Abbreviations and Acronyms

BC – Beneficiary Country

CD – Communicable Diseases

CFCU – Department for Contracting and Financing of EU Funded Programs

EC – European Commission

EU – European Union

EUD – European Union Delegation to the Republic of Serbia

IPA- Instrument for Pre-Accession Assistance

ISP - Indicative Strategy Paper

MOH – Ministry of Health

MS – Member State

NRL - National Reference Laboratories

PL – Project Leader

RS - Republic of Serbia

STE - Short Term Experts

DG SANTE - Directorate general for health and food safety

CARDS - Community Assistance for Reconstruction, Development and Stabilisation

TWL – Twinning light

ANNEX C1[1]

STANDARD TWINNING PROJECT FICHE

1. Basic Information

1.1 Programme: National program for Serbia under the IPA – Transition Assistance and Institution Building Component for the year 2013

1.2 Twinning Number: SR 13 IPA HE 01 17 TWL

1.3 Title: Improving microbiology diagnostic system quality in the function of surveillance on communicable diseases in the Republic of Serbia

1.4 Sector: Health and consumer protection

1.5 Beneficiary country: Republic of Serbia

2. Objectives

2.1 Overall Objective(s):

To improve surveillance system on communicable diseases, hereinafter: CD in line with EU acquis and EU standards and to develop sustainable institutional capacities to respond to serious public health threats of cross-border relevance.

2.2 Project purpose:

t The purpose of this project is to map out an overall implementation approach with a series of achievable initiatives for improving microbiology diagnostic system quality in the function of surveillance on CD in compliance with EU acquis and EU standards, by focusing on:

- public and private microbiology laboratory capacities
- core functions and capacities of National Reference Laboratories (NRLs)

In this respect, the Twinning light (TWL) project is aiming to develop a roadmap that will serve as a reference document outlining the organisation of the work, the specific activities/initiatives, milestones and targets to be achieved and framework for mobilising, harnessing and leveraging resources, specifically indicating the interventions intended to:

- overcome identified gaps between EU standards for confirmation of communicable diseases in line with EU case definition (Commission Implementing Decision 2012/506/EU) in public and private laboratories (including NRLs) in terms of laboratory equipment, software and hardware IT, infrastructure and human capacities/resources and diagnostic testing practices (methods and technologies) and reporting practices
- Implement core functions (reference diagnostics, reference material resource, scientific advice, collaboration and research and monitoring, alert and response, external QA) for NRLs in the context of national public health system and public health added value.

[1] For Twinning light the Project fiche should be detailed as it will form an annex to the Twinning light contract together with the selected Member State proposal.

2.3 Contribution to National Development Plan/Cooperation agreement/Association Agreement/Action Plan

In 2008, a **European Partnership for Serbia** was adopted, setting out priorities for the country's membership application, and in 2009 Serbia formally applied. In March 2012, Serbia was granted EU candidate status. In September 2013 the **Stabilisation and Accession Agreement (SAA)** between the EU and Serbia entered into force.

In line with the decision of the European Council in June 2013 to open accession negotiations with Serbia, the Council adopted in December 2013 the negotiating framework and agreed to hold the 1st Intergovernmental Conference with Serbia in January 2014.

On 21 January 2014, the 1st Intergovernmental Conference took place, signaling the formal start of Serbia's accession negotiations. Explanatory screening and bilateral screening meetings on Chapter 28 - Consumer and Health Protection - Public Health started at the end of 2014.

Screening Report on Chapter 28, in the field of serious cross-border health treats including communicable diseases (CD), highlights the need for further alignment of legislation with EU acquis, together with strengthening surveillance and response capacities including microbiology laboratory capacities. Report stresses out that the major problem relates to data analysis. Also, the report calls for development of information and communication system that should incorporate different systems, such as early warning and rapid alert system (EWRS) or integrated laboratory data and reporting.

Joint Commission/ECDC assessment mission organized in 2013, preceded preparation of Screening Report. Assessment mission resulted in production of ECDC Technical Assessment Report upon on which Ministry of Health (MoH) and Institute for Public Health of Serbia (IPHS) **drafted Action Plan for improvement of the communicable diseases surveillance and response system in Republic of Serbia in line with EU acquis/EC and ECDC recommendations, 2016-2020 (hereinafter: Draft CD Action Plan)**. Activities presented in this TWL are recognized by the Draft CD Action Plan as being the basis for improvement of communicable diseases surveillance system and development of sustainable institutional capacities to respond to serious public health threats of cross-border relevance.

According to the latest **EC Progress Report for 2015** in the area of CD, surveillance and response capacity, including microbiology laboratory capacity, remains limited, and, therefore, requires modernization as well as human resource management and organizational strengthening. More attention needs to be paid to effective and sustainable financing of disease-specific strategies, including the national HIV/AIDS strategy and awareness-raising. Additional work is needed in particular on surveillance of antimicrobial resistance and inter-sectoral cooperation.

As defined in the **National Plan for the Adoption of the Acquis 2014-2018 (NPAA**) adopted in July 2014, the process of approximation to the European regulations and standards at all levels of health care will continue in accordance within defined timeframe. Serbia as state candidate for EU has obligation to fulfill many EU decisions and regulations (Decisions: 2013/1082, 1998/2119, 2002/253, 2009/363, 2003/534, 2007/875, 2000/96, 2000/57, 2003/534, 2003/542, 2007/875, 2009/312, 2009/539, 2012/492, 2008/351, 2009547, 2003/534, 2008/426, 2009/540, 2012/506 and Regulations: 2004/851, 2003/1882, 2009/596) that regulate communicable diseases. The development and improvement of a sustainable system in the fields of communicable diseases is currently a priority of the reform process. Needs that have been

identified include establishment of an integrated national surveillance information system for communicable diseases according to EU standards and directives and the EC/ECDC technical assessment report.

In the context of programming IPA II and adoption of Sector Approach, Health sub-sector is included in overarching sector on Human Resources and Social Development (HRSD). As such, priorities for financing from international assistance, including IPA II funding, in the Health sub-sector have been recognized by main national planning document: **National Priorities for International assistance for 2014-2017 with projections for 2020**, under Priority 4 - Improving the health status of the population by strengthening the accessibility, availability, affordability and efficiency of healthcare services. Likewise, **Indicative Strategy Paper (ISP) 2014-2020 for Serbia,** recognises the need in providing support for consumer and health protection in line with the EU *acquis* requirements. Thus, this TWL goes in line with ISP expected result on harmonisation of legislation with the EU acquis and strengthening institutional framework and administrative capacity for implementation of acquis.

In addition, The Action is in line with **Sector Planning Document's (Human Resources and Social Development 2015-2017**) as by strengthening the human resources and technical capacities related to the prevention, identification and reporting of communicable diseases, the health care system will also become more closely aligned with the surveillance and reporting protocols typically used by EU member states.

3. Description

3.1 Background and justification:

The major concepts of the EU legislation related to communicable diseases and public health threats of infectious origin have been transposed in the **Law on Protection of Population from Communicable Diseases** ("Official Gazette of Republic of Serbia" No 15/2016). However these legal, regulatory and technical requirements have still to be implemented in practice in order to be able to: (i) design and implement more sensitive surveillance system; (ii) collect all necessary data for proper communicable diseases case classification in line with EU case definitions (Commission Implementing Decision 2012/506/EU) at regional and national level; and (iii) have good quality data reported on time by all health professionals from both public and private health sector.

