ANNEX C1: Twinning Fiche

Project title: Enhance National Disease Surveillance System in Georgia through Improvement of the Epidemiological and Molecular (Genomic) Surveillance

Beneficiary administration: Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia (MoIDPLHSA), L. Sakvarelidze National Center for Disease Control and Public Health (NCDC)

Twinning Reference: GE 21 NDICI HE 01 23,

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EU funded project
TWINNING TOOL

AA	Association Agreement
AFP	Acute Flaccid Paralysis
AIDS	Acquired Immunodeficiency Syndrome
AMR	Anti-Microbial Resistance
BA	Beneficiary Administration
BC	Beneficiary Country
BI	Beneficiary Institution
BSL	Biosafety Level
CCHFV	Crimean–Congo Hemorrhagic Fever Virus
CDC	Centers for Disease Control and Prevention
DTRA	Defense Threat Reduction Agency
ECDC	European Centre for Disease Prevention and Control
EH	Environmental Health
EFSA	The European Food Safety Authority
EIDSS	Electronic Integrated Disease Surveillance System
EQA	External Quality Assessment
EUD	EU Delegation to Georgia
GISAID	Global Initiative on Sharing All Influenza Data
GoG	Government of Georgia
GSS	Genomic Surveillance System
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
LA	Legal Approximation
LEPL	Legal Entity of Public Law
Lugar Center	Richard Lugar Center for Public Health Research
MES	Ministry of Education and Science
MoESD	Ministry of Economy and Sustainable Development
MoIDPLHSA	Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia
MEPA	Ministry of Environmental Protection and Agriculture
MS	Member State
NGS	Next Generation Sequencing
NCA	National Competent Authority
NCDC	National Center for Disease Control and Public Health
PAO	Programme Administration Office
PL	Project Leader
PSC	Project Steering Committee
RAMA	State Regulation Agency for Medical Activities
RTA	Resident Twinning Advisor
SLA	State Laboratory of Agriculture
SOP	Standard Operating Procedure
SDGs	Sustainable Development Goals
STE	Short Term Expert
TA	Technical Assistance
TB	Tuberculosis
TAIEX	Technical Assistance and Information Exchange Instrument
ToR	Terms of Reference
UNSGM	The United Nations Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons
WHO	World Health Organization

1. Basic Information

1.1 Programme:

The financing decision is under the "Support to the Implementation of the EU-Georgia Association Agreement and Migration Management" OPSYS reference: ACT-60617

1.2 Twinning Sector: Health and Consumer Protection (HE)

1.3 EU funded budget: 1 200 000 EUR

1.4 Sustainable Development Goals (SDGs): SDG 3: Good health and well-being; SDG 2 Zero Hunger

2. Objectives

2.1 Overall Objective(s):

To contribute to the strengthening capacity for legislative approximation and implementation of the Association Agreement.

2.2 Specific objective:

Building genome sequencing capacity at the National Center for Disease Control and Public Health (NCDC) and introducing relevant legal and regulatory framework in line with EU directives and the one-health concept[1].

2.3 The elements targeted in strategic documents i.e. National Development Plan/Cooperation Agreement/Association Agreement/Sector reform strategy and related Action Plans

Strengthening the public health capacity through improved epidemiological surveillance in Georgia is in line with the national strategic documents and legislation of Georgia, particularly:

Law of Georgia on Health Care [2] - Chapter XIII of the law is devoted to the Public Health and Primary Health Care. Article 853 describes that the competence of the public health offices shall include: a) establishing a system of registration and notification of infectious and non-infectious diseases, analyzing the data obtained, and forecasting; b) implementing epidemiological surveillance and control to identify and study the causes, transmission routes, and risk factors of diseases;
Law of Georgia on Public Health [3]- the law describes obligations of the ministry of health to support and prevent the spread of communicable and non-communicable diseases (Chapter III, Article 7) which along with other activities includes laboratory confirmation of epidemic outbreaks and epidemics.

Government Program 2021-2024 **"Toward Building a European State"**[4] **-** Chapter 3.1 Healthcare, describes oncology disease management which includes using effective modern methods of treatment of diseases, need for early diagnosis, and implementation of modern technologies and improvement of postgraduate and continuous professional education.

[1] One health concept - a collaborative, multisectoral, and transdisciplinary approach — working at the local, regional, national, and global levels — with the goal of achieving optimal health outcomes recognizing the interconnection between people, animals, plants, and their shared environment.
[2] https://matsne.gov.ge/en/document/view/29980?publication=37
[3] https://matsne.gov.ge/en/document/view/21784?publication=37
[4] https://www.gov.ge/files/41_78149_280277_GP.pdf

Ordinance of the Government of Georgia #336 of 09.07.2015 on Approval of the **Rules for Functioning of the National Integrated Disease Surveillance System for Infectious Diseases, Including Diseases Caused by Especially Dangerous Pathogens**[5] - the main goal of the ordinance is defining the rules for timely identification of biological threats, detection of the reason and source. The findings are urgently informed to people responsible for threat elimination nationwide.

Ordinance of the Government of Georgia #347 of 13.05.2014 on **Especially Dangerous Pathogens and Biological Incidents Response Plan** [6] - response measures to be implemented at the national level in case of spread of diseases caused by especially dangerous pathogens. The response plan includes detection of disease / biological threat, laboratory testing, identification, confirmation and characterization of biological agent.

Ordinance of the Government of Georgia #508 of 24.09.2015 on **National Civil Security Plan** [7] - it defines the roles and responsibilities of different sectors in case of emergency and includes functional segments, which unite 17 functions at national and local levels. Appropriate ministry, having the most competencies, resources and means of managing the given emergency, manages each function. For example, in case of public health emergency, MoIDPLHSA together with NCDC will act as the leading institutions. Paragraph 5 of the Article 9 – "Management of Emergency Situations" defines the basic preventive measures during emergencies, including the sanitary-hygienic and epidemiological surveillance. Moreover, Article 12 defines that MoIDPLHSA among others is responsible to predict biological threats.

Ordinance of the Government of Georgia #230 of 02.05.2022 on the **Approval of the National Healthcare Strategy of Georgia for 2022-2030** [8] - Strategic Goal 7: strengthening of the public health system to improve preparedness and response to public health threats, implies: improvement of management and financing mechanisms of preparedness and response to public health threats; strengthening of the epidemic surveillance system; increasing laboratory capacity and strengthening medical response measures to respond to public health threats; Ensuring a multifaceted effective communication campaign.
Moreover, Task 1.4. "Strengthen scientific and public health research and their usage for the evidence-based decisions" implies, that MoIDPLHSA will support the development of modern scientific potential, including the strengthening of precision medicine based on the human genome. The latter, based on the unique genetic variation of a specific individual, provides the opportunity to detect the risks of diseases at an early stage, to use customized prevention strategies and to provide individual treatment. Currently, precision medicine is used mainly in oncology in Georgia.

Order of the Minister of IDPs from the Occupied Territories, Labour, Health and Social Affairs of Georgia N01-26/N 25.03.2019 on the approval of the Rules of **Production and Delivery of Medical Statistical Information, Case Definitions of Infectious Diseases/Cases**[9] - list of Notifiable Diseases approved by the order is based on WHO and ECDC guidance. Article 1 of the order defines that the effectiveness of infectious disease management depends on the functioning of the surveillance system, which includes: case/outbreak detection, registration, investigation, confirmation, data reporting, analysis, response and preparedness activities, feedback and communication. Article 2 further defines that in order to properly detect the diseases, the surveillance system must be accurate enough to correctly identify all cases of a particular disease.

[5] https://matsne.gov.ge/ka/document/view/2904356?publication=0
https://matsne.gov.ge/en/document/view/2904356?publication=0
[6] https://matsne.gov.ge/ka/document/view/2344612?publication=0
https://matsne.gov.ge/en/document/view/2344612?publication=0
[7] https://matsne.gov.ge/ka/document/view/2993918?publication=0
https://matsne.gov.ge/en/document/view/2993918?publication=0
[8] https://matsne.gov.ge/ka/document/view/5453716?publication=0
https://matsne.gov.ge/en/document/view/5453716?publication=0
[9] https://matsne.gov.ge/ka/document/view/4509878?publication=0
https://matsne.gov.ge/en/document/view/4509878?publication=0

"**Health Sector Capacity Building and Emergency Preparedness in terms of COVID-19 Pandemic. Action plan**"[10] - the plan defines that COVID-19 cannot be considered as an isolated issue, but the enhancement/reorganization of public health care system, epidemiological surveillance, enhancement of lab network.

The Twinning Project is in full compliance with the requirements of the **Association Agreement between the European Union and Georgia**[11], particularly the Public Health Chapter (Title VI, Chapter 15, Articles 355, 356 (a, b, c, e, and f) and its XXXI Annex (Public Health), committing the parties, "to develop their cooperation in the field of public health, with a view to raising the level of public health safety and protection of human health as an essential component for sustainable development and economic growth". Article 356 of AA stipulates, that the cooperation, among others, shall cover the following areas:
"(a) **strengthening of the public health system of Georgia**, in particular through continuing health sector reform, ensuring high-quality healthcare, development of human resources for health, improving health governance and healthcare financing;
(b) **epidemiological surveillance** and control of communicable diseases, such as for example HIV/AIDS, viral hepatitis, tuberculosis as well as antimicrobial resistance, as well as increased preparedness for public health threats and emergencies;
(c) **Prevention and control** of non-communicable diseases, mainly through exchange of information and best practices…"

Chapter 5.4. (Public Health) of the **Association Agenda between the European Union and Georgia (2021-2027)**[12] defines, as a short –term priority to strengthen national multi-sectoral action to fight anti-microbial resistance inter alia by strengthening surveillance, prudent use of antimicrobials and infection control in healthcare settings;

Objectives of the project also align with the general aims and directions of the European Union (EU), European Centre for Disease Prevention and Control (ECDC) and World Health Organization (WHO) in the field, particularly:

- ECDC strategic framework for the integration of molecular and Genomic typing into European surveillance and multi-country outbreak investigations[13]
- ECDC Single Programming Document 2023−2025[14]
- WHO strategy "Global Genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032"[15]

ECDC strategic framework suggests the molecular and Genomic surveillance improvement to monitor various pathogens/diseases to effectively investigate and control outbreaks. Strategic framework sets a number of priorities, namely, "Member States should receive support for the gradual use of sequence-based typing so they can participate in joint response and surveillance operations with EU/EEA Member States."

