ANNEX C1: Twinning Fiche[1]

Project title: Improving human capital and implementation of the institutional Policy of the National Vaccine Institute Ghana

Beneficiary administration: National Vaccine Institute, Ghana

Twinning Reference: GH 22 NDICI HE 01 25

Publication notice reference: 184869

EU funded project

TWINNING TOOL

[1] In case of different language versions of the Twinning Fiche it must be clearly indicated which language version prevails.

1. Basic Information

1.1 Programme: NDICI AFRICA 2022/ ACT-60936– Support Measures – Direct Management mode

1.2 Twinning Sector: Health and consumer protection

1.3 EU funded budget: EUR 1,200,000.00

1.4 Sustainable Development Goals (SDGs): This project is contributing to:

SDG 3: Good Health and Well-being

SDG 9: Industry, Innovation and Infrastructure and

SDG 17: Partnerships

2. Objectives

2.1 Overall Objective:

To enable the National Vaccine Institute (NVI) to coordinate and supervise research, development, manufacture, and market access of safe, efficacious and affordable vaccines and sera in Ghana and the African continent through the facilitation of Public Private Partnership arrangements.

2.2 Specific objective:

The specific objective of this project is to improve human resource capacity and strengthen institutional policy implementation to create a well-resourced, structured and efficient organisation capable of advancing Ghana's vaccine manufacturing ambitions.

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

Ghana's Medium-Term National Development Policy Framework (MTNDPF) for 2024–2028 (building on the 2022–2025 framework) sets out broad goals and specific objectives aimed at accelerating socio-economic development and improving the welfare of Ghanaians. The framework is aligned with the long-term vision "Ghana@100" (Agenda 2057) and integrates national priorities with international commitments such as the SDGs, African Union Agenda 2063 and the African Continental Free Trade Area. These are broken down into six pillars: (1) build a prosperous country; (2) create opportunities for all Ghanaians; (3) safeguard the natural and built environment; (4) maintain a stable, united and safe country; (5) build resilience to threats; (6) improve delivery of development outcomes. Ghana's Medium-Term Policy Framework (2024–2028) integrates vaccine manufacturing as a cross-cutting priority to achieve health security, economic development, and universal health coverage. Ghana's Universal Health Coverage (UHC 2020-2030) policy is anchored in the **UHC Roadmap 2020-2030**, which outlines the government's commitment to ensuring that all Ghanaians have timely access to high-quality essential health services without financial hardship. The policy builds on the National Health Policy (2020) and National Medicines Policy (2017) and aligns with global frameworks such as the Sustainable Development Goals.

Partners at national and regional levels have identified several targets in response to the increasing interest in the industry, with the Africa Centres for Disease Control and Prevention (Africa CDC's) notable goal being that 60 percent of all vaccines used on the continent will be produced in Africa by 2040. This vertically structured, politically driven objective, has generated substantial influence by stimulating progress to achieve equitable vaccine access as a core component, the goal is to ensure that local vaccine manufacturing for Ghana will enhance health security by reducing dependency on imported vaccines, which are often subject to supply disruptions and high costs. This supports UHC's principle of leaving no one behind by ensuring continuous vaccine availability and the Government of Ghana's national roadmap for local vaccine and sera production by 2030.

In Ghana, the FDA will exercise critical control functions competently and independently, backed up with enforcement power for locally produced vaccines. The mandate of the FDA to regulate medicines is enshrined in the Public Health Act 2012, Act 851, Part 7, Sections 112, 115, 118, 125, 148 and 131, Part 8, which covers Standards, Control of manufacturing, Registration, Safety Monitoring, Licensing & Permits, Guidelines, Codes of Practice and Clinical Trials. The FDA is currently at World Health Organisation (WHO) Maturity Level 3 and requires funding to enhance its regulatory capacity for vaccines.

It is also key to strengthen research and development (R&D) for vaccine manufacturing, for various institutions such as the University of Ghana (UG), Kwame Nkrumah University of Science & Technology

(KNUST), University of Health & Allied Sciences (UHAS), and Council for Science and Industrial Research (CSIR), which have made significant progress in building capacity for vaccines R&D. Some key initiatives such as the Team Europe Initiative (TEI) on Manufacturing and Access to Vaccines, Medicines and Health Technologies in Africa (MAV+) is supporting Ghana's ambition to develop a sustainable local vaccine manufacturing ecosystem. MAV+ collaborates closely with Ghana's National Vaccine Institute (NVI) by providing comprehensive support across capacity building, regulatory compliance for research and development, and technology transfer.