Moreover, **Regulation on Program on Health Protection of Population from Communicable Diseases (**"Official Gazette of Republic of Serbia" No 22/2016), defines priorities and specific objectives and measures in defined key areas (epidemiology, microbiology, hygiene, health education, health informatics and epidemiology and hygiene in extraordinary situation), organization and partners in program implementation, as well as monitoring and control of program implementation and financial sources, including the surveillance based on EU case definitions for selected infectious diseases as of the highest priority. In the area of microbiology two objectives are prioritized: (i) improvement of sensitivity of laboratory diagnostics of communicable diseases by improvement of microbiology methods for human samples in clinical microbiological labs at all level of health care and in NRLs; *and* (ii) improvement of detection and monitoring of antimicrobial drug resistance of causative agents of epidemiological important infectious diseases, both in hospital and community.

Law on Public Health (“Official Gazette of the Republic of Serbia” 15/2016) regulates the functioning of the public health authorities, responsibilities, planning, implementation of activities related to the conservation and improvement of the population's health, as well as the method of financing. The aim of this law is the public interest, the creation of conditions for the preservation and improvement of the population's health through comprehensive activities of the society.

The alignment and adoption of new legislation needs to be accompanied by rulebooks/bylaws for its effective implementation and enforcement. With regards to Law on Protection of Population from Communicable Diseases, additional 13 bylaws will also be adopted until March 2017. This goes alongside measures identified in NPAA.

The surveillance system is based on passive mandatory reporting by doctors and microbiologists. Notifiable diseases and identified pathogens, as well as carriers of some infectious agents and other specified health issues are reported to the network of epidemiologists in RIPHs who report periodically mostly aggregate data to the Institute of Public Health of Serbia (IPHS). Routine passive surveillance and aggregated reporting is complemented by urgent case based reporting for defined diseases of public health importance. There are two additional parallel surveillance systems, one for tuberculosis (TB) and the other for HIV, and a sentinel surveillance system for influenza. Key national disease programmes for HIV and TB have been established.

Furthermore, objectives and priorities for the surveillance system in Serbia are not specified. ICD-10 codes assigned by clinicians are used as de facto case definitions for the surveillance system, and routinely obtained data for several diseases would be insufficient for classification of reported cases in line with EU case definition and for reporting to authorities at EU level.

The main challenges of the current system for surveillance is the lack of integrated national surveillance information system, to enable efficient electronic reception of both clinicians case-based communicable disease notifications and laboratory notifications verifying individual cases, and to implement electronic dissemination, analysis, interpretation, use and reporting of clinical, laboratory and epidemiological information about cases at both regional, and national levels (under defined appropriate data protection arrangements at the different levels).

Laboratories are able to detect and/or confirm 80% of EU-reportable communicable diseases according to EU case definitions. Pathogen characterization services for public health purposes, provided by NRLs, use generally adequate technology for 35 communicable diseases and antimicrobial resistance. NRLs for TB, HIV, influenza, measles, poliomyelitis, and AMR participate actively in laboratory surveillance networks and projects lead by WHO or ECDC.

Number and type of services provided by labs, as well as available diagnostic testing practices/methods in private health sector are not available and notification of detected infectious agents or immunological response to infections which is mandatory by the Law is not performed or it is performed in a very limited scale.

The majority of diagnostic microbiology laboratories in the public health sector across the country do not have adequate technical facilities and state-of-the-art technology.

NRLs equipped mainly through vertical funding initiatives, have also limitations in their technology and facilities and it seems to duplicate advanced technical platforms such as bio-containment, DNA sequencing and bio-bank facilities. NRLs for some communicable diseases of interest are missing. Because of this situation in the reference testing, capacity for surveillance

and outbreak detection and response support for some communicable diseases remains substandard. The main elements contributing to this situation are lack of regulation for funding, and its fragmentation, incomplete implementation of projects, as well as dispersed management and budget planning for the National Reference microbiology services. Contribution of NRLs to applied research and technology development is missing.

The existing paper based notification/reporting is cumbersome, and besides laboratory information system for TB laboratory network, there are no modern laboratory information management systems and data exchange networks.

The quality assurance system for microbiology laboratories are missing, including sufficient provision of a national EQA system for clinical laboratories. Lack of biosafety regulation for microbiology laboratories and an inadequate bio-risk management system, such as lack of BSL 3 containment facilities, lead to substandard laboratory practices and potential exposure to biological hazard for some diagnostic laboratory work, such as culture for tuberculosis and viral haemorrhagic fevers.

Development and improvement of current system for diagnostic, collecting and reporting data from microbiology laboratories in both public and private sector to relevant health institutions is needed in order to obtain prompt laboratory case-based reporting and to improve sensitivity of epidemiological surveillance system.

In this manner, laboratory data shall not be used only for individual patient care but also for public health and higher surveillance goals through better connection with epidemiology units and accessibility from all the laboratories in the country.

It will also provide possibilities for more adequate data analysis and link to other patient data – e.g. epidemiological information.

This Twinning Light (TWL) represents an initial phase of a broader Action aimed at improving microbiology diagnostic system quality and improving surveillance system on CD. TWL will lay the foundation to respond to the before mentioned identified challenges, relying heavily on the experience and expertise of the EU member state, TWL partner. The EU partner in the TWL will be indispensable and functional to the elaboration of defined gaps between EU standards for confirmation of communicable diseases in line with EU case definition standards and current situation in the whole laboratory system (including civil, military and private microbiology labs, NRLs), in the function of the epidemiological surveillance and for development of the roadmap for further activities.

The analysis that will be used to define gaps, will cover all relevant laboratory elements in function of surveillance (equipment, technical capacities including IT support in terms of software and hardware requirements, infrastructure, diagnostic methods and technologies and reporting practices) and will include also a stakeholder mapping, underlining the most relevant actors and their capacities in this field in both health sectors - public and private. MoH will provide data on microbiology laboratories in public and private sector.

The objective of the assessment of capacities and diagnostic testing practices and analysis, is to identify the gaps to be further articulated through a roadmap. The roadmap will result in the elaboration of recommendations that will include: activities that need to be conducted with deadlines, relevant responsible institutions, budget and sources of financial coverage for the strengthening of a laboratory surveillance system in Serbia. The roadmap elaborated on the basis

of the analysis will clearly demonstrate the rationale, the focused target and methodology on which necessary future projects, activities will be based to achieve the main goal to improve the epidemiological surveillance system in Serbia and the best solution for efficient implementation of the relevant EU acquis in the area of communicable diseases.

If communicable diseases of public health importance are not recognized, diagnosed, confirmed, and sufficiently characterized, the surveillance system is inherently limited. In order to improve functioning of communicable diseases surveillance system, it is recognized that adequate infrastructure, human capacities and space/facilities are needed to be provided in microbiology and epidemiology services. Advancement of microbiology laboratory services is also needed for appropriate diagnostic testing practices and to support the surveillance system on communicable diseases and other health issues that are being provided.