Moreover, the document refers to the applications and pathogens, which are particularly relevant:

- "**Outbreak investigation objective; support to multi-country outbreak investigations through sequence-based typing**: *Campylobacter* spp., *Clostridium difficile*, hepatitis A virus, *Legionella* spp., *Listeria monocytogenes*, multidrug-resistant *Mycobacterium tuberculosis* (MDR TB), *Neisseria meningitidis*, outbreaks of emerging multi- or extensively drug-resistant (MDR or XDR) bacteria, outbreaks of new pathogens or new modes of transmission of healthcare-associated or community pathogens, *Salmonella enterica*, Shiga-toxin producing *E. coli* and West Nile virus.

[10] https://eprc.ge/wp-content/uploads/2022/02/small-book-6-eng.pdf
[11] https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=CELEX:22014A0830(02)
[12] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0103
[13] https://www.ecdc.europa.eu/sites/default/files/documents/framework-for-Genomic-surveillance.pdf
[14] https://www.ecdc.europa.eu/sites/default/files/documents/SPD-2023-2025.pdf
[15] https://www.who.int/publications/i/item/9789240046979

- **Control and strategy-oriented objectives**; EU-wide sequence-based continuous surveillance: influenza virus, *Listeria monocytogenes*, MDR TB, *Neisseria meningitidis, Salmonella enterica* and Shiga-toxin producing *E. coli*.
- "**Strategy-oriented objective; sentinel surveillance or surveys**: antibiotic-resistant *Neisseria gonorrhoeae, Bordetella pertussis*, carbapenem- or colistin-resistant *Enterobacteriaceae*, carbapenem-resistant *Acinetobacter baumannii*, HIV-transmitted drug resistance, and *Streptococcus pneumoniae*."

The strategic framework states that "ECDC will continue to liaise and collaborate with EFSA, EU research and development projects on applied pathogen Genomics, WHO, and **national public health partners at EU and international levels**. **These collaborations aim at developing international surveillance standards and sequence-based strain type nomenclature to ensure strategic coherence and operational coordination for cost efficient delivery of the strategic framework in the global context**. ECDC will further collaborate with the Member States and provide support for managing the transition to genome-based typing methods by sharing technical guidance and providing multidisciplinary training in applied Genomic epidemiology.

ECDC single programming document stresses out the importance of the enhanced surveillance, preparedness planning and outbreak response, foresight, and modelling, as well as global health activities and calls upon enhanced Genomic-based infectious disease outbreak investigation, surveillance, and preparedness for future pandemics.

WHO's global Genomic surveillance strategy suggests that "Genomic surveillance is transforming public health action by providing a deeper understanding of pathogens, their evolution and circulation. Used with clinical, epidemiological and other multi-source data, Genomic data for pathogens with pandemic and epidemic potential inform risk assessments, the development of vaccines, therapeutics, diagnostic assays, and decisions on public health and social measures.

Considering the impact of emerging and re-emerging pathogens in the past century, the strategy underlines increased importance of coherent local to global Genomic surveillance systems: "Genomic surveillance for pathogens with pandemic and epidemic potential contributes to public health action within country, regional and global systems.

3. Description

3.1 Background and justification:

One of the important priorities of the Government of Georgia (GOG) is to ensure universal access to high-quality and effective health services for the population. The Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social affairs of Georgia (MoIDPLHSA) is a governmental agency, which oversees the health policy implementation in the country. The Ministry sets respective care standards and guidelines, defines framework for health service delivery, and participates in developing health legislation in close collaboration with the Parliament of Georgia. The national health policy relies on fundamental values, such as protection of human rights and social justice, equity and equality and ensuring the public participation in the decision-making processes.

After the introduction of the Universal Health Care Program in 2013, public spending on health doubled as a share of GDP, reflecting increasing priority to health within the government budget allocation. The out-of-pocket payment share of current spending on health has fallen substantially since 2011, approaching the upper-middle income average, but it is still high in comparison to European Region average.

MoIDPLHSA through NCDC, as a central agency for public health in the country, provides leadership in preventing and controlling communicable and non-communicable diseases, through developing of national standards and guidelines, disease surveillance, immunization, laboratory work, research, providing expert advice and responding to public health emergencies.

According to the WHO document "Health and sustainable development: progress in Georgia"[16] four ministries are instrumental in implementation of up to 30 national targets across 10 SDGs: the MoESD, MES, MEPA and MoIDPLHSA.

To verify the sustainability of the communicable diseases surveillance and response system and adequate administrative and institutional capacity, assessment of country capacities in communicable disease surveillance, prevention and control (ANECC) was carried out by the ECDC on November 11-15, 2019, organized by European Commission (DG SANTE) and ECDC. Assessment standards focused on existing EU acquis requirements, EU and international standards and guidelines, and on generally accepted practice in EU Member States. It evaluated critical system elements. Recommendations addressed the challenges in outbreak response and control and also, epidemic intelligence. Some of the recommendations referred commencing national surveillance of all diseases by implementing EU case definitions, defining and implementing disease or disease-group specific surveillance objectives across the whole range of surveillance actions in the country and integration of surveillance systems for several pathogens and data management.

The actions prioritized by the government of Georgia over the last decade have had positive impact on the progress towards achieving the SDG health targets. Country has made significant progress in reducing the burden of communicable diseases including Hepatitic C, HIV and Tuberculosis. The hepatitis C elimination program, was launched in 2015, which led to the seroprevalence of viral hepatitis C (HCV) in the country to decrease from 7.7% (2015) to 6.8% (2021), and active disease decrease from 5.4% to 1.8%. A second national sero-prevalence study conducted in 2021 confirmed the effectiveness of the elimination program and showed a 67% reduction in the prevalence of the disease.

Despite the progress, pre-existing and newly emerging communicable diseases continue to challenge the country's public health system. The importance of advancing Genomic surveillance system has been demonstrated in recent years, when at the end of 2019 an unexplained pneumonia cases emerged in the Eastern Asia, which was later identified as SARS-CoV-2 – the causative agent of COVID-19 global pandemic. This pandemic showcased the importance of having strong laboratory diagnostic capacity in the countries and particularly, the significance of developing molecular (Genomic) surveillance as a tool to detect control and monitor various public health threats. This twining project has been developed to mobilize resource for strengthening capacity of NCDC for planning and implementing Genomic surveillance of pathogens with the highest public health significance.

NCDC is a legal entity of public law under the state control of the MoIDPLHSA, which independently carries out public health, scientific and educational activities. The scope of its mission is oriented on protection and improvement of health of the Georgian population through evidence-based prevention, preparedness and timely response to public health threats. NCDC mandate includes a broad spectrum of roles and activities aimed at developing and implementing national public health programmes and strategies, aiming at reducing morbidity, disability and mortality caused by communicable, non-communicable diseases and environmental risk factors, preventing and responding to the public health threats, performing public health research and providing continuous education for public health workforce.

[16] https://georgia.un.org/sites/default/files/2020-08/Georgia%205.pdf

A precondition of implementation of NCDC mandate is its strong infrastructure, modern laboratories and well-trained human resources. NCDC lab department that is the **Richard Lugar's Center for Public Health Research** is a modern biosafety level (BSL) 2 and BSL 3 laboratory. Lugar's Center operates since 2013. It has bacteriology, virology, serology, Molecular Biology / Genomics and other laboratories. Several of them accredited by the international accrediting bodies. The quality control activities of the NCDC's Polio, Influenza and Measles / Rubella laboratories are accredited by the WHO and four labs are connected to WHO lab Network (Rota, Invasive meningitis, Malaria, Salmonelosis).

The Molecular Biology / Genomics Center at Lugar's laboratory is well-equipped facility with Illumina MiSeq, MiSeqDx (FDA approved for clinical applications), NextSeq and Oxford Nanopore MinION Mk1C platforms, which makes it a unique sequencing facility in the region. The Center has capacity to sequence up to 90 samples per week. During COVID-19 pandemic, up to June 2023, full genomes of 4 000 different SARS-CoV-2 strains were sequenced, uploaded to international database – Global Initiative on Sharing All Influenza Data (GISAID) and compared with the genetic data of the most common strains in region. Implementation of such Genomic surveillance activities for influenza, measles/rubella, polio, antimicrobial resistance, foodborne illnesses, arboviral diseases and viral hemorrhagic diseases will result in strengthening of a surveillance system in the country.

The poliovirus environmental and acute flaccid paralysis (AFP) surveillance is well established in Georgia since 2001 – wastewater collection and testing for vaccine / wild type polioviruses is performed regularly. Since 2016, molecular detection and strain identification has also been performed. In order to identify and differentiate imported and locally circulating vaccine derived virus strains, the Lugar's center plans to conduct Genomic sequencing of detected and isolated poliovirus strains.