3. Description

3.1 Background and justification:

The National Vaccine Institute (NVI) has been established under an Act of Parliament (National Vaccine Institute ACT, 2023) to provide for the coordination and supervision of research, development and manufacturing of vaccines and related matters in Ghana.

The political will and commitment fuelled by lessons from the COVID-19 pandemic, and the transition from Gavi Alliance support by 2030, make Ghana's desire to manufacture vaccines a pressing need in which a roadmap was developed for Ghana's vaccine development and manufacturing by the Presidential Committee on Vaccine Development and Production.

Since its creation, the NVI has secured partnerships with international organizations including the EU, GIZ, WHO, Africa CDC and AVMI. The NVI, currently in its startup phase, is focused on the urgent recruitment of requisite human resources to deliver its mandate set out in the NVI Act 1097 of 2023.

The National Vaccine Policy was developed in March 2022 with a vision of vaccine self-reliance for healthier lives and a goal to achieve self-sufficiency in vaccine manufacture for national use by 2030. The policy derived inspiration from global and regional compacts such as the Africa Medicines Agency Treaty, Pharmaceutical Manufacturing Plan for Africa and the African Continental Free Trade Area.

To achieve this mandate, the NVI is to (a) facilitate partnerships for vaccine and sera research, development and manufacturing; (b) mobilise resources for vaccine and sera research, development and manufacturing; (c) mobilise resources for human resource capacity-building and strengthening for vaccine and sera research, development and manufacturing; (d) facilitate sustainable financing for vaccine and sera research, development and manufacturing; (e) facilitate the establishment of domestic vaccine manufacturing plants and market development; (f) collaborate with the relevant regulatory bodies to ensure adherence to standards for vaccine and sera research, development and manufacturing; (g) facilitate technology transfer arrangements with vaccine developers and the pharmaceutical industry; (h) advise the Minister on matters of policy; and (i) perform any other functions that are ancillary to the achievement of the objectives of the Institute.

There are currently two local vaccine manufacturers in Ghana – Atlantic Life Sciences and DEK Vaccines Limited.

Atlantic Lifesciences Ltd (ALS) was incorporated in 2018 as a sterile manufacturing plant to produce infusions for large volume production. This project accelerated with the outbreak of COVID-19 and with Partnerships for African Vaccine Manufacturing's (PAVM) 60 by 40 goal (60 percent of vaccines made in Africa by 2040). The project is 3-phased, comprising two Fill & Finish (F&F) projects and one Greenfield end-to-end manufacturing plant. In 2021, ALS planned to produce anti-snake venom serum, since snake bite management is a major issue for the country. In October 2023, ALS partnered with Vins Bioproducts limited in India and by December 2023, they started the production for the FDA registration batches. In May 2025, the Ghana FDA approved the first locally produced anti-snake venom serum and ALS is looking to scale up commercial production by the end of 2025.

In April 2023, a ground-breaking ceremony marked the start of construction for a major vaccine manufacturing facility by DEK Vaccines Ltd. in Medie, Accra. This project is supported by a €5 million investment grant from the European Investment Bank (EIB), aimed at establishing Ghana's private sector vaccine manufacturing capacity focused on fill-and-finish operations. The facility is planned to produce up to 600 million doses annually, including vaccines for malaria, HPV, pneumonia, rotavirus, and cholera. This initiative is part of Ghana's broader strategy to become self-sufficient in vaccine production, improve vaccine equity, and access regional market by 2030.

The Government of Ghana invested initial funding of ($25 million) in NVI to coordinate and facilitate domestic manufacturing, to build institutional capacity in all aspects of vaccines and sera production. The initial funding was used to commission a modern office complex and setup the legal mechanisms to

collaborate with the relevant regulatory bodies to ensure adherence to standards for vaccine and sera research, development and manufacturing.