In order to prioritize the needs for renovation, purchase of laboratory and technical equipment, adequate software and hardware solution, etc. it is necessary to assess the current state of all microbiological laboratories in terms of infrastructure and equipment, available microbiology services and laboratory methods, human capacities, as well as reporting practices on detected infectious agents and/or immunological response to infections to the relevant health authorities.

The TWL will also encompass activities aimed towards the establishment of the external quality assurance system for laboratory testing. These activities will be mainly based on the mapping and assessment of the capacities (administrative and technical) of NRLs and the assessment of their needs. According to the actual Law on Protection Population from Communicable Diseases, referent laboratories are responsible to oversee and control microbiological laboratories. Through the TWL and assessment to be undertaken, the basis for quality assurance system (QAS) under standardized criteria will be established. Thus, part of TWL activities will be centered to lay the basis for the establishment and implementation of QAS. In more detail, departing from the findings and recommendation of the DILS project „Improvement of the performance of National Reference Laboratories" (2013/2014), this activity will further make analysis of the NRLs existing capacities. The analysis will be focused on: health system needs and core functions referred to the reference laboratories, in line with actual legislation; opportunities and possibilities for financial support of the system; equipment needs; professional staff requirements and needs. As a result of the evaluation, specific and valuable recommendations will be elaborated, indicating the necessary measures, activities and steps in securing adequate laboratory surveillance on reportable communicable diseases. In particular, the recommendations that will be provided in the road-map, will address the following:

- the restructuring of the National Referent laboratories (NRL) network according to the results from the evaluation realized in both civil and military health sector and the Academy of Military Medicine in Belgrade;
- guaranteeing and securing capacities for the installation of BSL III laboratories;
- designing a stable and sustainable financial model for NRLs;
- establishing and strengthening the capacities of individual NRL (with particular focus on the suitable and qualified staff, equipment to be procured, documents to be developed and improved reporting system);

Having in mind the above, this TWL should contribute to further improvement in the area of communicable diseases prevention and control facilitating improvement of surveillance on

communicable diseases, especially in the microbiology laboratory system by identifying key gaps including capacity building of key stakeholders and lay the basis for further activities and possible support.

3.2 Linked activities (other international and national initiatives):

The main partners in the health sector are the European Union and the World Health Organization (WHO):

- Together with the European Union, the Ministry of Health of Serbia and WHO implemented the EU Project on Integrated Health Information System for Serbia.
- The Global Fund to fight Aids, Tuberculosis and Malaria (GFATM) together with WHO provided technical assistance for implementation of GFATM HIV and TB activities.

There have also been international collaborations with varying intensity in the areas of enteric bacteria, tuberculosis, trichinellosis, Neisseria meningitidis, Haemophilus influenzae, influenza, measles and rubella, hepatitis A, haemorrhagic fever, poliomyelitis and toxoplasmosis. The major collaborations form part of WHO laboratory networks for vaccine preventable diseases and for tuberculosis. In addition, there is an ongoing participation of the NRL for Antimicrobial Resistance in the ECDC surveillance project EUSKAPE that is investigating the prevalence of carbapenemase-producing Gram-negative bacteria in clinical specimens

Serbia participated in the project on antimicrobial consumption surveillance organised by WHO/Europe in collaboration with the University of Antwerp and the former ESAC project) and reported data for the period 2004-2011. The methodology and protocol of this surveillance are aligned with that of the EU/ECDC ESAC-Net.

Already implemented project "Strengthening the Services of Public Health Laboratories in Serbia" 2006-2008 and DILS project „Improvement of the performance of National Reference Laboratories" 2013-2014 made significant progress in this field as the basis for further activities.

More recently, TAIEX workshop on the Implementation of National Electronic Communicable Disease Surveillance Systems has been organized in co-operation with Ministry of Health and Institute of Public Health of Serbia "Dr Milan Jovanovic Batut" in the period 25th -26th July 2016 in Belgrade. More than 50 participants from the Institute of Public Health of Serbia (IPHS), regional IPHs, Ministry of Health, national reference laboratories and other relevant health institutions and experts from EU MSs (Finland, Latvia, Croatia and Romania) took part in this workshop. The objectives of the workshop was to share experiences related to different models of integrated national e-surveillance systems on communicable diseases and challenges in their implementation.

3.3 Results:

Component 0 - Coordination and visibility

Result 0.1 - Established arrangements for information sharing, visibility and advocacy to all actors

Indicators for Result 0.1

- Coordination plan, including organisation of final event agreed during the kick-off meeting

Component 1 - Development of gap assessment methodology of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs

Result 1.1 - Determined framework for gap assessment, along with two main directions (hereinafter: two assessment directions): (i) between EU standards for confirmation of communicable diseases in line with EU case definition (Commission Implementing Decision 2012/506/EU) in public and private microbiology laboratories (including NRLs) in terms of laboratory equipment, IT, infrastructure and human capacities/resources and diagnostic testing practices /methods and technologies and reporting practices; and (ii) implementing core functions of NRLs

Indicators for Result 1.1

- Gap assessment methodology developed and approved during the first month of project implementation

Component 2 - Gap assessment of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs according to agreed methodology

Result 2.1 - Identified gaps and corresponding recommendations, along with two assessment directions, for improvement of knowledge, skills, IT support, laboratory equipment, infrastructure and diagnostic testing practices/methods and technologies and reporting practices

Indicators for Result 2.1

- Gap assessment report with synthesis of the current situation (through a SWOT analysis, for example) and recommendations drafted by the end of third month of project implementation containing:
    - Recommendations for strengthening human resources and capacity building covering microbiology labs including NRLs
    - Recommendations for improving diagnostic testing practices/ methods and technologies and reporting practices covering all microbiology labs including NRLs
    - Technical specifications for laboratory equipment covering labs in the network of RIPHs including IPHS and in NRLs
    - Technical specifications for IT software/hardware covering public health labs and NRLs
    - Recommendations for improving physical infrastructure covering labs in the network of RIPHs including IPHS and in NRLs

Component 3 - Development of roadmap to improve capacities and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases

Result 3.1 - Identified collaborative arrangements and specific and precise measures to improve capacities (human, technical and physical) and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases - highlighting roles and organization of work, milestones and targets, budget and financing sources - for the planning and programming process, focusing on the work in line with two assessment directions, as well as to a certain extent, that of the first following Action to be implemented under IPA II

Indicators for Result 3.1

- The roadmap, as a reference document outlining the organisation of the work, the specific activities/initiatives, milestones and targets to be achieved and budget framework (both national and international) developed by the end of the project.
- Draft Action concept to be included in IPA II programming (2017/2018) prepared by the end of the project
- Thematic workshop on organization and implementation of an effective external quality system in line with EU standards and requirements of duration of one day for 50 representatives of NRLs implemented in forth month of project implementation
- Thematic workshop on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD of duration of one day for 80 representatives of MoH, epidemiologist and microbiologist from IPHS, RIPHs, NRLs, microbiology labs implemented in the fifth month of project implementation

3.4 Activities:

Component 0 - Coordination and visibility

Activities to achieve Result 0.1

Activity 0.1.1 - Kick -off meeting (Beneficiary, TWL partner)

It is envisaged involvement of Member State Project Leader (MS PL) and Member State Short Term Experts (MS STEs)

Activity 0.1.2 - Project Steering Committee (PSC) Meetings (Beneficiary, TWL partner)

It is envisaged organization of two PSC meetings (after first quarter of project implementation and at the end of project implementation) with involvement of MS PL and MS STEs

Activity 0.1.3 - Final event (Beneficiary, TWL partner)

Final event will be agreed during the kick-off meeting and organized at the end of project implementation. It will overlap with organization of final PSC meeting, thus participation of MS PL and MS STEs is envisaged as well as participation of around 100 participants from relevant institutions (Ministry of Health, Republic Health Insurance Fund, IPHS with network of 24 RIPHs, Military Medical Academy in Belgrade), NRLs and other microbiology laboratories in public and private sector. The representatives from the EUD, ECDC, WHO and DG SANTE will also be invited. The objective of the final event is sharing the results of the gap assessment performed with recommendations and presentation of the developed roadmap to improve capacities and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases.