In 2019 Georgia received certificate of achieving the of rubella elimination status from the European Region Verification Commission for Measles and Rubella Elimination and became the part of the countries having achieved interruption of endemic measles and rubella transmission for a period of 36 months. According to the recommendations of the actions, the countries should assess their risks for re-establishing endemic transmission of diseases, recognizing that the risk of importation of the pathogen will exist as long as measles and rubella viruses circulate in other countries. Country has the capacity to detect, report, investigate and confirm/discard suspected cases all over the country on Measles, Rubella and CRS. In addition to routine surveillance activities, there are additional activities such as active case finding, retrospective case and data analysis, and addressing "silent" territories and populations. The integration of the laboratory segment with the surveillance system is crucial for confirming cases and identifying genotypes/lineages, especially in sporadic cases and outbreaks. Since clinical, epidemiological and laboratory aspects of surveillance are closely interrelated, it is important to identify details of genotype and lineages of the viruses to define origin of infection (imported, import-related or endemic case) and plan response activities accordingly.

NCDC supports new initiatives for creating new databases, e.g. the one for arthropod borne viral pathogens. The capacity of sequencing of viral pathogens using probe-based Next Generation Sequencing (NGS) approach is on the stage of implementation. It is already possible to obtain and compare full genomes of Crimean–Congo Hemorrhagic Fever Virus (CCHFV) and track the spread of infection.

Surveillance of bacterial enteric diseases is performed at NCDC for more than decade using pulse field gel electrophoresis (PFGE) technique and US-CDC recommended PulseNet database. But from 2022 transition to NGS based MLST typing has already started worldwide.

The NGS based oncology screening is implemented for BRCA markers and service is already provided for investigating somatic and germline variants in BRCA1 and BRCA2. Meantime, no study of country-specific mutations for other types of cancer was ever performed and while the state program for screening of cervical cancer is well implemented, molecular typing and sequencing of detected papillomaviruses can provide additional valuable information to the worldwide oncology community and help to identify correct treatment strategies.

There are number of external quality assessment (EQA) programs for pathogen detection in which the NCDC / Lugar Center for Public Health Research is involved. Among those are panels for SARS-CoV-2, influenza, Monkeypox, Malaria and other zoonoses detection provided by WHO, UKNEQAS, Institute of Pasteur; RefBio project EQA organized by Robert Koch Institute and supported by the United Nations Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM).

In addition, Lugar Center provides number of trainings including NGS techniques and bioinformatics for the university graduates, for local health care professionals and to colleagues from regional public health and veterinary sectors such as Armenia, Azerbaijan, Turkiye, Iraq. The training is also provided to the State Laboratory of Agriculture (SLA) of Georgia, which is in its stage of implementation of Illumina MiSeq NGS capacity at their laboratory. The training and implementation of NGS technology at the SLA laboratory will effectuate joint projects for sequencing pathogens of common public health and veterinary/food safety concern.

Currently Georgia lacks specific regulations that would bring Genomic surveillance into the overall disease surveillance framework in the country. The guidelines and relevant operating procedures manuals required for national molecular surveillance should be adopted (according to the Paragraph 2.3 of WHO strategy "Global Genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032", "ECDC strategic framework for the integration of molecular and Genomic typing into European surveillance and multi-country outbreak investigations and "ECDC Single Programming Document 2023−2025"). The twinning project will help to analyze and address gaps of the Georgia's existing technical and regulatory gaps to expanding Genomic surveillance capabilities.

Genomic surveillance is a modern and effective tool to guarantee the successful management and containment of any future health threats caused by emerged and re-emerged pathogens, especially, with the epidemic potential. It also has a key role in improving preparedness and creating a sustainable, integrated disease surveillance network, which contributes to the One Health perspective, tackling cross-border threats and strengthening the global health security.

Implementation of the Twinning project will further strengthen surveillance capacity of the country. Disease tracking and early reporting will be improved by adopting the Genomic surveillance strategy, which in turn will contribute to improvement of disease surveillance across public health and veterinary sectors. Besides, strengthening Genomic surveillance capacity will contribute towards establishing a modern cancer surveillance program and enable shift towards personalized medicine in cancer care in the future.

The importance of using next generation sequencing technologies with Genomic surveillance is well understood in developed countries. As an example, on 13th of December 2022 the Government of United Kingdom announced the launch of a Newborn Genomes Programme, a new research study that will explore the effectiveness of using whole genome sequencing to detect rare diseases in newborn babies. The goal of programme is to identify treatable genetic disorders through whole genome sequence and make an intervention in early life to avoid disability or harm. Therefore, development of Genomic surveillance in the country will open new areas of public health, where the gained experience and expertise can be manifested for future tracking of nationwide health.

By investing time in human capacity building throughout the twinning project, the Genomic Surveillance Project aims to develop a skilled workforce capable of effectively utilizing Genomic information for disease surveillance, outbreak investigations and the development of targeted public health interventions. Improved technical skills empower professionals to effectively conduct Genomic surveillance and contribute to research and public health initiatives. Staff involved in capacity building will stay up to date with the latest advancements, protocols, and tools in the field. The increased knowledge base will allow for more informed decision-making, accurate data interpretation, and effective implementation of Genomic surveillance strategies.

3.2 Ongoing reforms and other relevant initiatives

In May of 2022, the GoG adopted the new National Health Strategy for 2022-2030.[17] Ongoing health reforms are planned and implemented in line with the strategy. These include strengthening primary health care services, improving quality of clinical and laboratory services by introducing international accreditation, introducing new payment mechanism for hospitals related to diagnostic groups (DRG payment), introducing price regulations on drugs etc. With support from European partners Georgia has developed a new legal framework for nurses and midwifes, developing the new strategy for public health workforce in in progress. Reforms continue to build communicable disease response model for strengthening people-centered TB care model and achieving hepatitis C elimination targets.

Ministry and NCDC work with WHO on adopting the WHO Global Genomic Surveillance Strategy for Pathogens with Pandemic and Epidemic Potential 2022-2032. An important ongoing initiative supported by US Centers for Disease Control and Prevention (US-CDC) is considering the possibility for establishing a regional sequencing training center by implementing the project.

General Policy and legislative process

The National Policy Planning System Reform Strategy, adopted by the Government of Georgia in August 2015 recognizes the current weak link between the policy planning process and legislation drafting, the absence of practice of legislative impact assessment and the weak institutional capacity of ministries in legal drafting. The OECD/SIGMA 2018 assessment in the policy development and coordination area highlights a number of weaknesses in the quality of policy planning (costing, monitoring, coordination and public consultation), which are currently being addressed through the PAR roadmap and action plan. The document specifically notes the reoccurring problem with implementation of laws, which can be attributed to the low quality of laws due to weaknesses in the law-making process.

There is a pressure to complete numerous legal reforms in the shortest possible time. Improvement of the legislative drafting process and quality of legislation is now a priority area of action for the Administration of Government under the Prime Minister (steering the policy-making process) and all line ministries. This primarily involves the Administration of Government, Ministry of Justice, and Ministry of Economy and Sustainable Development. In order to meet the targets and obligations in law making process the Government introduced changes in Law on Normative acts (amended on June 13, 2018) and Regulation of the Government (amended on August 24, 2018). These amendments put more emphasis on concordance with union acquis and Regulatory Impact Assessment (RIA.)

In line with the 2018 OECD/SIGMA recommendations, a new Government decree was adopted end of 2019 and with its supporting Handbook on Public Policy Making, now lays the regulatory and procedural foundation for good evidence-based policy development. It has quickly become the primary guidance document for Ministries. Nevertheless, its implementation requires comprehensive training and support, to ensure better integration between policy and budget planning, and building the right capacities, structures and processes in the relevant ministries. Some key issues in the area are inter- and intra-institutions coordination, capacities in data analysis, policy budgeting, gender responsive budgeting. The introduction of a mandatory Regulatory Impact Assessment for specific legislation since January 2020 is also an important milestone, but also requires extensive training for proper implementation.

For increasing coordination and strengthening the effectiveness of the legal approximation process in the country, on January 30, 2020 Government of Georgia adopted Legal Approximation Guidelines19 that will provide additional guidance to all the line Ministries involved in the legal approximation process under the AA. The Guidelines prepared by the Ministry of Justice provide key principles and techniques of approximation that will assist and orient legal drafters throughout the approximation process. The Guidelines should be used consistently, not only by MoJ, but also by all line ministries, and institutions tasked with the approximation exercise. Such proceedings will help to ensure the achievement of a steady and sustainable approximation path.

[17] Technical assistance was provided by the EU Public Administration Reform Project

3.3 Linked activities

In order to fulfil the commitments under the AA and enhance legislative and institutional framework in different public health related directions, NCDC participated in EU supported 4 Twinning projects[18] in recent years, among them 2 have been successfully finished already and 2 are ongoing:

Twinning project GE22 Institutional Strengthening of Environmental Health System of Georgia (2017-2019), supported in revising the Georgian legal and regulatory framework in the environmental health field, in-line with Georgia's commitments under the AA and multilateral environmental agreements and international pledges in the environmental health field. Also, the project supported in elaboration of the National Environmental Health Action Plan (2018-2022)[19], adopted by the GoG Ordinance #604 of December 29, 2018. The project also resulted in strengthening the institutional and human capacities, including on management and decision maker level, along with operationalization of an effective EH management system, with Environmental Health Department establishes at the NCDC

Twinning project GE/18/ENI/HE/01/09 Strengthening Blood Safety System in Georgia (2020-2022) was successfully implemented followed by the adoption of the "Law of Georgia on quality and safety of human blood and its components", by the Parliament of Georgia on December 15, 2022. The new law is in line with the European Parliament and Council Directives in blood safety, listed in the AA and creates the legal basis for a new model of blood safety system with centralized functions: establishment of a National Competent Authority (NCA); licensing and hemovigilance; conversion of blood establishments into non-profit entities; full transition to voluntary non-remunerated blood donations; establishment of a national central blood establishment (BE) and centralized testing laboratory; upgrading licensing requirements for blood establishments and permits for hospital blood banks; creation of national hemovigilance system (including traceability and monitoring of serious adverse reactions (SAR) and serious adverse events (SAE)); creation of the unified standards for quality systems for BEs and hospital blood banks (HBBs). Currently the secondary legislation (by-laws), envisaged by the new law, is being developed, in accordance with the EU directives to complement provisions of the new law, which should be adopted by January 2025.