In this regard, strengthening human resources is critical for the NVI to fulfil its mandate of coordinating vaccine research, development and manufacturing, ensuring sustainable domestic vaccine production capacity. A skilled personnel is essential for advancing vaccine R&D, regulatory compliance, manufacturing, quality assurance, and distribution, which collectively support Ghana's goal of vaccine self-reliance and health security. In addition, capacity building through specialized training and knowledge exchange will enable the NVI to develop a workforce capable of operating and managing modern vaccine technologies, such as mRNA platforms, and to maintain international standards. This will then enhance human resource capacity, whilst supporting the NVI's role in facilitating partnerships, technology transfer, and innovation, which are vital for establishing Ghana as a regional vaccine manufacturing hub.

The FDA Ghana, a WHO Maturity Level 3 regulatory authority, would leverage its existing capacity and planned upgrades, including a new laboratory for evaluating and authorizing locally produced vaccines and imported ones, to provide rigorous safety and efficacy assessments for vaccines developed under NVI initiatives and other vaccines developed. The FDA's role in processing vaccine registration, marketing authorization, and post-approval changes is critical to ensuring that locally manufactured vaccines meet international standards and can be confidently deployed within Ghana and beyond. The FDA is crucial for the joint development of streamlined regulatory pathways and lot release capabilities, which will accelerate market access for NVI-supported vaccine products and ensure regulatory readiness and compliance throughout the manufacturing scale-up process.

A twinning project focused on human resource strengthening will enable the NVI to leverage international expertise, improve institutional frameworks, and build sustainable training programmes that align with national vaccine policies and strategies.

This investment in human capital will contribute to long-term resilience against future pandemics and improve Ghana's ability to respond effectively to public health emergencies through locally produced vaccines.

3.2 Ongoing reforms.

In recent years, Ghana has taken several steps to improve its health sector, including enhancing the efficiency of healthcare, implementing infrastructure projects and applying effective policies aimed at improving the healthcare system in the country. Ghana is upgrading its healthcare infrastructure and the consistent availability of essential medicines and non-drug consumables. Facilities, particularly at the primary level, are being equipped to meet minimum service standards, while digital health systems are improving supply chain efficiency and reducing stock-outs. These efforts ensure that basic healthcare services are accessible and reliable, especially in rural and underserved areas.

Ghana is also utilizing data and implementation research to guide its reforms. Real-time health information systems and research-based evidence are shaping policies and enhancing service delivery. This data-driven approach is exemplified by the CHPS model, which transitioned from a pilot to national policy based on rigorous field studies.

A significant innovation under the UHC Roadmap is the introduction of a Network of Practice—a model that integrates preventive, promotive, curative, rehabilitative, palliative, emergency, and mental health services into a cohesive delivery framework. This network connects providers across different levels, strengthening referral systems, enhancing collaborative care, and improving both coverage and quality of services.

3.3 Linked activities: NVI has benefited from support from a limited number of partners so far, but the landscape is expanding and NVI is looking forward to building further strategic partnerships.

EU's €32 million Special measure on MAV+: The European Union launched a €32 million Special Measure on Manufacturing and Access to Vaccines, Medicines, and Health Technologies in Africa (MAV+) to support Ghana's vaccine manufacturing ecosystem. This contribution agreement focuses on developing skilled human resources, strengthening research and development, enhancing regulatory systems, facilitating technology transfer, and fostering partnerships for vaccine and pharmaceutical production. This Action is being and will be implemented by various implementing partners (including GIZ, with the programme PharmaVax Ghana; WHO; and FDA). Under the WHO and GIZ contracts, some activities on capacity building and institutional strengthening are foreseen for the NVI.

World Bank (**$3 million)**: The International Finance Corporation (IFC) also supported the market assessment and development of business plans for potential local manufacturer together with German Development Agency (Deutsche Gesellschaft für Internationale Zusammenarbe, GIZ), EU, USAID and other HDPs. In addition, the World Bank Additional Financing (AF3) supported the acquisition of vehicles, equipment for FDA for the vaccine lot release capacity building and essential laboratory equipment for vaccine Research and Development for researchers and academia.

WHO: is supporting the NVI in implementing the required policy actions and strategic interventions for human resource capacity building internally and WHO prequalification, development/validation of regulatory documents for local vaccine manufacturers.

BMZ: ($5 million): The BMZ previously supported the vaccine manufacturing initiative through GIZ which led to the development of the roadmap and the establishment of the National Vaccine Institute (NVI).

