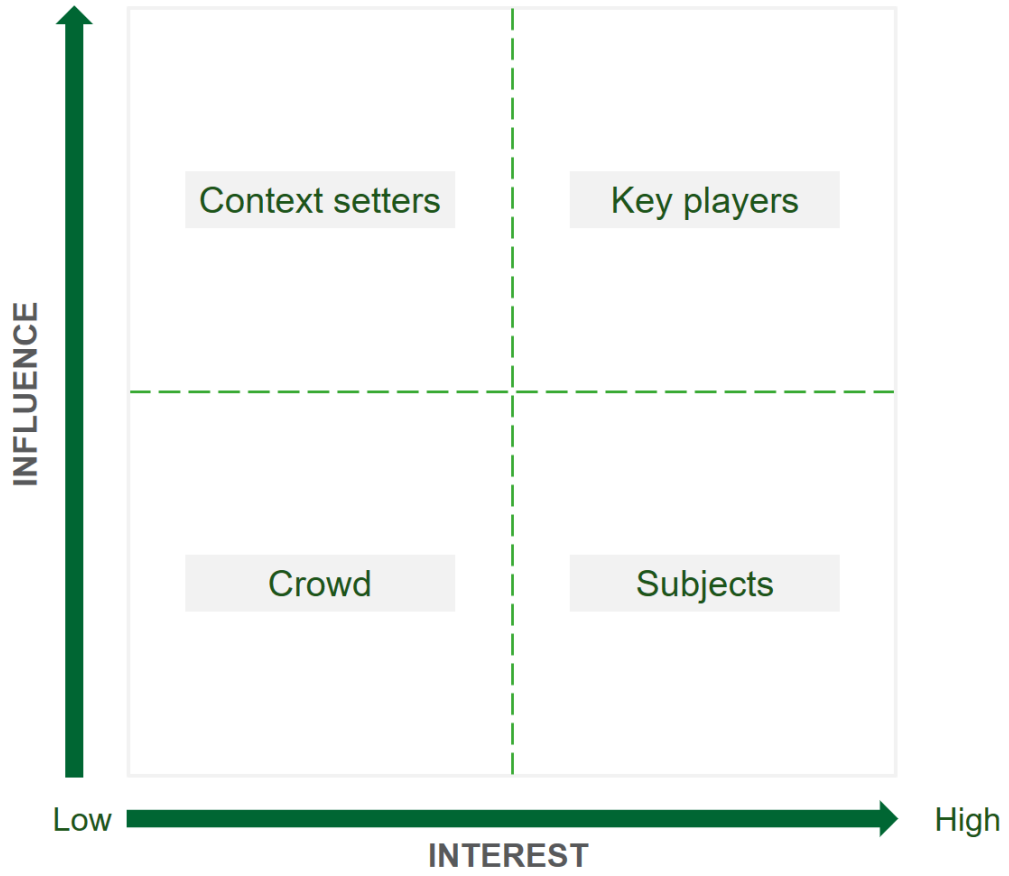
How will we create visibility? Planned activities?

Stakeholder analysis: General

- Goal: Gathering the target groups according to their **level of interest and influence** in the project.

- Dependent on this, the stakeholders can be grouped in four different categories:

  - **Context setters**
  - **Key players**
  - **Crowd**
  - **Subjects**

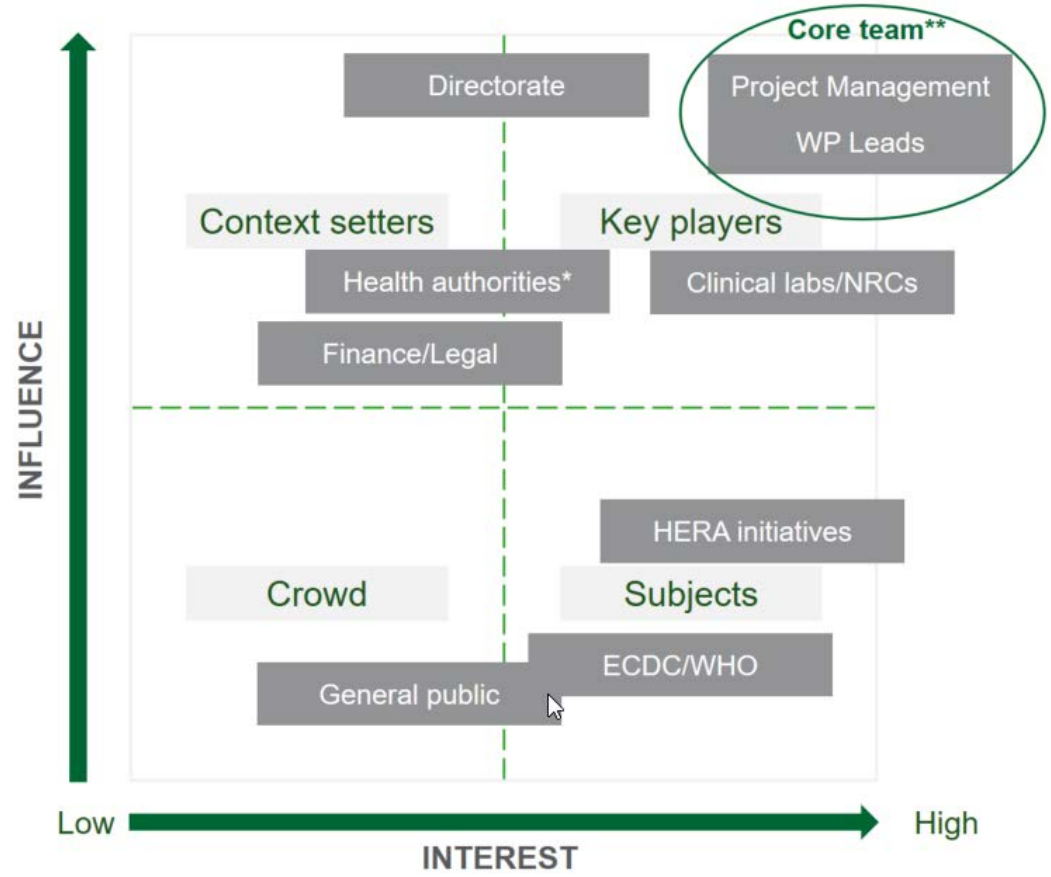


sciensano

.be

Stakeholder analysis: HERA-BE-WGS

- HERA-BE-WGS specific stakeholder analysis
- Communication **dependent** on the group
- Continuous monitoring of this HERA-BE-WGS stakeholder analysis will be performed



Demonstrating progression and tackling problems

- *Ad-hoc* meetings: Dependent on actions

- Recurrent meetings:

What	Frequency	Who
Internal kick-off meeting	1 time	All internal involved actors
Information meeting with external stakeholder	At least one time	External stakeholders
Advisory Committee meetings	Three monthly	External stakeholders
Coordination meetings	Monthly	All internal involved actors
Alignment meeting	Weekly	Core-team
Regular meetings with Finance	Depends	Finance + Project management

Planned activities

- Hands-on workshops and trainings
- Social media accounts: **#HERABEWGS**
  - LinkedIn
  - Twitter
- « Old » webpage HERA-Incubator-WGS remains active but **new webpage HERA-BE-WGS will be created**
  - Will be sent around for review
- **Information** meetings with (new) internal and external stakeholders

What's next?