Twinning project GE 20 ENI HE EN 02 21 "Support in Implementation of Health Impact Assessment Practice in Georgia"(ongoing: 2022-2024) aims to: support in approximation of Georgian legislation to EU directives in environmental health and in line with the AA; Support technical and administrative implementation of HIA in NCDC; building partnerships between Georgian institutions and improve data value chain for HIA and Improving public participation, involving civil society and disseminating results in HIA. The project envisages following activities:

Twinning project GE18 ENI TR 03 21 "Support in Establishment of Comprehensive Road Safety Database and Further Improvement of Road Safety (ongoing: 2022-2024) is implemented together with the Ministry of Economy and Sustainable development of Georgia and the Ministry of Internal Affairs of Georgia and intends to improve the policy-making capacity in the field of the road safety at the institutional level, as well as quality of the crash data collection and analysis methods, including the elaboration of trauma registry concept.

[18] 1) Twinning project GE22 Institutional Strengthening of Environmental Health System of Georgia (2017-2019);
2) Twinning project GE/18/ENI/HE/01/09 Strengthening Blood Safety System in Georgia (2020-2022)
3) Twinning project GE 20 ENI HE EN 02 21 "Support in Implementation of Health Impact Assessment Practice in Georgia"(2022-2024)
4) Twinning project GE18 ENI TR 03 21 "Support in Establishment of Comprehensive Road Safety Database and Further Improvement of Road Safety management in Georgia" (2022-2024) beneficiary administrations of this project together with NCDC are the Ministry of economy and Sustainable Development of Georgia and Ministry of Internal affairs of Georgia

[19] https://matsne.gov.ge/ka/document/view/4441562?publication=0

Besides the Twinning projects, NCDC benefitted from TAIEX[20] projects. These projects enhanced country's capacities in blood safety, environmental health, tobacco control, road safety and traumatism and other directions: helped in providing assessment of the system and thus, initiating the necessary legislative changes, supported in institutional strengthening, capacity development, public communication and awareness raising etc, Country also implemented number of Genomic projects[21] financed by US CDC and other partners, which helped to establish the solid ground for implementation of this project.

GHOST (Global Hepatitis Outbreak Surveillance technology) (2018-2022) was established at the R. Lugar Center for Public Health Research with the ultimate goal to improve HCV surveillance in Georgia, in close collaboration with Centers for Disease Control and Prevention (CDC Atlanta, GA). GHOST technology analyzes and offers visualization of transmission patterns of HCV infection, it can identify individuals at highest risk of transmitting HCV (high-centrality nodes with multiple molecular connections or high intra-host HCV variability, or HIV coinfected) within an injection drug use network. This tool provides a better understanding of the pathogen under surveillance, but Hep C Elimination State program on its own has contributed to the development of other areas of public health, such as blood safety, infection prevention and control, strengthening of laboratory diagnostics, Genomic surveillance, development of information technology, and expansion of treatment and harm reduction services.

United Nations Secretary-General's Mechanism for Investigation of Alleged Use of Chemical and Biological Weapons (UNSGM) (ongoing: 2019-2024) has NCDC / Lugar Center actively involved in External Quality Assurance Exercise (EQAE) for bacterial & viral pathogens and biotoxins as biological weapons in the framework of the project RefBio organized by Robert Koch Institute. The main goal of the program is to evaluate and strengthen capabilities of the bio-analytical reference laboratories in the UNSGM. The exercise involves molecular and bacterial detection and characterization of biotoxins and bacterial and viral pathogens as biological weapons and their further characterization with Next Generation DNA Sequencing and bioinformatics data analysis.

"Building Genomics Core Facility (GCF) and Twinning Lugar Center of Public Health Research with the Countries from the CDC Eastern Europe and Central Asia (EECA) Region" (planned from 2025) project with the support from US CDC is planned to be implemented. The goal of the project is 1) to facilitate improved technical assistance for Genomics capacity development for CDC globally through work with CDC HQ Genomics experts and regional laboratory advisor; and 2) to extend existing Genomic surveillance capacity in Uzbekistan, Kyrgyzstan, Kazakhstan, Ukraine, and Moldova through collaboration with R. Lugar Center. The project will increase the knowledge of participants from Lugar Center and other institutions in Genomic surveillance in general and introduce them to ways to use and plan national Genomic surveillance actions at participant's respective countries.

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[20]

TAIEX Expert Mission on the Approximation of National Blood Safety Legislation to EU Regulations (18-20 June 2018)
TAIEX Multy-country Workshop "Environmental and Public Health Tracking (EPHT) as a tool for an overall capacity improvement "" (30 January – 1 February, 2019)
TAIEX Multi-Sectoral Workshop on Promoting the Accession to the Protocol to Eliminate Illicit Trade in Tobacco Products (14-17 December2020)
TAIEX Workshop on improving the tobacco cessation services (20-21 June 2022)
TAIEX Workshop on Improving the Mechanism for Regulating the Content of Tobacco Products (20-22 September 2022)
TAIEX Workshop on Promotion of the harmonization of Georgian Tobacco Control Legislation with the EU acquis and Accession to the Protocol to Eliminate Illicit Trade in Tobacco (25-27 April, 2023)
TAIEX series of events "Scaling up Cancer Early Detection and Organized Cancer Screening in Georgia" was accepted and project activities will start in 2023

[21] 1) DTRA, G-20211068133: The Mediterranean and Black Sea Flyway: Transboundary Determinants of Avian Zoonotic Infectious Diseases – Avian Zoonotic Disease Network (AZDN)/15.04. 2022- 15.04.2024
2) CDC: Extension of SARS-CoV-2 Genome Sequencing Capacity. May 2020 - officially Ongoing
3) Funding Opportunity Number: CDC-RFA-GH20-2130 "Funding Opportunity Title: Expanding Efforts and Strategies to Improve and Protect Public Health in Georgia". Component: "Extension of SARS-CoV-2 Genomic sequencing capacity" Catalog of Federal Domestic Assistance Number: 93.318
4) CDC: Strengthening detection, response and prevention of enteric diseases, outbreak detection and response in Georgia

Related Programs and Projects

The Public Administration Reform (PAR) is of utmost importance for the country and the process is supported through donor community. The EU total contribution to the "Support to the Public Administration Reform in Georgia" 2016-2019, was EUR 30 000 000 Euro, out of which EUR 20 000 000 was budget support share and EUR 10 000 000 for complementary support. The objective of the programme was to improve the efficiency, accountability and transparency of the public administration of Georgia, in line with the key Principles of Public Administration that have been developed by OECD/SIGMA in close cooperation with the European Commission. It has a particular focus on the improvement of the policy planning and coordination capacities and processes in the central public administration. The professionalization of the civil service (including the reform of the civil service training system) is also supported through the programmes.

TA project **"Support to the Public Administration in Georgia"-** EU funded; Duration: 2019-2023; Description: The objective of the project is to improve the efficiency, accessibility, accountability and transparency of the Georgian Public Administration in accordance with European principles of Public administration and best practices. More specifically, the project is mainly focused on improving the results-based approach in policy planning, development, coordination, monitoring and evaluation, increasing the awareness of the Civil servants and streamlining the implementation of the civil service reform in public institutions, improving the intra and inter-ministerial business processes related to policy making and service delivery enhancing thus the efficiency of the administration and the quality of service delivery, strengthening policy development and implementation of the Anti-Corruption and transparency national policies, thus increasing the accessibility, accountability and transparency of the executive branch and combating corruption, and raising public awareness and increasing visibility of the Government's public administration reform agenda.

TA project **"Facility for the implementation of the Association Agreement in Georgia II "**- EU funded; Duration: 2019-2023; Description: The project provides policy advice and capacity building support to the Georgian Government in coordinating the implementation of the Association Agreement, strengthening the institutional capacities of the line ministries and other public institutions to carry out the required reforms, including on policy development and legal approximation processes.

3.4 List of applicable Union acquis/standards/norms:

Union acquis/standards/norms applicable to implementation of an advanced disease surveillance (including Genomic surveillance) model in Georgia are listed below:

- *EU Acquis* concerned in the XXXI Annex of AA, to which Georgia should harmonize its legislation and which is pursuant to this project proposal are: Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.
- Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council
- Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)

The concept of Genomic surveillance is quite new and there are no EU regulations directly mentioning this topic. Therefore, the guidance is provided with the help of WHO ("Global Genomic surveillance strategy for pathogens with pandemic and epidemic potential, 2022–2032") and ECDC (ECDC strategic framework for the integration of molecular and Genomic typing into European surveillance and multi-country outbreak investigations; ECDC Single Programming Document 2023−2025) guidelines and recommendations, with the main goal to establish and further improve Genomic surveillance in the country.

3.5 Components and results per component

Component 1/ Mandatory Result 1: Approximation of Georgian legislation with the EU legislation on Genomic surveillance performed

This component aims at developing legal acts and normative documents in accordance with European guidelines and WHO recommendations on Genomic sequencing and its integration into public health surveillance models. More specifically, technical work should be undertaken to establish a policy framework that defines the objectives, scope, and guiding principles of Genomic surveillance. This framework will address broad range of issues including sample collection, sample processing, assessment, results interpretation and reporting, data privacy, data sharing and Genomic data protection etc.