3.4 List of applicable *Union acquis*/standards/norms:

The following EU legal texts are relevant to medicinal products and vaccine production issues:

- Directive 2001/83/EC of 06/11/2001 on the Community code relating to medicinal products for human use.
- Regulation (EC) No 726/2004 of 31/03/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
- Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use.
- Clinical trial Directive 2001/20/EC and Clinical Trials Regulation (Regulation (EU) No 536/2014) from 31 January 2022.
- Regulation (EU) 2021/522 of 24/03/2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021–2027.
- The twinning project could also benefit from the experience of the European Health Emergency Preparedness and Response Authority (HERA), which, among other activities, identifies and ensures the availability of critical production sites for medical countermeasures, engages in intelligence gathering and surveillance in relation to health threats and relevant medical countermeasures, and promotes research and innovation. Commission Decision C (2021)6712 on establishing the Health Emergency Preparedness and Response Authority could therefore be relevant in this context.

The twinning project responds to the following domestic legislations:

- Food and Drugs Authority (FDA) in Ghana operates under the civil Service Act 1993 (PNDL 327) and the civil service (ministries) instrument 2017, Executive instrument (E1) 28.https://fdaghana.gov.gh/
- The Ministry of Health in Ghana operates under Civil Service Act 1993 (PNDL 327) and civil service (Ministries) instrument 2017, Executive Instrument (EI) 28 https://www.moh.gov.gh/

3.5 Components and results per component

Component 1: Supporting the development and implementation of institutional policy and multi-sectoral collaboration.

Result 1.1 Institutional policies and governance structures are strengthened and aligned with national priorities and international best practices. *Below is a tentative list of proposed activities:*

- Assist the NVI with the development, update, and enforcement of comprehensive policies, guidelines and protocols that govern the coordination and supervision of vaccine research, development, manufacturing, and market access.
- Support the establishment of clear governance structures, roles, and responsibilities within the NVI for effective coordination and supervision.

Result 1.2 Strategic partnerships and multi-sectoral collaboration mechanisms are strengthened to support national vaccine development and manufacturing. *Below is a tentative list of proposed activities:*

- Assist the NVI in the facilitation of multisectoral collaboration and private sector engagement through supportive policies and partnership frameworks.
- Support NVI to conduct a scenario analysis on competitive advantage in vaccine manufacturing, strategies for integration into regional and continental manufacturing plans, and identification of global funding opportunities to secure market share.
- Support NVI to structure working agreements with the two private vaccine manufacturers to assure complementary strategies for long-term viability of all entities.
- Assist the NVI in the coordination of a functional network of Ghanaian universities engaged in vaccine R&D, and in identifying opportunities for international collaboration or support.

Component 2: Support the implementation of monitoring and evaluation systems and institutional performance tools.

Result 2.1 Support is provided for the establishment of M&E systems and data management related to R&D, manufacturing, and policy compliance. *Below is a tentative list of proposed activities:*

- Support capacity building: Train staff and stakeholders in M&E methodologies, data management, and use of tools to improve data quality and utilization.
- Assist NVI to develop a Monitoring & Evaluation framework with accompanying monitoring tools to enable NVI to effectively monitor and evaluate R&D, Manufacturing and NVI Directorate activities.
- Assist the set-up of a Data Command Centre at NVI using digitization, data analytics and data visualization techniques for effective tracking of core NVI functions.

Result 2.2 Institutional systems and practices are strengthened to promote operational efficiency, transparency, and continuous improvement. *Below is a tentative list of proposed activities:*

- Assist NVI to develop standard operating procedures (SOPs) and workflows to enhance operational efficiency.
- Assist NVI's efforts to promote a culture of accountability, transparency, and continuous improvement.

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

The implementation of the project requires one Project Leader (PL) with responsibility for the overall coordination of project activities and one Resident Twinning Adviser (RTA) to manage implementation of project activities, plus Component Leaders (CL) and a pool of short-term experts within the limits of the budget. It is essential that the team has sufficiently broad expertise to cover all areas included in the project description.

The RTA will be supported by an assistant that will handle administrative arrangements for conferences, training, seminars, etc., including provision of interpreters and the ensuring of translations.

Proposals submitted by Member States shall be concise and focused on the strategy and methodology and an indicative timetable underpinning this, the administrative model suggested, the quality of the expertise to be mobilized and clearly show the administrative structure and capacity of the Member States entities. Proposals should be detailed enough to respond adequately to the Twinning Fiche but are not expected to contain a fully elaborated project. They shall contain enough detail about the strategy and methodology and indicate the sequencing and mention key activities during the implementation of the project to ensure the achievement of overall and specific objectives and mandatory results/outputs.