20/01/2023

National Sequencing platform monthly meeting - Genomic surveillance

14/02/2023

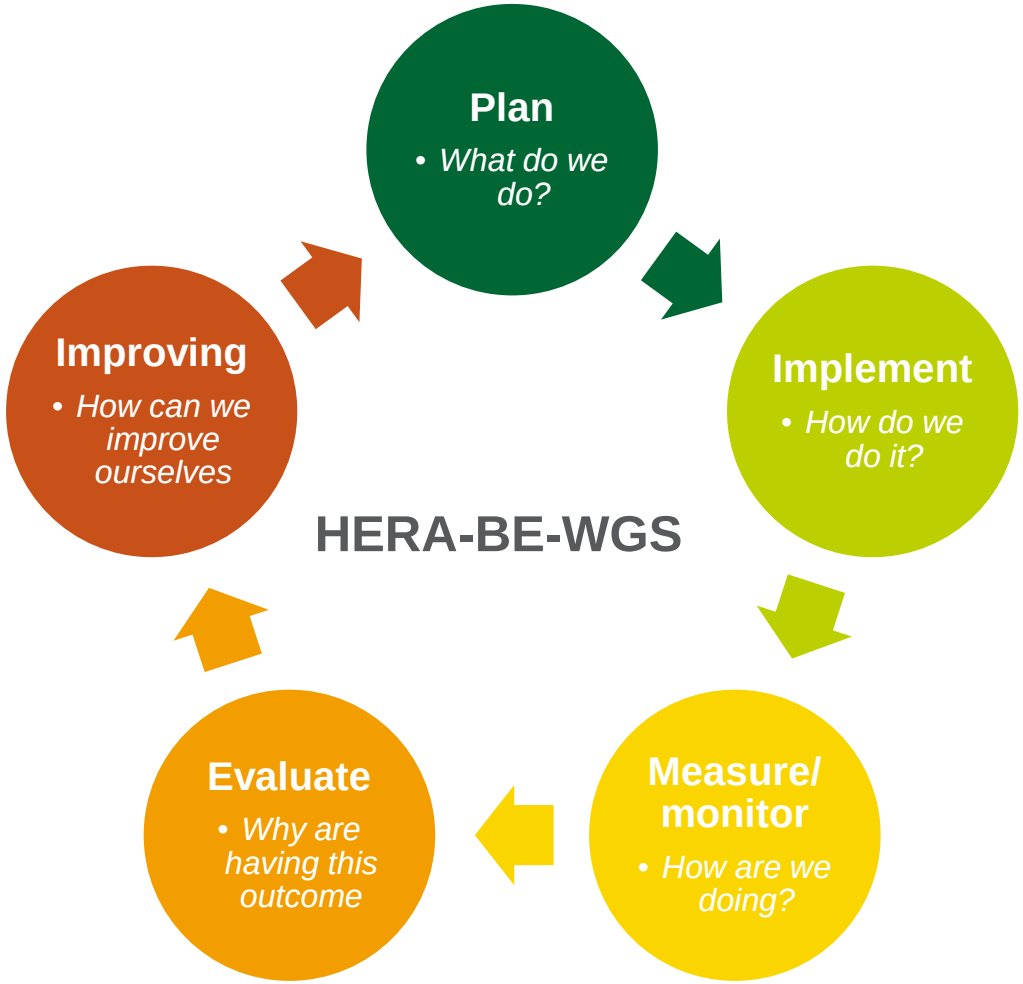
VTI-TIA Platform / Plateforme VTI-TIA

28/03/2023

Towards a new (H)ERA: Developments to strengthen surveillance of infectious diseases @ EpiTuesday