Sub-Result 1.1: Genomic surveillance policy framework developed

The process of delivering sub-results will focus on developing the policy framework and respective supporting documents for establishment of the regulative framework for Genomic surveillance.

Sub-Result 1.2: Relevant legislative package elaborated

This sub-results will focus on amendments to the Law on Healthcare, Law on Public Health and State Healthcare Programmes to help incorporate Genomic Surveillance as an integral part of the healthcare system in the country.

Component 2/Mandatory Result 2: The national Genomic surveillance system strengthened

This component envisages a wide range of systemic and structural changes ranging from the strengthening the Genomic surveillance services, to improving sequencing and bioinformatic capacities, establishing efficient quality control mechanisms and enhancing clinical use of Genomic investigations. The Genomic Surveillance system (GSS) strategy should focus on strengthening Lugar Center Genomic surveillance capabilities, building data management systems, developing Standard Operating Procedure (SOP) documents. SOPs with workflows for sample collection, processing, sequencing, and analysis. Genomic surveillance programs should also emphasize quality control, data management and adherence to ethical guidelines.

Genomic surveillance relies on the sharing and analyzing of large-scale Genomic datasets, sharing mechanisms, data standards, and platforms for data integration and analysis will be established. Encouraging data sharing between institutions, countries, and international networks fosters a collaborative approach to Genomic surveillance, allowing researchers to access diverse datasets for comparative analyses and comprehensive insights.

Sub-Result 2.1: Optimization plan for the development of Genomic center in order to strengthen Genomic surveillance system and address disease threats developed

The project activities under this sub-result will focus on conducting a comprehensive assessment of Genomic surveillance as well as on analyzing gaps and prioritizing areas and needs for future interventions; developing the GSS strategy (optimization plan for the development of Genomic center). The GSS implementation and contingency plans should be developed. The plans should take into consideration organizational, budgetary, and logistical aspects as well as reflect the possibility of international collaboration with EU member states.

Acquiring new skills and capabilities through the twinning program will strengthen the foundation for the National Genome Center, which is thought to be a centralized facility for performing Genomic surveillance on the pathogens in the region, as well as, conducting genome study of the population of Georgia.

Component 3/Mandatory Result 3: Institutional capacities strengthened to ensure safety and quality of Genomic investigations

This component will focus on strengthening the capacities of institutions, such as R. Lugar center and SLA in order for the institutions to have the capability to conduct Genomic investigations correctly and effectively. The activities will include assessment of laboratory capacities and capacity building. Training needs assessment should be conducted at the Genomic center and SLA to develop the training plan. Training of trainers will be undertaken to create a cohort of trainers for future training interventions.

Sub-result 3.1: Capacities of the NCDC, Lugar Center for Public Health Research and other institutions (SLA) strengthened.

At least ten individuals from beneficiary institution (BI) will be trained in wetlab sequencing methodology. This includes proficiency in Genomic sequencing techniques, data analysis, and interpretation of Genomic data and other laboratory practices, quality assurance and internal audit capabilities. At least five Genomic epidemiologists and three bioinformaticians from BI will be trained on raw sequence data processing of Genomic surveillance studies, sequence data management and organization of respective digital libraries for safe and easy data access and traceability of the results. Workshops will be organized regarding the Genomic surveillance topic from various experts in the field.

Component 4/Mandatory Result 4: Public understanding about the importance of Genomic services increased.

The activities for reaching the result will focus on developing an effective communication strategy and conducting intensive informational and educational campaigns to raise awareness in the field of Genomic investigations among decision makers, general public, and target groups, such as medical personnel, students and academia, private sector and civil society. Public awareness raising activities will be conducted, which will be developed and targeted at the general population. This will include public lectures, workshops, webinars and educational materials that explain the basics of Genomic surveillance, its applications in public health and its potential benefits. Information about Genomic surveillance will be shared through communication channels such as websites and social media.

Sub-result 4.1: The level of awareness of the general population and specific target groups on Genomic surveillance improved.

In order to raise constant awareness of Genomic surveillance in general population regular updates on advancements, research findings, and policy developments related to Genomic surveillance will be shared with general public to expand their knowledge on the topic. Also, general public will be encouraged to share feedback, address concerns, and demonstrate the value of public input in shaping Genomic surveillance policies and practices.

During the public lectures, webinars a pre-test and post-test can be created for the audience, in order to evaluate their understanding of Genomic surveillance before and after the activity they take part in. The questionnaires will be shared on social media and websites and general public will be encouraged to share their understanding of Genomic surveillance through these activities.

3.6 Means/input from the EU Member State Partner Administration(s)*:

Member State(s) is/are kindly requested to develop activities in the submitted proposal, which are needed in order to achieve the results stipulated in the fiche.

The MS Project Leader (PL) will be expected to devote a minimum of 3 days per month to the project in his/her home administration. In addition, s/he will coordinate from the Member State side the work of the Project Steering Committee (PSC). MS PL may participate in the project also as Short-Term Expert (STE). In this case the MS Project Leader should satisfy requirements stipulated in the fiche for both the Project Leader and the relevant STE profile.

The Resident Twinning Advisor (RTA) will be located in the headquarter (HQ) of the MoIDPLHSA (Labour Inspection Office) in the beneficiary country on a full-time basis and will be responsible for the direct implementation of the project under the overall supervision of the MS PL. The RTA will maintain day-to-day cooperation with the beneficiary administration and coordinate the work performed by the STEs. The RTA will have a key role in the coordination of the inputs required for the successful implementation of all the project activities.

The RTA should be supported by component leaders and a permanent RTA Assistant. The component leaders will be responsible for the coordination, guidance and monitoring of their components, analyse the component areas and draft relevant thematic/ technical contributions. They will liaise with MS and BC PLs and have daily contacts with RTA and Beneficiary Administration (BA) counterpart.

The RTA assistant should be in close collaboration with the BA. S/he will perform general project duties and provide translation and interpretation services as necessary, practical arrangements for the project, such as organizational issues of expert missions, conferences, training, seminars, maintaining project records, etc. Until the RTA can select and hire an assistant, the BA makes a member of its staff available to support the RTA in his/her daily tasks.

The required MS experts must either be civil/public servants of the relevant MS administration or be permanent staff of authorised mandated bodies. All experts must comply with the requirements set in the Twinning Manual Revision 2017 - update 2022.

Minimum two visibility events will be organized in the course of the implementation of the project: Launching event at the start of the implementation and the Closing event at the end of the implementation of the project activities.

A full-time language assistant should be recruited. S/he should perform most of the required interpretation/translation services. S/he will provide day-to-day interpretation/translation to the RTA and project experts during missions.

Whenever required and needed for simultaneous interpretation during seminars and workshops, translation of large volume of documents additional interpretation will be procured and funded by the project.

Proposals shall include only the CVs of the proposed PL, of the RTA and of the Component Leaders.
Any description of the suggested arrangements and scheduling shall remain broad enough to offer Member States the possibility to elaborate a proposal of their own, demonstrating the added value of their own methodological approach and comparative advantage of their contribution.

3.6.1 Profile and tasks of the PL:

The Member State PL should have the capacity to lead the implementation of the project and the ability to mobilize the necessary expertise in support of project's efficient implementation. She/he will be expected to devote a minimum of 3 days per month to the project in his/her home administration. In addition, as co-chairperson, he/she will coordinate from the Member State side the work of the Project Steering Committee (PSC), which shall meet in Georgia on a quarterly basis at least.

Profile:

- A high ranking current official of a Member State administration with a sufficient managerial position in Health policy development/implementation/coordination;
- University level education in a relevant discipline (e.g. Medicine, Biology or Public Health), or equivalent professional experience in a related field 8 years;
- at least 3 years' of professional experience in the field of public health administration;

- Previous experience in the field of project management, with a demonstrable record of organizational leadership and reform implementation;
- Good understanding of regulatory/supervisory system of Genomic surveillance and its organizational models in a Member State;
- Comprehensive knowledge of EU/WHO public health legislation with special focus on Genomic surveillance;
- Experience in international collaboration in public health;
- Excellent command of spoken and written English;
- Good communication, presentation and interpersonal skills;
- Good leadership and managerial skills;
- Excellent Computer literacy.

Tasks:

- Overall direction, supervision, guidance and monitoring of the project;
- Mobilization of the necessary expertise in support of the efficient implementation of the project;
- Lead an operational dialogue, advocate, thrust and back up the project at political level;
- In cooperation with the PL counterpart signing and submission the interim quarterly and final project reports prepared with the support of the RTA to the concerned authorities;
- Produce project impact assessment with the support of the RTA;
- Formal signing of project work plan(s) and/or their updates;
- Ensuring timely achievement of the project results;
- Provision of legal and technical advice whenever needed. Co-chairing of project steering committees.

3.6.2 Profile and tasks of the RTA:

The RTA will be located in the premises of the BA on a fulltime basis and will be responsible for the direct implementation of the project under the overall supervision of the MS Project Leader.

He/she will work closely with the BC Project Leader and the RTA Counterpart to deliver the project outputs.

The RTA will maintain day-to-day cooperation with the beneficiary administration and coordinate the work performed by the STEs for the whole duration of the project implementation. The RTA will have a key role in the coordination of the inputs required for the successful implementation of all the project activities.

The RTA should be supported by a permanent RTA Assistant. The RTA assistant should work in close collaboration with the beneficiary administration BA. The RTA assistant will perform general project duties and will be providing translation and interpretation services as necessary, practical arrangements for the project, such as organizational issues of expert missions, conferences, training, seminars, maintaining project records and etc. Until the RTA can select and hire an assistant, the Beneficiary administration will make a member of its staff available to support the RTA in his/her daily tasks.