The interested Member State(s) shall include in their proposal the CVs of the designated Project Leader (PL) and the Resident Twinning Advisor (RTA), as well as the CVs of the potentially designated Component Leaders (CLs).

The Twinning project will be implemented by close co-operation between the partners aiming to achieve the mandatory results in sustainable manner.

The set of proposed activities will be further developed with the Twinning partners when drafting the initial work plan and successive rolling work plan every 6 months, keeping in mind that the final list of activities will be decided in cooperation with the Twinning partner. The components are closely inter-linked and need to be sequenced accordingly.

3.6.1 Profile and Tasks of the Project Leader (PL):

The project leader is expected to be an official or assimilated agent with a sufficient rank to ensure an operational dialogue at political level. They work in close cooperation and ensure the overall steering and coordination of the project.

- Educational Background and Experience: A university degree in a relevant field such as Biological Sciences, Public Health, Health Economics, MBA or a related discipline is essential. At least 7 years of professional experience in the relevant sector, preferably with experience in vaccine-related and pharma projects, business development, and/or public administration, is typically required
- Project Management and Coordination: Proven experience in managing or assisting in the management of multiple projects, including planning, coordination, supervision, and monitoring of activities to ensure timely achievement of project results.
- Leadership and Communication Skills: Strong leadership to guide the project team, including Resident Twinning Advisor and short-term experts, and excellent communication skills in written and spoken English to liaise with high-level officials, stakeholders, and partners.
- Technical Expertise Relevant to Vaccines: Understanding of vaccine development, immunization programmes, public health policies, and regulatory frameworks to ensure the project aligns with national vaccine institute goals and EU standards.
- Interpersonal and Cultural Sensitivity: Ability to work effectively with diverse stakeholders, including government officials, international partners, and technical experts, respecting cultural differences and fostering cooperation.
- Computer Literacy: Proficiency in MS Office, project management software, and other relevant IT tools for documentation, reporting, and communication.

Tasks to be completed:

- To liaise with the Beneficiary Counterpart administration at the political level.
- To ensure timely availability of the expertise.
- To prepare the project progress report with the support of the RTA.
- To co-chair the project steering committees.
- To consider the work of relevant EU bodies and agencies and establish links where appropriate.

3.6.2 Profile and tasks of the RTA:

The Resident Twinning adviser will be based in Accra (Ghana) to provide full time input and advice to the project for its entire duration. She/he will oversee the day-to-day project implementation and co-ordination of project activities according to the rolling work plan and liaise with the RTA counterpart in Ghana. She/he should co-ordinate the project and have a certain level of understanding of all components.

Educational and Professional Background

- University degree in a relevant field such as public health, health economics, public administration, medicine, pharmacy, virology, biotechnology, pharmaceutical sciences or equivalent professional experience.
- Specific experience in health, preferably with a minimum of 5 years in drug regulatory affairs, market control, market authorization, vigilance, inspection, or international cooperation.

Core Skills and Competencies

- Coordination: Strong skills in coordinating diverse teams, liaising with national and international partners, and ensuring coherence and continuity across project inputs and activities.
- Technical Expertise: Good knowledge of regulatory functions related to vaccines and pharmaceuticals, including legal frameworks, market surveillance, batch release, and regulatory harmonization.
- Partnership Building: Experience in building and maintaining multi-actor partnerships, particularly with European agencies, regulatory authorities, and beneficiary institutions.
- Monitoring and Reporting: Ability to assess project progress, prepare monitoring materials, and provide regular technical advice and support.

Additional Skills

- Communication: Excellent written and verbal communication skills, including the ability to draft reports, coordinate meetings, and facilitate workshops and training sessions.
- Intercultural Competence: Capacity to work effectively in international and multicultural environments, demonstrating flexibility and professionalism.
- Administrative and Financial Oversight: Experience in office management, financial administration, and supporting the logistical organization of project-related events.
- Language Proficiency: Very good spoken and written command of English with additional language skills considered an asset.
- Computer Literacy: Advanced skills in Microsoft Office suite (Word, Excel, PowerPoint, Outlook) and proficiency with digital collaboration tools.