Component 1 - Development of gap assessment methodology of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs

Activities to achieve Result 1.1

Activity 1.1.1 - Reviewing relevant documentation and organization of meetings with key national institutions, such as MoH and its inspection department, IPHS as well as with

association of microbiology laboratories (TWL partner). Reviewing relate to diagnostics of relevant EU and national legislation and relevant reports: EU directives, relevant national documents and legislation in the field of public health with emphasis on communicable diseases, DILS report, ECDC technical assessment report (Law on health care, Law on protection of population from communicable diseases and bylaws, Law on Public Health, Law on Personal Data Protection, Law on medical documentation and health records, Law on Patient Rights etc) and Regulation on Program of Health Care of Population from Communicable Diseases. The process will be backed-up with meetings in order to clearly define and understand the current situation in terms of progress made in adoption of legislation and its implementation. This will be further used for development of gap assessment methodology.

Activity 1.1.2 - Development of gap assessment methodology along with two assessment directions (definition of benchmarks for assessing gaps (on the basis of EU acquis requirements and EU standards), composition of questions for assessment, and means for data collection such as web based application as well as appropriate tool for storing acquired data (database), interviewing methods (on the spot checks, focus groups, area to be covered, etc), template for gap assessment report). (TWL partner)

Gap assessment methodology should take into considerations specific requirements related to the two assessment directions: (i) identification of gaps between EU standards for confirmation of communicable diseases in line with EU case definition (Commission Implementing Decision 2012/506/EU) in public and private microbiology laboratories (including NRLs) in terms of laboratory equipment, IT (software and hardware), infrastructure and human capacities/resources and diagnostic testing practices /methods and technologies and reporting practices; and (ii) identification of gaps in relation to implementation of core functions of NRLs. MoH will provide list of all laboratories in private health sector which are registered in Serbian Business Register Agency with relevant contacts details.

Methodology should comprehend the approach towards conducting gap assessment, elaborate the questionnaire, as well as the way the data will be collected, entered, and stored (using web-based application), identify the interviewing methods and field work, and identify the template for gap assessment report. It is envisaged involvement of all MS STEs in this activity. The STEs will define information, on the content side, that needs to be collected and will define the set of indicators that will be used for pooling out data from the database and their processing. Same applies for MS STE IT expert that is in charge of defining questions related to IT information that need to be assessed in laboratories, but which in addition will be in charge of designing web based application for data collection and storage. In this respect, involvement of IPHS IT specialist is envisaged, as the developed web-based application will be based on IPHS server and will be further administered by the IPHS.

Activity 1.1.3 - Reviewing of proposed methodology and decisions from the MoH and IPHS

Component 2 - Gap assessment of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs according to agreed methodology

Activities to achieve Result 2.1

Activity 2.1.1 – Collection of data from all labs will be coordinated and managed by the Ministry of Health (MoH) with support of IPHS with network of RIPHs and Inspection Department of MoH

Activity 2.1.2 - Data processing (TWL partner) - The gap assessment methodology (Activity 1.1.2) shall specify the shape of the database for storing collected data (using web-based application). By accessing data, MS STE IT expert will pooled out data, according to previously agreed set of indicators (Activity 1.1.2) and made them available for further interpretation.

Activity 2.1.3 - Field work (interviewing, on the spot checks, focus groups) (TWL partner)

The gap assessment methodology (Activity 1.1.2) shall specify the way field work will be carried out, and on the basis of collected data decision will be made on number of labs to be visited as well as territorial distribution.

Field work is aimed at validating and analyzing the information collected through the questionnaires. It is also intended to assist the MS STEs in preparing and developing a comprehensive gap assessment report. IPHS specialists will be involved in this activity as well.

Activity 2.1.4 - Execution of gap analysis and preparation of gap assessment report with recommendations- desk work (TWL partner)

Gap analysis and gap assessment report shall contain identified gaps as well as recommendations and proposals for improvement and these should be based on:

- The analysis of the current state of play related to microbiology laboratory capacities and practices along with two assessment directions. It will be based on the information collected through the review of relevant documents, questionnaires and through field visits. Analysis should provide a review of conclusions, strengths, weaknesses, opportunities and threats along each area of assessment;
- prioritisation of solutions, opportunities, threats to the country accession process;
- Recommendations to strengthen human resources and capacities covering microbiology labs including NRLs; to improve diagnostic testing practices/ methods and technologies and reporting practices/ covering all microbiology labs including NRLs; to strengthen technical capacities (in terms of laboratory equipment) covering labs in the network of RIPHs including IPHS and in NRLs and IT capacities (both software and hardware) covering public health labs and NRLs; and recommendations for improving physical infrastructure covering labs in the network of RIPHs including IPHS and in NRLs.

Component 3 - Development of roadmap to improve capacities and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases

Activities to achieve Result 3.1

Activity 3.1.1 - Workshop 1 - for health professionals from NRLs on organization and implementation of an effective external quality system in microbiology in line with EU standards and requirements (TWL partner)

It is envisaged to organize a one day workshop targeting up to 50 participants from relevant institutions (Ministry of Health, IPHS with network of 24 RIPHs, Military Medical Academy in Belgrade) and NRLs. The aim of the workshop is to share experiences with TWL partner based on QAS examples and to discuss practical steps that need to be implemented in the next period in

regards to the quality assurance system for microbiology laboratories which is currently missing. This implies also provision of a national EQA system for clinical laboratories and need to be developed and implemented in line with the actual Law on Protection Population from Communicable Diseases.

Activity 3.1.2 - Workshop 2 - for all relevant partners/key stakeholders on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD (TWL partner)

A one day workshop will be organized for up to 80 participants from relevant institutions (Ministry of Health, IPHS with network of 24 RIPHs, Military Medical Academy in Belgrade), NRLs and other microbiology laboratories. The workshop should raise the understanding of participants and stimulate discussions on communicable diseases of public health importance, the consequences if they are not recognized, diagnosed, confirmed, and sufficiently characterized, and impact on the surveillance system. Also, the workshop will address issues relating to the advancement of microbiology laboratory services that are needed for appropriate diagnostic testing practices and to support the surveillance system on communicable diseases and other health issues.

Activity 3.1.3 - Preparation of the Road map - Desk work (TWL partner)

A Road map should elaborate the organization of the work, the specific activities/initiatives, milestones and targets to be achieved and budget framework (both national and international).