A full-time language assistant should also be recruited. She/he should perform most of the required interpretation/translation services. She/he will provide day-to-day interpretation/translation to the RTA and project experts during missions.

Whenever required and needed for simultaneous interpretation during seminars and workshops, translation of large volume of documents additional interpretation may be procured and funded by the project.
Minimum two visibility events will be organized in the course of the implementation of the project. Kick-off meeting at the start of the implementation and the Final meeting at the end of the implementation of the project activities. These will have to be coordinated with the EU Delegation to Georgia.

Profile:

- University level education in a discipline relevant to this project (e.g. Medicine, Biology, Public Health, Management) or equivalent professional experience in a related field 8 years;
- At least 3 years of professional experience in Genomic surveillance or related subjects;

- Good knowledge of legal approximation (LA) process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of Genomic center organization, management, quality control and supervision;
- Working experience on EU Genomic surveillance studies for communicable and non-communicable diseases in a Member State would be an asset;
- Collaboration experience with WHO and ECDC and other relevant international organizations would be an asset;
- Good team-working, communications, presentation and interpersonal skills;
- Good organizational and project management skills;
- Strong analytical and report writing skills;
- Excellent command of spoken and written English;
- Excellent Computer literacy;
- Previous experience in project management or relevant.

Tasks:

- Overall coordination of project implementation and of all activities;
- Develop the initial and subsequent work plans, and project progress reports together with PL to be submitted to the Steering Committees;
- Provide technical input to the project whenever needed and provision of advice in his/her field of Expertise;
- Coordinate activities of the team members in line with the agreed work plan to monitor quality of their outputs and enable timely completion of project outputs;
- Liaise with PL counterparts and daily contacts with RTA counterpart;
- Liaise with EU Delegation to Georgia (EUD) Project Manager and Programme Administration Office (PAO);
- Liaise with key stakeholders, other relevant projects and relevant Georgian institutions;
- Contribute to the work of the sector development process set up in the Beneficiary Country.

The RTA will be introduced to the BC stakeholder of the project, counterparts and staff. He/she will attend trainings at the Commission Headquarters, including on the technical provisions of the Twinning Manual, the EU policy and cooperation framework and/or on the latest EU legislation in the relevant policy area/sector. The PL counterpart and the RTA counterpart can attend the trainings together with the RTA of the project.

3.6.3 Profile and tasks of Component Leaders*:*

To achieve coherence in the implementation of all activities pertaining to the specific components and accomplish mandatory results/outputs, Component Leaders (short-term experts) will be designated to each specific component who will coordinate the intervention of all other Member State experts mobilized for the same component. Beneficiary institution will assign a Component Leader counterpart for each component who will be the permanent interlocutor of the MS Component Leader coordinating the specific component. The Component Leaders will work in close collaboration with the RTA and the Beneficiary counterparts in order to achieve mandatory results/outputs pertaining to the specific component and to contribute to overall success of the project.

The profile, exact number and specific Terms of Reference for each Component Leader along with the names and functions of the Component Leader counterparts will be defined at the Work Plan preparation stage by the MS Project leaders and/or the RTA and its counterpart. The ToR will specify the detailed inputs of the Component Leaders and the duration of their missions.

Component leader 1 profile:

- University level education in a relevant discipline, or equivalent professional experience in a related field of 8 years;
- At least 3 years of professional experience in the field related to the component 1;
- Good experience in standard setting and legal drafting processes relevant to the project scope;
- Good experience in capacity building activities;
- Specific knowledge in the field of standards, technical requirements and specifications related to Genomic surveillance studies would be considered as asset;
- Good knowledge of LA process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of Genomic surveillance, its organization, management, quality control and supervision;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial, organizational and mentoring skills;
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Computer literacy.

Component leader 1 Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Providing recommendations regarding the tasks and activities relevant to the component
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Preparing timely proposals for any corrective measures;
- Provision of legal and technical advice and analysis whenever needed;
- Supporting RTA in report writing relevant to the component;
- Liaise with MS and BC PLs and daily contacts with RTA and BA counterpart.

Component leader 2 profile:

- University level education in a relevant discipline, or equivalent professional experience in a related field of 8 years;
- At least 3 years of professional experience in the field related to the component 2;
- Good experience in standard setting and legal drafting processes relevant to the project scope;
- Good experience in capacity building activities;
- Specific knowledge in the field of standards, technical requirements and specifications related to Genomic surveillance studies;
- Good knowledge of LA process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of Genomic surveillance, its organization, management, quality control and supervision;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial, organizational and mentoring skills;
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Computer literacy.

Component leader 2 Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Providing recommendations regarding the tasks and activities relevant to the component;
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Preparing and conducting training programs, information and dissemination seminars with various Stakeholders;
- Preparing timely proposals for any corrective measures;
- Provision of legal and technical advice and analysis whenever needed;
- Advocate for policies and funding that support genomic surveillance efforts at the national and international levels;
- Supporting RTA in report writing relevant to the component;
- Liaise with MS and BC PLs and daily contacts with RTA and BA counterpart.

Component leader 3 profile:

- University level education in a relevant discipline, or equivalent professional experience in a related field of 8 years;
- At least 3 years of professional experience in the field related to the component 3;
- Good experience in standard setting and legal drafting processes relevant to the project scope;
- Good experience in capacity building activities;
- Specific knowledge in the field of standards, technical requirements and specifications related to Genomic surveillance studies;
- Good knowledge of LA process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of Genomic surveillance, its organization, management, quality control and supervision;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial, organizational and mentoring skills;
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Computer literacy.

Component leader 3 Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Providing recommendations regarding the tasks and activities relevant to the component
- Drafting thematic/technical contributions and documents relevant to the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Preparing and conducting training programs, information and dissemination seminars with various Stakeholders;
- Preparing timely proposals for any corrective measures;
- Coordinate capacity-building activities, considering importance of the ethical guidelines, legal requirements, and institutional policies;
- Provision of legal and technical advice and analysis whenever needed;
- Supporting RTA in report writing relevant to the component;
- Liaise with MS and BC PLs and daily contacts with RTA and BA counterparts.

Component leader 4 profile:

- University level education in a relevant discipline, or equivalent professional experience in a related field of 8 years;
- At least 3 years of professional experience in the field related to the component 4;
- Good experience in standard setting and legal drafting processes relevant to the project scope;
- Good experience in capacity building activities;
- Specific knowledge in the field of standards, technical requirements and specifications related to Genomic surveillance studies;
- Good knowledge of LA process, relevant EU legislation and institutional requirements related to various components of this project;
- Sound comparative knowledge of Genomic surveillance, its organization, management, quality control and supervision;
- Previous experience in project management would be an asset;
- Strong analytical and report writing skills;
- Good managerial, organizational and mentoring skills;
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Computer literacy.

Component leader 4 Tasks:

- Component coordination, guidance and monitoring;
- Conducting analysis of the area relevant to the component;
- Providing recommendations regarding the tasks and activities relevant to the component;
- Drafting a sound communication strategy and plan
- Design and execute awareness campaign to highlight the significance of genomic services in healthcare, disease prevention, and personalized medicine;
- Drafting thematic/technical contributions and documents relevant for the results of the component, in close collaboration with BC counterparts and relevant project experts, and Georgian institutions;
- Preparing and conducting training programs, information and dissemination seminars with various Stakeholders;
- Preparing timely proposals for any corrective measures;
- Provision of legal and technical advice and analysis whenever needed;
- Supporting RTA in report writing relevant to the component;
- Liaise with MS and BC PLs and daily contacts with RTA and BA counterpart.

3.6.4 Profile and tasks of other short-term experts*:*

Short term experts made available for the implementation of a Twinning project shall be fully integrated within the Member State institutions involved in the delivery of the required expertise. Short-term experts are officials or assimilated agents of a Member State public administration, or mandated body. They deliver their expertise under the overall responsibility of the Member State PL and the coordination and supervision of the RTA in in close cooperation with the Component Leader in order to meet the specific objectives as set out above:

Profile:

- University level education in a relevant discipline, or equivalent professional experience in a related field of minimum 8 years;
- At least 3 years of professional experience in the relevant field;

- Specific knowledge and working experience with genome surveillance studies, epidemiological and molecular;
- Specific knowledge in Genomic surveillance of communicable and non-communicable diseases;
- Sound knowledge and working experience in Genomic surveillance studies and quality control, quality assurance and quality management;
- Sound knowledge and working experience in molecular epidemiology;
- Sound knowledge and particular skills in development and coordination of regional and national Genomic surveillance studies;
- Experience in awareness raising, information campaigns and knowledge of different communication tools;
- Coaching, training and facilitator skills;
- Experience in developing of training modules and materials, good record in training delivery;
- Experience in network management, software development and database administration relevant to blood safety;
- Previous experience as an STE on an EU-funded Twinning Project would be an asset.
- Good team-working, communication, presentation and interpersonal skills;
- Fluency in written and spoken English;
- Excellent computer literacy (word, excel, power point etc.).

Tasks:

- Contributing in drafting project related legal documents in accordance with the national rules for legislative development in their respective fields;
- Contributing in preparation of strategy documents, guidelines, operational procedures and manuals/instruction handbooks related to their field of expertise;
- Assistance with the preparation of trainings, study tours, conferences, workshops, seminars, awareness raising activities etc;
- Supervision and on-site coordination of all activities related to their field of expertise and performed under this project;
- Contributing to the sustainability of the project by ensuring that aspects of the project related to their field of expertise are implemented timely and properly;
- Provision of legal and/or technical advice and consultations whenever needed in their respective fields;
- Preparing timely proposals for any corrective measures;
- Communicate with stakeholders and media;
- Liaise with RTA, Component leaders and BA counterparts.