Desirable Experience

- Prior involvement in EU Twinning or international donor projects.
- Experience working with emerging economies.
- Experience in implementation of relevant EU legislation and EU instrument related to the project components.

Tasks:

- Coordinate and ensure project implementation and implementation of all project activities.
- Prepare the initial and subsequent work plans and project progress reports, together with the PL.
- Ensure the coherence and continuity of successive inputs and the on-going progress.
- Coordinate the activities of all team members in line with the work plan.
- Assess continuously project progress to assure its timely implementation.
- Prepare material for regular monitoring and reporting.
- Liaise with MS and Beneficiary Country (BC) PLs and maintain regular contact with the BC RTA.
- Provide technical advice, support and assistance to the Beneficiary institution in the areas specified in the work plan.
- Liaise with the Project Manager and Team Leader of the EU Delegation.
- Liaise with other relevant institutions in Ghanaian and with other relevant projects.

3.6.3 Profile and tasks of Component Leaders:

The Component Leaders will work in close cooperation with the RTA and the Beneficiary administration to meet the mandatory results. Their main task is to plan and coordinate activities under their respective areas of responsibility in collaboration with the partner institutions.

Basic skills requirements:

- University degree (Master's degree) in relevant discipline to the component of the twinning for which the candidate is proposed.
- Minimum 3-5 years of professional experience at an operational level in relevant EU MS health administration or mandated body in a field relevant to the component for which the candidate is proposed.
- Background in leading multidisciplinary teams and managing complex stakeholder relationships.

- Understanding of vaccine science, manufacturing processes, regulatory standards, and quality assurance.
- Advanced skills in strategic planning, scenario analysis, and organizational development.
- Excellent communication, negotiation, and partnership-building abilities.
- High integrity, adaptability, and commitment to continuous learning and improvement.
- Very good spoken and written English.

Tasks:

- To provide component coordination, guidance and monitoring in close cooperation with the PL, other component leaders, RTA and RTA counterpart.
- Continually monitor the achievement of objectives related to their component and comparing actual progress with the specified benchmarks and timeframe.
- Support the RTA in preparing the interim, quarterly and final reports related to their component.
- To provide practical expertise and technical advice, as well as coaching to the relevant staff in the Beneficiary administration for the execution of activities relevant to their project components.
- To analyse policies and practices in the thematic area relevant to the respective component.
- To support the drafting of action plans, training plans, studies.
- To prepare and conduct training programs, to facilitate stakeholders' dialog.
- To draft technical documents relevant to their component's results in close cooperation with the BC counterparts.
- To suggest improvements of relevant procedures and systems

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

The STEs should be identified by the Project Leader/RTA and will be agreed with the Beneficiary Administration during the negotiation phase of the Twinning contract and following these indicative (but not exclusive) areas: pharmacy and pharmaceutical sciences, quality control laboratory operations, clinical trials, biotechnology, Chemistry and biochemistry, Biochemical Engineering, Vaccine Policy and strategy, Vaccine management and logistics, capacity strengthening, technology transfer, virology, good regulatory practices, good manufacturing practices, health system strengthening, good distribution practices and pharmaceutical law.

Educational and professional skill

University degree in a relevant field such as public Health, health economics, public administration, medicine, pharmacy, or equivalent professional experience.

Desirable Skills

- Familiar with international vaccine manufacturing and regulatory environments.
- Ability to support legal framework alignment and regulatory capacity strengthening.
- Experience in organizing study tours, technical exchanges, or mentoring programs.
- Very good spoken and written English.
- Experience in delivering capacity building activities.
- Experience in providing inputs to policy/regulatory documents, methodological guides and/or handbooks.

Tasks:

- To provide advice, expertise and/or coaching to the relevant staff of the Beneficiary administration for the execution of specified project activities.
- To plan and deliver capacity building activities (workshops, study tours, trainings).
- To suggest improvements of relevant procedures and systems including suggestions to the revision of regulatory framework.
- To provide support in drafting action plans and roadmaps.
- To report on the results of the missions.
- To liaise with RTA and BC counterparts.

4. Budget

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 Delegation of the European Union to the Republic of Ghana for the above (tendering, contracting, and accounting). The National Vaccine Institute will work in close co-operation with the EU Delegation all the time for the smooth implementation of the project.