In order to construct the road map, decision on measures to fill identified gaps, identification of stakeholders and their involvement need to be agreed and prioritization and sequencing the measures in road map shall be defined as well as measurement framework. Two workshops envisaged under Activities 1.3.1 and 1.3.2 shall be used to stimulate discussion and facilitate a decision on the above elements. It is important to emphasize that Proposal on the Action concept to be considered for financing under IPA 2018 programme shall also come out as the deliverable of this process and will be annexed to the road map as its necessary part.

Activity 3.1.4 - Review of the Road map and decisions from MoH and IPHS

3.5 Means/ Input from the MS Partner Administration:

3.5.1 Profile and tasks of the Project Leader

- University degree education in a relevant field (health sciences)
- Minimum ten years of general professional experience
- At least five year experience of work relevant to EU legislation on communicable diseases
- Specific knowledge on issues related to CD surveillance, EU Acquis and epidemiology
- Experience in the management of Twinning projects and/or similar projects
- Experience in preparation of major strategic documents and in analysis
- Good management, organizational and communication skills
- Excellent knowledge of written and spoken English
- Computer literacy

The Project Leader will have the following tasks:

- Overall management and coordination of the project in cooperation with short-term experts and BC Project leader
- Overall coordination of MS expert's work and availability (Mobilizing STEs)
- Monitoring of activities and results achieved in line with implementation schedule
- Participation in Steering Committee meetings
- Project reporting Ensuring backstopping and financial management of the project in the MS
- Overall responsibility and direction of the MS Twinning partner inputs and proposing corrective measures, if needed

3.5.2 Profile and tasks of the RTA

N/A 3.5.3 Profile and tasks of the short-term experts

Profile of the Short-term experts

STE 1– Expert for organizational aspects of the integrated surveillance system on CD field

STE2- Expert for organizational aspects of microbiology system in function of the surveillance on CD

STE3-organizational aspects in reference labs and implementation of QAS in microbiology labs

The twinning partner will decide on the profile, number and involvement of the short term experts during the drafting of the project work plan. STEs should be identified by the Project Leader/RTA and have to be agreed with the beneficiary institutions in the course of designing and delivery of the expected project outputs. Selection procedures shall be transparent and based on pre-defined criteria, including detail professional qualifications, and work experience. Each expert will have individual Terms of Reference, including the expert profile requirements and outputs to be produced which will be endorsed by the beneficiary institutions. Following the endorsement by the beneficiary institutions, the terms of reference and selected experts are subject to final approval.

Main areas of expertise required by the team of short-term experts should cover the following fields (the list of fields is non-exhaustive):

- STE1-organizational aspects of the integrated surveillance system
- STE2-organizational aspects of microbiology system in function of the surveillance on CD
- STE3-organizational aspects in reference labs and implementation of QAS in microbiology labs
- STE4 - IT expert

Tasks of the short- term experts:

STEs will provide specialized know-how for the individual tasks in this project. Therefore, the experts should have a relevant professional experience in administration and minimum qualifications required, as well as specific skills needed for individual task. As a general approach, the STEs will take the responsibility for the implementation of the Project and the achievement of the results, each for his/her individual mission tasks, as defined by individual CV. They will also prepare the required reports and the output described.

Detailed profiles and tasks of short - term experts and including the duration of their assignments will be provided in the Twinning Work Plan. The indicative requirements are the following:

Profile of the short- term experts:

Requirements:

- University level education and equivalent professional experience of 10 years in health care in relevant field.
- At least 5 years of professional working experience in the field for which the expert is mobilized;
- Proven contractual relation to public administration or mandated body, as defined under twinning manual 5.4.5;
- fluency in English, both written and spoken
- experience with the implementation of gap assessment

Assets:

- work experience in building microbiology laboratory capacities and/or practices in public and private sector in close relation with national laboratories
- work experience in transition on/or pre-accession countries

Tasks:

- plan and coordinate outputs
- to prepare outputs in the required field of expertise in co-ordination with the Project Leader and the Serbian Ministry of Health

Profile of the Short-term expert 4 (STE 4) – IT expert

- University degree in information technology or engineering or computer science
- At least 5 years of progressively responsible work experience in information technology, including, knowledge of web-based packages and applications

- At least 5 years of experience in data processing, database management and application of statistical methods is required
- Experience in statistical analysis and technical writing is desirable
- Experience in assessment, monitoring and evaluation and training in the field of IT system for epidemiological surveillance purposes
- Experience in project preparation in the health sector under structural or cohesion funds
- Excellent knowledge of written and spoken English
- Excellent analytical, organizational and communication skills

Tasks of the Short-term expert 4

- Reviewing of relevant legislation, documents and reports in the field of public health with emphasis on communicable diseases
- Developing gap assessment methodology along two assessment directions with emphasis on current state of IT support and development of tool for collection of data, tool for storing relevant data (database) and application of statistical methods/ statistical analysis of data
- Conducting field work (interviewing, on the spot checks, focus groups) as part of agreed gap assessment process with emphasis on current state of IT support in terms of software and hardware requirements in microbiology labs and reporting practices
- Conducting gaps and needs analysis and preparing assessment synthesis document (baseline situation) with emphasis on current state of IT support in terms of software and hardware requirements in microbiology labs
- Preparing gap assessment report and corresponding recommendations for improvement of IT support in terms of software and hardware requirements in microbiology labs for the implementation of the national common IT system in the microbiology services in function of surveillance on CD
- Conducting consultations with BC stakeholders and experts and workshop(s) and constructing the road map (the organisation of the work, the specific activities/initiatives, milestones and targets to be achieved and budget framework- national and international)) aiming to improve capacities and practices and sensitivity of epidemiological surveillance system on communicable diseases
- Close cooperation with the BC stakeholders and experts in undertaking all activities
- Participating in all relevant project activities in cooperation with other short-term experts, including the final event agreed during the kick-off meeting, Project Steering Committee Meetings and final event

3.5.4 Translation/interpretation:

Translation and interpretation have been included in calculating entire budget for the TWL and these services will be needed for implementation of following Activities:

- Activity 0.1.1 - Kick -off meeting

- Activity 0.1.2 - Project Steering Committee (PSC) Meetings
- Activity 0.1.3 - Final event
- Activity 1.1.2 - Development of gap assessment methodology
- Activity 2.1.3 - Field work (interviewing, on the spot checks, focus groups)
- Activity 3.1.1 - Workshop 1 - for health professionals from NRLs on organization and implementation of an effective external quality system in line with EU standards and requirements
- Activity 3.1.2 - Workshop 2 - for all relevant partners/key stakeholders on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD

4. Institutional Framework

Indicate the beneficiary institution(s) and, if applicable, specify Department/Directorate within the beneficiary institution.

If several, specify their relationship and organisation for the implementation of the project, as well as the coordination mechanism.

Indicate whether the results of the project will lead to a change of the institutional framework as described.

According to the Law on Protection of Population from Communicable Diseases (“Official Gazette of Republic of Serbia” No 15/2016), the Institute of Public Health Serbia (IPHS) “Dr Milan Jovanovic Batut” with the network of 24 regional Institutes of Public Health (RIPHs) are responsible for coordination and implementation of surveillance on communicable diseases and special health issues. IPHS with network of RIPHs are also responsible for planning, organizing and implementation of prevention and control measures in their jurisdiction in partnership with healthcare institutions, private practice and other legal entities who provides health services and with the Ministry of Health in line with the law. Relevant surveillance data are periodically collected, analyzed and reported by the IPHS to the Ministry of Health (MoH) and other partners at regional and national level, including reporting to WHO, ECDC and other international organizations.