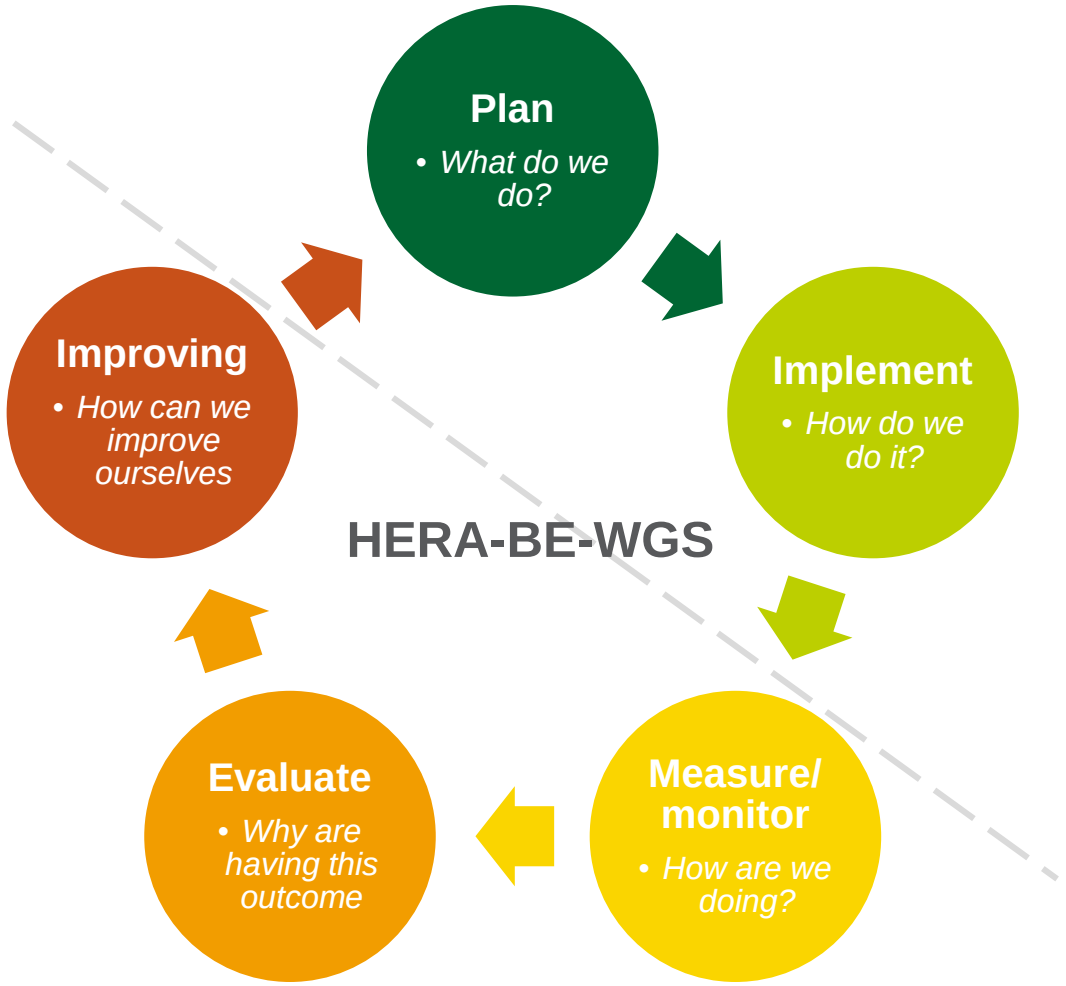
Visibility is creating opportunities

Evaluation as part of communication



Evaluation as part of communication

- Continuously monitoring the (action-level) indicators: *e.g.*
  - Inclusion number of pathogens
  - Minimal amount of social media posts
  - …
- Recurrent moments will be foreseen to evaluate the progression of the project
  - Internal
  - External: AC Board
  - Concrete data to be defined
- Analyze results



sciensano

.be

Sustainability

Aligning with other HERA-initiatives

- EU-HERA call: Strengthening Member States' IT systems ensuring interoperability with HERA's IT platform for intelligence gathering

  - Scope: National IT systems (existing or to be developed) for health threat assessment and intelligence gathering in the field of medical countermeasures
  - EU interoperability with HERA's IT platform (EU-HIP)
  - EU-HIP project: start 01/01/2023, duration 2.5 years (until 06/2025)
  - Collaboration between 18 EU / EEA countries (Sciensano one of the partners)
  - Integration of extended surveillance in this project

  Contact person: Joris Van Loenhout

- Evaluate a cross-border cooperation based on the current systems and developments in each Member State

Consolidation of HERA-Incubator-WGS/HERA-BE-WGS projects beyond 2024

- 2023 EU4Health Work Programme:

  - CP-g-23-01 Direct grants to Member States' authorities: improving and strengthening national surveillance systems (Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU27)

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	**Estimated call publication**	**Budget**
Direct grants - CP-g-23-01	Q1-Q2/2023	EUR 97 300 000
Procedure type	**Implemented by**	**Type of applicants targeted**
Direct grant to Member States in accordance with Article 195, first paragraph, point (c) of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

THANK YOU FOR YOUR ATTENTION