Address: The Round House, 81 Cantonments Road, P.O. Box 9505 KIA, Accra

Telephone: +233 30 277 4201

https://www.eeas.europa.eu/delegations/ghana_en

The persons in charge of the project at the EU Delegation are:

Ms Juliet DEKOU
Programme Manager
Juliet-Emefa.DEKOU@eeas.europa.eu

Ms Zahina ASSANI
Deputy Head of Finance, Contracts and Audit
Zahina.ASSANI@eeas.europa.eu

5.2 Institutional framework

The NVI is the central counterpart and beneficiary of the Twinning Project. However, the project will also extend assistance to other institutions, as specified in this fiche. Other Ghanaian stakeholders for strengthening NVI's functions related vaccine production include the Ministry of Health and the Food and Drugs Authority.

The National Vaccine Institute (NVI) of Ghana is a statutory body established under the National Vaccine Institute Act, 2023 (Act 1097). This Act provides the legal foundation for the creation, governance, and operations of the Institute. The NVI is established as a body corporate with perpetual succession and a common seal.

The primary objective of the NVI is to coordinate and promote vaccine research, development, manufacturing, and in Ghana. The Institute serves as the central authority for vaccine-related activities, aiming to strengthen local capabilities, encourage innovation, and ensure the sustainable production and availability of vaccines in the country. It also plays a key role in building the capacity of domestic pharmaceutical companies and enhancing collaboration among public, private, and academic stakeholders.

In pursuit of its mandate, the NVI performs several core functions. These include supervising vaccine research and development, facilitating partnerships between research institutions and industry, supporting the creation and scaling of local vaccine manufacturing infrastructure, and mobilizing resources for vaccine initiatives. The Institute is also responsible for setting standards and protocols for vaccine quality assurance in collaboration with the Food and Drugs Authority, advising the Ministry of Health on vaccine-related policy matters, and maintaining a national database on vaccine production and distribution.

The governance of the Institute is vested in a Board of Directors, composed of representatives from relevant ministries, regulatory bodies, academia, and the pharmaceutical sector. The Board is chaired by a presidential appointee and is responsible for setting strategic direction and overseeing the implementation of the Institute's functions. The day-to-day management is entrusted to a Chief Executive Officer, also appointed by the President, who ensures operational efficiency and the execution of Board decisions.

The Institute's operations are funded through allocations from Parliament, as well as grants, donations, internally generated funds, and other approved sources. Financial management and accountability are ensured through adherence to the Public Financial Management Act, and the Institute is required to submit annual reports, including audited financial statements, to the Minister for Health, who in turn lays the report before Parliament.

To ensure effective implementation of the Act, the Minister may, upon the advice of the Board, issue regulations governing various aspects of vaccine research, production, ethical standards, licensing, and compliance.

In sum, the National Vaccine Institute Act, 2023 (Act 1097) provides a comprehensive legal and institutional framework to enable Ghana to achieve self-reliance in vaccine production and to strengthen the country's public health security through innovation, regulation, and collaboration.

5.3 Counterparts in the Beneficiary administration:

The PL and RTA counterparts will be staff of the Beneficiary administration and will be actively involved in the management and coordination of the project.

5.3.1 Contact Person

Dr Sodzi Sodzi-Tettey
Chief Executive Officer,
No. 1 First Rangoon Street, Off 5th Avenue Extension, Cantonments, Accra, Ghana

5.3.2 PL Counterpart

Dr Sodzi Sodzi-Tettey
Chief Executive Officer,
No. 1 First Rangoon Street, Off 5th Avenue Extension, Cantonments, Accra, Ghana

5.3.3 RTA Counterpart

Mr Edmund Togobo
Senior Accountant, No. 1 First Rangoon Street, Off 5th Avenue Extension, Cantonments, Accra, Ghana

6. Duration of the project

The execution period of the project shall be 21 months (18 months of implementation + 3-month closure period).