Ministry of Health is responsible for development of rulebooks for implementation of the above Law, improvement of protection of population from communicable diseases, nomination of national reference laboratories (NRLs), inspection control of the Law implementation and other actions defined by the Law and for financing of some measures and programs, confirmed international contracts and international sanitary conventions.

Public microbiology laboratories are located at general hospitals (23), RIPHs (23), and tertiary care centers and institutes (13) are responsible for the primary diagnostic services.

The 25 **National Reference Laboratories (NRLs)** are in regional institutes of public health (8 NLRs), Medical Faculty of the University of Belgrade (5NRLs) and 5 that are united with the Clinical Centre of Serbia, and in the institutes with multidisciplinary research activities in the fields of biological, medical and agricultural sciences (7 NRLs).

Ministry of Health and Institute for Public Health of Serbia jointly started preparations for defining starting points for action plan for part of Chapter 28 dealing with systems for communicable diseases surveillance and control. In this regard, during 2015 and 2016, Working Group nominated by Minister of Health has created a preliminary review of all tasks and deadlines that were mentioned during the debriefing session of the assessment mission and which were contained as recommendations in the ECDC Technical Report. The working group in consultation with other national experts prepared first draft of Action Plan, followed by the ECDC review, on the basis of which Working group nominated by Minister of Health has prepared the revised draft of the action plan as a starting point for further work until its final adoption. For each activity in Action Plan the institution or body to be responsible for its implementation has been particularly determined based on institutional capacities and position in the public health hierarchy and system. In certain cases and for certain activities that require involvement of several institutions and/or inter-sector cooperation, first listed is the institution in charge to be a bearer and/or coordinator of implementation of the activity(s) while other listed institutions have been given supportive role in order to achieve better quality and more efficient degree of realization of the activity. Implementation of this plan will be monitored by the joint coordinating body of Ministry of Health and Institute of Public Health of Serbia. This body will have regular two annual meetings and in case of need, meeting shall be organized even more frequently. Coordinating body will strongly cooperate with Working group for preparation of negotiations on Serbia's accession to the European Union concerning negotiation Chapter 28.

In regards to the TWL management and implementation and in line with the Decree on the management of EU Pre-Accession Assistance programmes under component I of the Instrument for Pre-Accession (IPA) – Transition Assistance and Institution Building for the period 2007-2013, Ministry of Health (MoH) is the final beneficiary institution while the Institute of Public Health of Serbia (IPHS) represents the end-recipient of assistance. IPA unit within MoH will bear overall responsibility for implementation and monitoring the implementation of contract, and will coordinate and supervise IPHS in the process of the implementation of the activities. IPHS will delegate persons responsible for project implementation.

Monitoring arrangements, including Steering Committee(s) for the implementation of this Action, shall be established in accordance with the relevant provisions of the applicable legal acts regulating IPA 2007-2013.

Steering Committee that will be established will be composed of: MS PL, MS STEs, Beneficiary (MoH), end-recipient (IPHS), SEIO and CFCU.

Monitoring of the progress in TWL implementation will be done in accordance with the rules and procedures for monitoring under Indirect Management (IM), as specified in the Decree on the management of EU Pre-Accession Assistance programmes under component I of the Instrument for Pre-Accession (IPA) – Transition Assistance and Institution Building for the period 2007-2013 and related Manuals of Procedures, while regular monitoring of the implementation will be done through the Steering Committee meetings and regular reporting by the TWL partner.

5. Budget

Estimated input of man days (MD) per TWL activity and Components

Indicative work-plan	Estimated input in man days (MD)	Estimated input in MDs in %
Component 0 - Coordination and Visibility	**22**	**10.73**
Activity 0.1.1 - Kick -off meeting	4	
Activity 0.1.2 - Project Steering Committee Meetings	3	
Activity 0.1.3 - Final event	15	
Component 1 - Development of gap assessment methodology	**60**	**29.27**
Activity 1.1.1 - Reviewing relevant documentation and organization of meetings with key national institutions	28	
Activity 1.1.2 - Development of gap assessment methodology	32	
Activity 1.1.3 - Reviewing of proposed methodology and decisions from the MoH and IPHS	0	
Component 2 - Gap assessment	**65**	**31.71**
Activity 2.1.1 - Collection of data from all labs	0	
Activity 2.1.2 - Data processing	5	
Activity 2.1.3 - Field work (interviewing, on the spot checks, focus groups)	20	
Activity 2.1.4 - Execution of gap analysis and preparation of gap assessment report with recommendations	40	
Component 3 - Development of roadmap	**58**	**28.29**
Activity 3.1.1 - Workshop 1 - for health professionals from NRLs on organization and implementation of an effective external quality system	10	
Activity 3.1.2 - Workshop 2 - for all relevant partners/key stakeholders on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD	20	
Activity 3.1.3 - Preparation of Road map - Desk work	28	
Activity 3.1.4 - Review and decisions from MoH and IPHS	0	
Total input in MDs	**205**	**100**

Budget breakdown

Component 0 - Coordination and Visibility	**29,112.00**
Activity 0.1.1 - Kick -off meeting	4,800.00
Activity 0.1.2 - Project Steering Committee Meetings	3,767.00
Activity 0.1.3 - Final event	20,545.00
Component 1 - Development of gap assessment methodology	**65,144.00**
Activity 1.1.1 - Reviewing relevant documentation and organization of meetings with key national institutions	32,220.00
Activity 1.1.2 - Development of gap assessment methodology	32,924.00
Activity 1.1.3 - Reviewing of proposed methodology and decisions from the MoH and IPHS	0.00
Component 2 - Gap assessment	**74,095.00**
Activity 2.1.1 - Collection of data from all labs	0.00
Activity 2.1.2 - Data processing	5,673.00
Activity 2.1.3 - Field work (interviewing, on the spot checks, focus groups)	24,574.00
Activity 2.1.4 - Execution of gap analysis and preparation of gap assessment report with recommendations	43,848.00
Component 3 - Development of roadmap	**66,042.00**
Activity 3.1.1 - Workshop 1 - for health professionals from NRLs on organization and implementation of an effective external quality system	11,912.00
Activity 3.1.2 - Workshop 2 - for all relevant partners/key stakeholders on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD	23,942.00
Activity 3.1.3 - Preparation of Road map - Desk work	30,188.00

Activity 3.1.4 - Review and decisions from MoH and IPHS	0.00
Total budget for Activities	**234,393.00**
Visibility costs (lump sum: 1 Subject to ceiling of € 5000 for projects with a budget up to and including 1M€ and € 10.000 for projects above that threshold)	5,000.00
Audit certificate costs (lump sum: 2 Recommended estimate for a period of 12 months: € 4000)	4,000.00
Total budget including visibility and audit certificate costs	243,393.00
Provision for changes in prices (at maximum 2.5% of sub-total)	6,084.83
TOTAL TWL BUDGET	**249,477.83**

6. Implementation Arrangements

6.1 Implementing Agency responsible for tendering, contracting and accounting (AO/CFCU/PAO/ Commission), including contact person and full contact details.