Proposals shall include only the CVs of the proposed PL, of the RTA and of the Component Leaders (STEs CV should not be included in the MS proposal) The Project Leader/RTA are free to propose additional STEs as they see fit, based upon the needs of the project and in agreement with the beneficiary.

4. Budget

The budget for this grant is EUR 1,200,000.

5. Implementation Arrangements

5.1 Implementing Agency responsible for tendering, contracting and accounting (AO/CFCU/PAO/European Union Delegation/Office):

The EUD will be responsible for the tendering, contracting, payments and financial reporting and will work in close cooperation with the BA. The person in charge of this project within the EUD is:

Ms. Nino Kochishvili
Programme Manager,
Delegation of the European Union to Georgia

64b Ilia Chavchavadze Avenue, 0179 Tbilisi, Georgia
Tel: +995 32 2364364
E-mail: Nino.Kochishvili@eeas.europa.eu

5.2 **Institutional framework**

The direct beneficiary institution for the Twinning project will be the National Center for Disease Control and Public Health - a key agency for public health in Georgia. The NCDC has a significant role in improvement of population health, through implementation of public health state programs in the country. Its mission is protection and improvement of health of Georgian population through scientific, evidence-based prevention, preparedness and timely response to public health threats. (The organizational chart is provided in Annex II).

To achieve outlined priorities and objectives, NCDC develops annual plans, based on the Georgian Government's Program of work, the MoIDPLHSA priorities, WHO guiding principles, scientific research, the UN SDGs and the commitments under the EU-Georgia AA and other international agreements and conventions in the field of public health.

The scope of its activities is oriented on preventive medicine, performing laboratory diagnostic activities, responding to public health emergencies, including the environmental and other behavioral risk factors and carries out public health state programs in the fields of disease early detection and screening, immunization, epidemiological surveillance, blood safety, maternal and child health, prevention of occupational diseases, management of HIV/AIDS, tuberculosis and hepatitis C, and health promotion.

Within the NCDC, the functional responsibilities are distributed across several departments and divisions: a) Communicable Diseases Department conducts epidemiological surveillance of communicable diseases and immunization; b) Non-communicable Diseases Department deals with communicable diseases and their risk factors and promotes healthy life-style within the health promotion state program; c) Public Health State Programs and Regional Management Department is responsible for the implementation of the public health state programs and coordinates activities with the regional/district public health centers and laboratories; d) Environmental Health Department is responsible for assessment of environmental hazards and climate change affecting human health e) Legal Division under the Administrative Department prepares legal and administrative documents for adoption and participates in the law making processes; f) International and Public Relations Division provides coordination with the donor/partner organizations, including the EU and participates in public awareness raising together with the Health Promotion Division; g) Financial Economic Department provides the state procurement activities and other related activities; h) Richard Lugar Center for Public Health Research conducts laboratory activities and with its BSL-2 and BSL-3 facilities serves as a reference laboratory of the public health system of Georgia..

Department of Virology, Molecular Biology and Genome Research at Lugar Center will be a main implementing partner of the project. The department has well established sequencing capacity with several NGS platforms – Illumina MiSeq, MiSeqDX, NextSeq and Oxford Nanopore MinION Mk1C (sequencing machines), capillary electrophoresis systems, as well as, data analysis hardware and tools. The experience of using this generation technique at NCDC counts already ten years – it was initiated under US Defense Threat Reduction Agency (DTRA) funding and mentoring of Los Alamos National Laboratory (LANL). The novel NGS methodologies / approaches are implemented regularly and used for sequencing bacterial, viral and metagenomic samples. NCDC is capable to perform sequencing of isolated bacterial strains, metagenomic samples using shotgun sequencing and enrichment techniques for viruses.

Above mentioned departments/divisions will be involved in the implementation of the Twinning project within the scope of their competencies. Up to 14 people will form a task force and will be involved in day-to-day activities, while others will participate according to the needs and implementation phases of the project. It is anticipated that the results of the project will strengthen R. Lugar Center's capacities for providing Genomic investigations and contribute institutional strengthening by supporting other involved structural units and agencies and coordination among them.

Besides, NCDC will be closely collaborating with MoIDPLHSA, including the Health Policy Department, Donor Coordination Division, PR Department etc; as well as the LEPL State Regulation Agency for Medical Activities (RAMA), line ministries, including the Ministry of Environmental Protection and Agriculture, State Laboratory of Agriculture and other stakeholders in the field.

Through the activities of the project and experience gained through trainings and workshops capacity of R. Lugar center laboratory staff will be strengthened. This would have a positive effect on capacity building of the staff of other institutions, as trained staff from R. Lugar center will share acquired knowledge and expertise with other institutions such as SLA. Currently SLA is in process of developing and implementing sequencing techniques at their laboratory facility, with the help of R. Lugar Molecular Biology/Genomics department's laboratory staff. SLA and other institutions will be invited to take part in workshops with experts to raise their understanding and knowledge about Genomic surveillance even further.

5.3 Counterparts in the Beneficiary administration:

5.3.1 Contact person

Ms. Nana Kavtaradze
Head of International and Public Relations Division
National Center for Disease Control and Public Health
Kakheti Highway 99, Tbilisi 0198, Georgia

5.3.2 PL counterpart

Dr. Paata Imnadze
Deputy Director General
National Center for Disease Control and Public Health
Kakheti Highway 99, Tbilisi 0198, Georgia

5.3.3 RTA counterpart

Mr. Nika Khachidze
Specialist, R. Lugar Center for Public Health Research
National Center for Disease Control and Public Health
Kakheti Highway 99, Tbilisi 0198, Georgia

6. Duration of the project

The duration of the project is 24 months. [The implementation process/ period will end 3 months after the completion of the work plan which will take 27 months].

7. Management and reporting

7.1 Language

The official language of the project is the one used as contract language under the instrument (English). All formal communications regarding the project, including interim and final reports, shall be produced in the language of the contract.

7.2 Project Steering Committee

A project steering committee (PSC) shall oversee the implementation of the project. The main duties of the PSC include verification of the progress and achievements via-à-vis the mandatory results/outputs chain (from mandatory results/outputs per component to impact), ensuring good coordination among the actors, finalizing the interim reports and discussing the updated work plan. Other details concerning the establishment and functioning of the PSC are described in the Twinning Manual.

7.3 Reporting

All reports shall have a narrative section and a financial section. They shall include as a minimum the information detailed in sections 5.5.2 (interim reports) and 5.5.3 (final report) of the Twinning Manual. Reports need to go beyond activities and inputs. Two types of reports are foreseen in the framework of Twining: interim quarterly reports and final report. An interim quarterly report shall be presented for discussion at each meeting of the PSC. The narrative part shall primarily take stock of the progress and achievements via-à-vis the mandatory results and provide precise recommendations and corrective measures to be decided by in order to ensure the further progress.

8. Sustainability

The mandatory results and outcomes of the project are in full compliance with the state policy priorities in public health. The project will have an impact on Georgian healthcare system and enhance its capacity for accurate and timely detection of relevant communicable conditions and cancer.
It envisages institutional changes through the establishment of new structures (Genomic Surveillance Center) and integrating new functions into existing structures (such as national Genomic center, National biobank, etc.) at both public and private sectors, as well as veterinary sector, based on sectoral policy, relevant legislation for the maintaining Genomic Data. Furthermore, financial sustainability of the project outputs will be guaranteed by the state budgetary assignations allocated for the institutional (NCDC) sustainability, the project achievements will be embedded in the routine functions and works of the Ministry and its subordinated agencies.

9. Crosscutting issues

The project will be implemented by NCDC, the Beneficiary Administration (BA), where more than 70% of the employees are women with equitable engagement in the organizations management, impartial access to decent work for women of all ages and equal opportunity to participate in the organizational policy, decision making and governance processes. The project declares equal health opportunities as its specific objective aims at “Genomic Surveillance for Communicable and Non-Communicable Diseases” which means that project outcomes will ensure equity and equality in the access to quality preventive and curative health care and will benefit Georgian population irrespective of gender, disability, racial, religion, and belief, ethnic or social origin. The principles of equal opportunities will be applied to all involved parties and stakeholders through the project implementation process as well as will be reflected in all documents developed during the project. The project objectives reflect the principles of The Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine imposing prohibition of financial gain and disposal of a part of the human body, including blood. Whilst environmental requirements are not immediately applicable to the implementation of the project, if any such situation arises, both partners are required to comply with the environmental requirements of the EU.

10. Conditionality and sequencing

The main concepts of the project are based on current successful cooperation with EU instruments. The success of the project also depends on macroeconomic factors such as understanding of external conditions and identifying the binding constraints that guide selectivity of activities that spur and sustain healthcare reforms. The twinning project will accomplish the ongoing developments of below indicated topics/projects: project outcomes will be stemmed from the sequencing of institutional adjustment and structural reforms and could therefore be initiated early on, in particular:

a) Establishing more focused approach for Genomic surveillance of communicable and non-communicable diseases;
b) Creating a competent staff at the genome department of Lugar Center and developing institutional capacities.
c) Introduction of new methods and approach for Genomic surveillance studies around the country.

11. Indicators for performance measurement

The project partners will ensure the smooth implementation of project activities and assess performance measurement in line with the logical framework. Through the project operation phase the project counterparts will meet regularly to ensure consistency of project implementation and achievement of the results.

Performance indicators linked to Component 1 - Approximation of Georgian legislation with the EU legislation on Genomic surveillance performed

- Number of the legal acts harmonized
- Number of the legal acts elaborated in compliance with the WHO guidelines on genomic surveillance

Sub-Result 1.1: Genomic surveillance policy framework developed

- Availability of assessment of existing legal framework
- Availability of Concept on Genomic Surveillance Policy Framework

Sub-Result 1.2: Relevant legislative package elaborated

- Status of law/decree/order (Amendments could be introduced to the law of Georgia on Health Care/ to the Public Health Law of Georgia/ to the Patients' rights and other relevant legislative acts).