7. Management and reporting[2]

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, finalising the interim reports and discuss 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 section 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 National Vaccine as beneficiary institution is fully willing and committed to ensure the sustainability of the present twinning project. Several strategies will be put in place, including transferring knowledge by the staff trained from this project through peer-to-peer trainings in the workplace to their workmates. The training programmes and arrangements will be discussed and agreed at the high level of the National Vaccine Institute to create a culture of

[2] Sections 7.1-7.3 are to be kept without changes in all Twinning fiches.

peer-to-peer learning approach. In addition, staff will be offered additional learning opportunities to acquire the knowledge and skills they need to supplement peer-to-peer trainings. This implies commitment by NVI, Ministry of Health and Ministry of Finance to avail sufficient budget and human resources to the Institute, to fulfil its mandate linked to its coordination and supervision of vaccines. The sustainability of the project results is dependent on enough personnel from the beneficiary administration to be assigned to work in the implementation of and benefit from the project.

9. Crosscutting issues *(equal opportunity, environment, climate etc…)*

The overall objective of this project is to support NVI in building its capacity to supervise, oversee and coordinate locally manufactured pharmaceutical products including vaccines for the local, continental, and international markets. This will help respond to vaccine inequity issues and help contribute to the SDG Goal 3 of Good Health and well-being SDG.

The Affirmative Action (Gender Equity) Bill, signed into law in September 2024, aims to promote gender equity across political, social, economic, educational, and cultural spheres in Ghana, address discrimination, and establish an accountability framework. The goal is to ensure equitable participation of women in government and other decision-making processes, as women have historically been underrepresented in key leadership roles. While this bill is a significant step towards gender equality, several challenges exist. There are concerns around whether the government has the capacity to implement and enforce these new regulations effectively, and whether the public is willing to abide. There are also concerns around cultural resistance, as patriarchal norms and beliefs are deeply rooted in society. However, if effective, this bill has the power to make transformative changes in general, the principles of equal opportunity will be observed to ensure equitable gender participation in the project. Furthermore, the principle of implementation of this partnership project will minimise paper use during project implementation (paperless work).

NVI will implement initiatives that integrate gender mainstreaming into climate change adaptation strategies in the health and vaccine sectors. These initiatives will include the integration of gender-sensitive assessments and planning into climate adaptation initiatives that affect the delivery of health services and vaccines. This will foster the engagement of women health professionals and community members as active participants and leaders in the health response and resilience to climate change. By collaborating with gender and environment ministries, it will assist in the establishment of gender-responsive climate policies and the development of capacity.

This will be consistent with international frameworks, such as Generation Equality and will leverage partnerships to secure funding and technology support. Consequently, International Vaccine Institute (IVI's) experience with Sida will serve as a foundation for the integration of environmental and climate change norms into the production and distribution of vaccines.

Equal opportunity in the project will be assured in accordance with EU standards and equal opportunity policies. Equal treatment of women and men will be observed in the project staffing, implementation and management. Attention to the equality principle will be given to the selection of personnel for training and capacity building activities.

10. Conditionality and sequencing

There is no preconditions or prior activities for this Twinning project. Nevertheless, it is important that NVI remains committed to achieve the envisaged results and objectives, throughout the duration of the project. The NVI will ensure operational and logistical support to the RTA and the Twinning experts, as well as provide effective coordination with the other Ghanaian institutions involved in the project.

11. Indicators for performance measurement

See annex 1 – Logical Framework

12. Facilities available

The Beneficiary commits itself to deliver the following facilities:

- Adequately equipped office space for the RTA and the RTA's assistants for the entire duration of the secondment.
- Supply of the office room including access to computer, telephone, internet, printer, photocopier.
- Adequate conditions for the STEs/MTEs to perform their work while on mission.
- Suitable venues for meetings and training sessions that will be held under the project.

The beneficiary will also guarantee the availability of staff who will be involved during the twinning project implementation. Full coordination and transparency are expected among all key players involved.

The EU Partner Country commits itself to deliver the following facilities:

- Be respectful of the political priorities, professional organizational norms and of colleagues of the host nation and host NVI organisation.
- Refrain from any actions that undermine the vision, mission and mandate of the NVI in service of national priorities.
- Be open to full integration into the NVI team and to work collaboratively with colleagues in all NVI professional activities.
- Proactively and openly communicate any concerns encountered in the course of work with the NVI leadership and avoid opacity.
- Fully apply themselves to the objectives of the twinning initiative.

Annexes to the Twinning fiche

- Annex C1a: Simplified Logical Framework
- Annex C9: Standard Twinning – Publication of the Call for Proposals on the Internet
- Organigram of National Vaccine Institute
- National Vaccine Institute Act
- National Vaccine Roadmap