Ministry of Finance
Department for Contracting and Financing of EU Funded programmes (CFCU)
Sremska St, No. 3-5
11000 Belgrade, Serbia

Mr. Dušan Čarkić, Programme Authorising Officer (PAO)/Head of CFCU
Phone: +381 11 20 21 -115
E-mail: dusan.carkic@mfin.gov.rs

Mr. Darko Vasić, Twinning National Contact Point
Phone: +381 11 2021 412
E-mail: twinnning@mfin.gov.rs

6.2 Main counterpart in the BC

Ministry of Health
Nemanjina St, No. 22 – 26
11000 Belgrade, Serbia

Senior Programming Officer (SPO): dr Danijela Urošević, Head of Division for European integrations, planning and preparation of projects

Institute of Public Health "Milan Jovanovic Batut"
Dr Subotića Str, No. 5
11000 Belgrade, Serbia

BC Project Leader: dr Verica Jovanovic, Acting director

6.3 Contracts

One Twinning Light Contract, with an amount of EUR 250 000.

6.4 Language

The working language is English.

7. Implementation Schedule (indicative)

7.1 Launching of the call for proposals (Date) 27/12/2016

7.2 Start of project activities (Date) 02/06/2017

7.3 Project completion (Date) December 2017

7.4 Duration of the execution period (number of months): 6 months

Indicative work-plan	**M 1**				**M 2**				**M 3**				**M 4**				**M 5**				**M 6**			
Component 0 - Coordination and Visibility																								
Activity 0.1.1 - Kick -off meeting																								
Activity 0.1.2 - Project Steering Committee Meetings																								
Activity 0.1.3 - Final event																								
Component 1 - Development of gap assessment methodology																								
Activity 1.1.1 - Reviewing relevant documentation and organization of meetings with key national institutions																								
Activity 1.1.2 - Development of gap assessment methodology																								
Activity 1.1.3 - Reviewing of proposed methodology																								
Component 2 - Gap assessment																								
Activity 2.1.1 - Collection of data																								
Activity 2.1.2 - Data processing																								
Activity 2.1.3 - Field work																								
Activity 2.1.4 - Execution of gap analysis and preparation of gap assessment report																								
Component 3 - Development of roadmap																								
Activity 3.1.1 - Workshop 1																								
Activity 3.1.2 - Workshop 2																								
Activity 3.1.3 - Preparation of Road map - Desk work																								
Activity 3.1.4 - Review and decisions from MoH and IPHS																								

8. Sustainability

By identifying the needs and implementable interventions that will allow strengthening various key microbiology laboratory system elements – human, technical and physical capacities and diagnostic testing and reporting practices – the TWL will pave the way for improvement of surveillance system on CD and for development of sustainable institutional capacities to respond

to serious public health threats of cross-border relevance. The main outcome of the TWL is the development of a roadmap to meet these capacity requirements that is based on the assessment of national microbiology laboratory system. The roadmap shall further be implemented to ensure that the core capacities are present and functioning throughout the country.

Furthermore the result of the TWL and roadmap to be prepared is considered in the view of national commitments in line with draft CD Action Plan and requirements for closing negotiation chapter 28.

The TWL overall objective states its contribution to respond to serious public health threats of cross-border relevance. TWL is therefore expected to have a long term impact on preventing cross border transmission of CDs by having a well-functioning surveillance system that can facilitate the identification, monitoring and control of communicable diseases.

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

9.1 Civil society

The cooperation with CSOs is facilitated by the Government's commitment as part of its European Agenda. Regarding mechanisms for dialogue, two official mechanisms exist: (i) Office for Cooperation with Civil Society; and (ii) Sectorial Civil Society Organisations - SEKO for the processes of IPA programming. Both are examples of good practices in terms of CSO representation in general.

The Government Office for Cooperation with Civil Society still is the main institutional mechanism for the support of developing the dialogue between the Government and CSOs through offering support to its institutions in understanding and recognizing the role of CSOs in policy shaping and decision making processes.

Office for Cooperation with Civil Society also established the mechanism that allows involvement of CSOs in negotiations on the accession of the Republic of Serbia to the European Union. During 2013 and 2014, Office for Cooperation with Civil Society in cooperation with the Negotiating team for the accession and relevant institutions for different negotiation chapters included CSOs in negotiations. CSO participation in this process so far included monitoring of explanatory screenings, participation in the preparation of the bilateral screening for some negotiating chapters and participation in briefing meetings that followed bilateral screenings.

In addition, NIPAC TS - SEIO established a consultation mechanism with the civil society organization (CSOs)[2.] This mechanism is based on the consultative process with Sectorial Civil Society Organizations (SECOs) and serves as a platform that enables exchange of information and contribution of CSOs in relation to planning development assistance, particularly programming and monitoring of the Instrument for Pre-Accession Assistance (IPA). Extensive consultations with CSOs have been undertaken in drafting Sector Planning Document (2015 – 2017) for HRSD sector, whereas support to Health sub-sector has been envisaged and particularly support to improvement of surveillance on CDs.

9.2 Equal Opportunity

2 Introduced in 2011

The project will be implemented according to the regulations of the national legislation providing equal opportunities for men and women. Twinning partners will be expected to comply with EU Equal Opportunity policies.

Enforcement of equal opportunity principles will be ensured through specific administrative procedures applied in accordance with the Law on non-discrimination. No discrimination on the basis of racial or ethnic origin, religion or belief, disability, sex or sexual orientation or on any other grounds.

9.3 Environmental considerations

Any ecological friendly initiative which can be taken will have to be implemented.

10. Conditionality and sequencing

10.1 Conditionality

Appointment of the relevant staff by the beneficiaries to participate in training activities is a condition to be reflected during project implementation.

10.2 Sequencing

Due to lack of necessary feasibility studies and needs assessments regarding microbiology laboratory system in function of CDs, the first Phase reiterated in this TWL, will cover activities related to assessing the needs, identifying the gaps and mapping interventions aimed at improving microbiology diagnostic system and capacities in the function of surveillance on CD and in compliance with EU acquis and EU standards. Focus of the assistance is on public and private microbiology laboratory capacities and core functions and capacities of National Reference Laboratories (NRLs).

The broader Action will be the subject of the 2018 IPA II programmes with technical assistance and investment activities based on the gaps identified and roadmap developed in the first stage. It is important to note that there might be a need to implement the investments gradually based on the results of the gap assessment conducted under this TWL.

ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (optional)

ANNEX 1

LOGFRAME PLANNING MATRIX		**Total budget: € 250 000**	**IPA budget: € 250 000**
Overall objective	**Objectively verifiable indicators**	**Sources of**	**Assumptions**

		Verification	
To improve surveillance system on communicable diseases, hereinafter: CD in line with EU acquis and EU standards and to develop sustainable institutional capacities to respond to serious public health threats of cross-border relevance.	Progress made towards meeting accession criteria in Chapter 28	EC Progress Report	
Project purpose	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
The project purpose is to map out an overall implementation approach with a series of achievable initiatives for improving microbiology diagnostic system quality in the function of surveillance on CD in compliance with EU acquis and EU standards, by focusing on: • public and private microbiology laboratory capacities • core functions and capacities of National Reference Laboratories (NRLs)	The roadmap, as a reference document outlining the organisation of the work, the specific activities/initiatives, milestones and targets to be achieved and framework for mobilising, harnessing and leveraging resources (both national and international) developed by the end of the project. The roadmap specifically spells out interventions aimed at: • overcome identified gaps between EU standards for confirmation of communicable diseases in line with EU case definition (Commission Implementing Decision 2012/506/EU) in public and private laboratories (including NRLs) in terms of laboratory equipment, software and hardware IT, infrastructure and human capacities/resources and diagnostic testing practices (methods and technologies) and reporting practices • implement core functions (reference diagnostics, reference material resource, scientific advice, collaboration and research and monitoring, alert and response, external QA) for NRLs in the context of national public health system and public health added value.	• TWL final report • Annual report on implementation of Action Plan for improvement of the communicable diseases surveillance and response system in Republic of Serbia in line with EU acquis/EC and ECDC recommendations, 2016-2020	• The relevant necessary legislative, administrative, technical and financial set up to implement road-map is in place
Results	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
Component 0 - Coordination and visibility			
Result 0.1 - Established arrangements for information sharing, visibility and advocacy to all actors	Coordination plan, including organisation of final event agreed during the kick-off meeting	• Meeting minutes	• Decision makers and all relevant actors are timely informed about progress during project implementation
Component 1 - Development of gap assessment methodology of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs			
Result 1.1 - Determined framework for gap assessment, along two main directions (hereinafter: two assessment directions): (i) between EU standards for confirmation of communicable diseases in line with EU case definition (Commission Implementing Decision 2012/506/EU) in public and private microbiology laboratories (including NRLs) in terms of laboratory equipment, IT, infrastructure and human capacities/resources and diagnostic testing practices /methods and technologies and reporting practices; and (ii) implementing core functions of NRLs	Gap assessment methodology developed and approved during the first month of project implementation	• Document elaborating gap assessment methodology	•

Component 2 - Gap assessment of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs according to agreed methodology			
Result 2.1 - Identified gaps and corresponding recommendations, along two assessment directions, for improvement of knowledge, skills, IT support, laboratory equipment, infrastructure and diagnostic testing practices/methods and technologies and reporting practices	Gap assessment report with synthesis of the current situation (through a SWOT analysis, for example) and recommendations drafted by the end of third month of project implementation containing: o Recommendations for strengthening human resources and capacity building covering microbiology labs including NRLs o Recommendations for improving diagnostic testing practices/ methods and technologies and reporting practices covering all microbiology labs including NRLs o Technical specifications for laboratory equipment covering labs in the network of RIPHs including IPHS and in NRLs o Technical specifications for IT software/hardware covering public health labs and NRLs o Recommendations for improving physical infrastructure covering labs in the network of RIPHs including IPHS and in NRLs	• Gap assessment report • TWL final report	•
Component 3 - Development of roadmap to improve capacities and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases			
Result 3.1 - Identified collaborative arrangements and concrete measures to improve capacities (human, technical and physical) and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases - highlighting roles and organisation of work, milestones and targets, budget and financing sources - for the planning and programming process, focusing on the work in line with two assessment directions, as well as to a certain extent, that of the first following Action to be implemented under IPA II	• The roadmap, as a reference document outlining the organisation of the work, the specific activities/initiatives, milestones and targets to be achieved and budget framework (both national and international) developed by the end of the project. • Draft Action concept to be included in IPA II programming (2017/2018) prepared by the end of the project • Thematic workshop on organization and implementation of an effective external quality system in line with EU standards and requirements of duration of one day for 50 representatives of NRLs implemented in forth month of project implementation • Thematic workshop on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD of duration of one day for 80 representatives of MoH, epidemiologist and microbiologist from IPHS, RIPHs, NRLs , microbiology labs implemented in fifth month of project implementation	• Road map • Draft AD concept • TWL final report	• Decision makers and all relevant actors are timely informed about progress during project implementation
Activities	**Means**	**Specification of costs**	**Assumptions**
Component 0 - Coordination and visibility **Activities to achieve Result 0.1** **Activity 0.1.1** - Kick -off meeting (Beneficiary, TWL partner) **Activity 0.1.2** - Project Steering Committee (PSC) Meetings (Beneficiary,	TWL Man-Days (MD) Premises for kick – off (provided by IPHS) Venue for final event Translation costs for final event Interpretation costs Printing		• Organisation, selection and appointment of staff

TWL partner) **Activity 0.1.3** - Final event (Beneficiary, TWL partner)			
Component 1 - Development of gap assessment methodology of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs **Activities to achieve Result 1.1** **Activity 1.1.1** - Reviewing relevant documentation and organization of meetings with key national institutions **Activity 1.1.2** - Development of gap assessment methodology along two assessment directions (definition of benchmarks for assessing gaps (on the basis of EU acquis requirements and EU standards), composition of questions for assessment, and means for data collection such as web based application as well as appropriate tool for storing acquired data (database), interviewing methods (on the spot checks, focus groups, area to be covered, etc), template for gap assessment report). (TWL partner) **Activity 1.1.3** - Reviewing of proposed methodology and decisions from the MoH and IPHS	TWL MD Premises for desk work (provided by IPHS) Translation costs		• Relevant documentation available
Component 2 - Gap assessment of current microbiology laboratory capacities and practices in public and private sector including NRLs and core functions of NRLs according to agreed methodology **Activities to achieve Result 2.1** **Activity 2.1.1** – Collection of data from all labs will be coordinated and managed by the Ministry of Health (MoH) with support of IPHS with network of RIPHs and Inspection Department of MoH **Activity 2.1.2** Data processing (TWL partner) **Activity 2.1.3** - Field work (interviewing, on the spot checks, focus groups) (TWL partner) **Activity 2.1.4** - Execution of gap analysis and preparation of gap assessment report with recommendations- desk work (TWL partner)	TWL WD Premises for desk work (provided by IPHS) Interpretation costs		• Organisation, selection and appointment of staff to participate in study tour, field visits • Willingness of laboratories to reply to the questionnaire and provide required data • Laboratories appoint relevant personnel to participate and provide data during field visits •
Component 3 - Development of roadmap to improve capacities and diagnostic testing practices and sensitivity of epidemiological surveillance system on communicable diseases **Activities to achieve Result 3.1** **Activity 3.1.1** - Workshop 1 - for health professionals from NRLs on organization and implementation of an effective external quality system in microbiology in line with EU standards and requirements (TWL	TWL WD Premises for desk work (provided by IPHS) Venues for workshops Interpretation costs		• Organisation, selection and appointment of staff to participate in workshops

partner) **Activity 3.1.2** - Workshop 2 - for all relevant partners/key stakeholders on practical steps aiming to improve microbiology diagnostic system in the function of surveillance on CD (TWL partner) **Activity 3.1.3** - Preparation of the Road map - Desk work (TWL partner) **Activity 3.1.4** - Review of the Road map and decisions from MoH and IPHS			
Preconditions: • Appointment of counterpart in the beneficiary before launching the tender procedure; • Allocation of working space and facilities by the beneficiary for technical assistance before launching the tender procedure; • Relevant legislation/regulations regulating this field is in place • Mapping of microbiology laboratories carried out and database created			