Performance indicators linked to Component 2 - The national Genomic surveillance system strengthened

- Availability of Genomic surveillance protocols
- Status of priority list of pathogens for Genomic surveillance
- Level of Genomic surveillance integrated into the public health system of Georgia

Sub-Result 2.1: Optimization plan for the development of Genomic center in order to strengthen Genomic surveillance system and address disease threats developed

- Availability of functional review report of the Genomic surveillance system

Performance indicators linked to Component 3 - Institutional capacities strengthened to ensure safety and quality of Genomic investigations

- Availability of Strategic plan outlining clear objectives, actionable goals, and measurable outcomes for strengthening institutional capacity
- Number of TOTs

Sub-Result 3.1: Capacities of the NCDC, Lugar Center for Public Health Research and other institutions (SLA) strengthened.

- Availability of training needs analysis

- Number of WetLab specialists trained
- Number of Bioinformaticians trained
- Number of Genomic epidemiologists trained

Performance indicators linked to Component 4 - Public understanding about the importance of Genomic Services increased

- Status of communication strategy
- Level of awareness in General Public about Genomic surveillance services

Sub-Result 4.1: Awareness of the general population and specific target groups on Genomic surveillance improved

- Availability of elaborated informational material for general population
- Number of thematic informational sessions on Genomic surveillance for target groups (people working in a relevant medical field, university and high school students).

12. Facilities available

The Beneficiary commits itself to deliver the following facilities:

- Adequately equipped office space for the RTA and the RTA assistant(s) for the entire duration of their secondment;
- Supply of office room including access to computer, telephone, internet, printer, photocopier;
- Adequate conditions for the STEs to perform their work while on mission;
- Provide suitable venues for the training sessions and meetings that will be held under the Project;
- Security related issues will be assured according to the standards and practices applicable for all Georgian public institutions.

ANNEXES TO PROJECT FICHE

1. The Simplified Logical framework matrix as per Annex C1a (compulsory)
2. Organizational Chart

Project title: Enhance National Disease Surveillance System in Georgia through Improvement of the Epidemiological and Molecular (Genomic) Surveillance				Programme name and number: The financing decision is under the "Support for the Implementation of the EU-Georgia Association Agreement" OPSYS reference: ACT-60617	
Beneficiary Institution: Ministry of Internally Displaced Persons from the Occupied Territories, Labour, Health and Social Affairs of Georgia, L. Sakvarelidze National Center for Disease Control and Public Health				Total budget: **1, 200,000 €**	EU ENI financing (100%)
	Description	**Indicators (with relevant baseline and target data)**	**Sources of verification**	**Risks**	**Assumptions (external to project)**
Overall Objective	To contribute to the strengthening capacity for legislative approximation and implementation of the Association Agreement	• Increased capabilities of Genomic surveillance by establishment of the molecular (Genomic) surveillance system **Baseline**: 2023 – Disease surveillance system exists with limited genome sequencing capacity – very few viral species are sequenced on regular bases. **Target**: 2025 – Genomic Surveillance well incorporated in national disease surveillance system	• National Center for Disease Control and Public Health Reports on implementation of the national surveillance programme	• Possible public health emergency which may require the changes of NCDC's priorities • Possible geopolitical instability in the region	
Specific (Project) Objective(s)	Building genome sequencing capacity at the National Center for Disease Control and Public Health (NCDC) and introducing relevant legal and regulatory	• Number of viral and bacterial pathogens genomic surveillance established **Baseline**: Genomic surveillance performed on 3 viral and pathogens as of 2023	• Legal and regulatory acts adopted	• Possible public health emergency which may require the changes of NCDC's priorities • Possible	

	framework in line with EU directives and the one-health concept	**Target**: Genomic surveillance performed on five additional pathogens by the end of 2025 - 8 pathogens in total • Number of additional global disease reporting networks connected **Baseline**: Georgia part of 2 networks as of 2023 **Target**: Georgia part of 3 additional networks by the beginning of 2026 - 5 networks in total		geopolitical instability in the region	
Mandatory results/outputs by components	**Mandatory result 1:** Approximation of Georgian legislation with the EU legislation on Genomic surveillance is performed	Number of the legal acts harmonized **Baseline**: No approximation done as of 2023 **Target**: Approximation of legislations done by the end of 2025 (at the beginning of 2026). Number of the legal acts elaborated in compliance with the WHO guidelines on Genomic surveillance **Baseline**: No legal acts elaborated as of 2023 **Target**: Number of legal acts elaborated in compliance with the WHO guidelines by the end of year	• Law/decree/order issued	• Possible public health emergency which may require the changes of NCDC's priorities • Possible geopolitical instability in the region	

		2025 – beginning of 2026			
Sub-results per component (optional and indicative)	**Sub-Result 1.1:** Genomic surveillance policy framework developed	Availability of assessment of existing legal framework **Baseline**: No assessment is done as of 2023 **Target**: Assessment conducted by beginning of 2025 Availability of Concept on Genomic Surveillance Policy Framework **Baseline**: No concept as of 2023 **Target**: Concept document elaborated at the beginning of 2025	• Assessment report • Concept Document of Genomic Surveillance policy framework adopted by Director General of NCDC		
	Sub-Result 1.2: Relevant legislative package elaborated	Status of law/decree/order (Amendments could be introduced to the law of Georgia on Health Care/ to the Public Health Law of Georgia/ to the Patients' rights and other relevant legislative acts). **Baseline**: No law/decree/order as of 2023 **Target**: Law/decree/order elaborated by the end of 2025	• Law/decree/order adopted		

Mandatory results/outputs by components	**Mandatory result 2:** The national Genomic Surveillance system strengthened	Availability of Genomic surveillance protocols **Baseline**: No existing protocols as of 2023 **Target**: Genomic surveillance protocols developed by 2026 Status of priority list of pathogens for Genomic surveillance **Baseline**: No existing priority lists available as of 2023 **Target**: Priority list adopted by the end of 2025 Level of Genomic surveillance integration into public health system of Georgia **Baseline**: Genomic Surveillance not integrated as of 2023 **Target**: Genomic Surveillance partially integrated by the end of 2026	• Assessment report of the Genomic surveillance system is available • Ordinance of the government establishing amendments to the Charter of NCDC • Order of the MoIDPLHSA adopting the list of pathogens for Genomic surveillance		

Sub-results per component (optional and indicative)	**Sub-Result 2.1:** Optimization plan for the development of Genomic center in order to strengthen Genomic surveillance system and address disease threats developed	Availability of functional review report of the Genomic surveillance system **Baseline**: No functional review report conducted as of 2023 **Target**: Functional review performed by beginning of 2025 Status of development plan of Genomic center **Baseline**: No existing status of development plan as of 2023 **Target**: Status of development plan prepared by the end of 2025	• National Genomic center / development plan document • Order of the minister of MoIDPLHSA about the structural arrangements and staffing of NCDC	• Potential delays by administrative procedures	
Mandatory results/outputs by components	**Mandatory result 3:** Institutional capacities strengthened to ensure safety and quality of Genomic investigations.	Availability of Strategic plan outlining clear objectives, actionable goals, and measurable outcomes for strengthening institutional capacity **Baseline**: No strategic plan available as of 2023	• Strategic plan available • Training records		

		Target: Strategic plan available at the beginning of 2026 • Number of TOTs **Baseline**: No TOTs as of 2023 **Target**: At least six TOTs by the end of 2026			
Sub-results per component (optional and indicative)	**Sub-result 3.1:** Capacities of the NCDC, Lugar Center for Public Health Research and other institutions (SLA) strengthened	• Availability of training needs analysis **Baseline**: No analysis available as of 2023 **Target**: Training needs analysis conducted at the beginning of 2025. • Number of WetLab specialists trained. **Baseline**: Three specialists available as of 2023 **Target**: Five new specialists trained by the beginning of 2026 • Number of Bioinformaticians trained **Baseline**: Three specialists trained as of 2023 **Target**: Four new specialists trained by the beginning of 2026	• Report of training needs analysis is available • Training Records	• Outflow of the trained personnel to other jobs	

		• Number of Genomic epidemiologists trained **Baseline**: No Genomic epidemiologists trained as of 2023 **Target**: At least five Genomic epidemiologists trained by the beginning of 2026			
Mandatory results/outputs by components	**Mandatory result 4:** Public understanding about the importance of Genomic Services increased.	• Status of communication strategy **Baseline**: No communication strategy available as of 2023 **Target**: Communication strategy developed by the beginning of 2025 Level of awareness in General Public about Genomic surveillance services **Baseline**: No information about the awareness in Genomic surveillance services as of 2023 **Target**: Increased Level Of Awareness in Genomic surveillance services by 2026	• NCDC General Director's order on adopting the communication strategy document • Published informational material through NCDC website/social media • Reports of educational campaigns	• Limited awareness of general population, coupled with disinformation by the bots, might result in an inaccurate perceptions and misconceptions about Genomic surveillance.	

Sub-results per component (optional and indicative)	**Sub-result 4.1:** Awareness of the general population and specific target groups on Genomic surveillance improved	Availability of elaborated informational material for general population **Baseline**: No informational material available as of 2023 **Target**: Information materials elaborated at the beginning of 2025 Number of thematic informational sessions on Genomic surveillance for target groups (people working in a relevant medical field, university and high school students). **Baseline**: No thematic informational sessions conducted as of 2023 **Target**: At least 6 informational sessions conducted by the beginning of 2026	• Communication strategy document • Reports on awareness raising campaigns • Pre-test and post-test results		

Annex II

The organizational chart of the National Center for Disease Control and Public Health