The OIE *ad hoc* Group on Sustainable laboratories met for the first time from 8-10 October 2019 at the OIE Headquarters in Paris, France.

1. **Welcoming remarks and background**

Dr Matthew Stone, Deputy Director General of the OIE, welcomed the participants on behalf of the OIE and presented the importance of sustainable laboratories in the current working programme of the OIE. Dr Stone explained the *ad hoc* Group (AHG) process and how AHGs help the OIE achieve their mandate.

In the introduction of the OIE’s on-going work on sustainable laboratories, he noted that the experts were invited to this meeting on the basis of their expertise and experience in laboratory management, leadership, and strategy in order to execute the specific task of advancing the enhancement of the PVS Sustainable Laboratories Tool and the analysis of related data. The AHG participants introduced themselves and agreed that Dr Ana Maria Nicola would act as the chairperson. The Group confirmed that Mrs Barbara Martin and Mr Dave Korcal, along with OIE staff, would be the rapporteurs. The adopted Agenda and List of Participants are presented in Annexes I and II of this report, respectively.

Ms Jennifer Lasley, OIE Sustainable Laboratories Programme Manager, reviewed the Performance of Veterinary Services (PVS) Pathway and the origins of PVS Laboratory Tool and presented the OIE and its PVS Laboratory Experts’ observations and experience related to laboratory sustainability activities undertaken at the OIE.

Recognizing the link between laboratory biosafety, biosecurity, and quality management, the OIE formed a technical advisory group in 2011 to develop a mechanism to analyse the supply and demand for veterinary laboratory analysis in the country, and develop a range of sustainable management, organizational, budgetary and financial solutions. Four tools and a supporting mission manual were developed to support the strengthening of veterinary laboratories under the umbrella of its overarching Performance of Veterinary Services (PVS) Pathway. In 2013, the OIE launched the PVS Pathway Laboratory Tool, with 15 missions having occurred to date.

From the observations of PVS Laboratory Experts, a functional and sustainable diagnostic laboratory requires: a high level of technical competence; a robust management framework (particularly for quality assurance, safety, and security); links to national, regional and international networks; appropriate equipment and reagents; support from a functional health system, including strong surveillance systems and disease control programmes; and economic sustainability.

To a varying degree but regardless of the development status of a country, veterinary laboratories across the world face challenges in meeting these critical requirements. These difficulties are compounded when dangerous pathogens are analysed and stored in laboratories and biobanks in under-resourced and poorly managed facilities, regardless if they are new, renovated, or older. Out of proportion infrastructure, over-investment in poorly managed or under-functioning structures,
unsustainable fixed costs, poorly trained staff, inaccurate or untimely results, insufficient sample flow, and systemic and chronic management deficiencies only augment the risk of accidental or intentional release once external resources are depleted and are not sustained by national or governmental resources. **Veterinary laboratories that are unable to contain dangerous pathogens in a secure and sustainable manner represent a real and present danger to national, regional, and global security and a liability to governments around the world.**

Furthermore, access to laboratory diagnostics, laboratory infrastructure, and quality assurance are crucial to understanding the ability of an OIE Member Country to implement and comply with OIE standards and to provide valid results to the Veterinary Services as the basis for decision making.

More specifically, Chapter 1.1.1 “Management of veterinary diagnostic laboratories” of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals outlines the range of issues to be addressed if laboratories are to meet international standards. These standards include key elements such as staff safety, biocontainment, biosecurity and quality assurance and specifically state that “the governance and management of these aspects are as important as the delivery of the actual diagnostic service.”. In addition, implementing these standards would reduce biological risks.

In closing, Ms Lasley also provided information on laboratory linkages to multiple OIE activities and publications including:

1. OIE Sixth Strategic Plan for the period of 2016 – 2020
2. Chapter 1.1.1 “Management of veterinary diagnostic laboratories” of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
3. OIE Consultation on Sustainable Laboratory Biosafety & Biosecurity held 1-2 March 2018 in collaboration with Chatham House and WHO.

**Meeting Objectives**

For this meeting, the AHG was convened to review the existing PVS Sustainable Laboratories Tool to determine how it can be further enhanced and developed. The AHG’s Terms of Reference (TOR) presented in Annex III were reviewed and discussed with a focus on expected minimum outputs and timelines.

**PVS Sustainable Laboratory Tool – mini training**

Ms Lasley led an overview of PVS Sustainable Laboratory Tool overview and training with support from Dr Nicola, Dr Natalie Bloch, and Dr Andre Mendonca. The objective of a PVS Laboratory Mission is to determine the resources needed by the national veterinary laboratory network, to evaluate the structure and viability of the network, and to provide scenarios for strategic decision making to the Veterinary Services. The PVS Sustainable Laboratory Mission process was described in detail as well as each of the tools used to collect data. Tools are adaptable and can be used for an individual laboratory or all laboratories in a country.

The tools are currently used to:

1. Analyse the current and prospective demand for veterinary Laboratory services, through current laboratory activity (number of samples and tests, geographical distribution of demand, and of the true cost of analysis including the cost of consumables, sampling kits, transport and reagents);
2. Analyse the existing supply of veterinary laboratory services at the national level as well as by other laboratories.
3. Present scenarios of sustainable management, organisational, budgetary and financial solutions, with different options and their costs, in order to assist decision making related to the structure and management of the national laboratory network.

2. Learning from experience and similar work
In order to capture the perspective of those who had previously participated in a PVS Sustainable Laboratory Mission, questionnaires were developed. Separate questionnaires were developed for Member Countries and PVS Laboratory Experts. The Member Country survey included demographics, mission preparation, the Supply Tool, the mission, and mission report. The Laboratory Experts questionnaire included questions related to demographics, training, tools, mission format, and the report. Each group was asked to provide input on the perceived strengths and weaknesses of each of the aspects of the missions.

Ms Lasley presented the results of the Member Country survey. All respondents believe the missions are useful for multiple purposes and expressed an interest in follow-up missions. Respondents also recognized the potential for improvement by providing overviews of the PVS Lab Mission process, providing training on how to complete the Supply Tool, and including a mission evaluation and follow-up component.

Ms Martin presented the results of the Laboratory Expert survey. Laboratory Experts believe the tools are useful but also saw the potential for improvement by streamlining tools and improving data visualization. Laboratory Experts felt that follow-up missions could assist in implementing changes.

Existing Tools for laboratories

Participants were asked to provide the background and purpose of existing tools targeting laboratories, as well as where tools are complementary, what redundancies exist, and where there are opportunities to link to laboratory sustainability tools to provide more comprehensive data and information.

The Chatham House Prior Assessment Tool was presented by Ms Emma Ross. The tool was initiated in 2018 because of need to work with high consequence agents in Africa. The purpose was to provide a framework for initial conversations, increase local ownership, and facilitate attention to relevant aspects. The Group agreed that the PVS Sustainable Laboratories Tool is well suited to quantify some (financial, cost-benefit, and human resources) aspects and therefore make a considerable contribution to the Prior Assessment Tool in Member Countries. Chatham House’s Prior Assessment Tool helps to answer the question, “Should we build a new laboratory or not?”, while the PVS Sustainable Laboratories Tool assists Members to answer the question, “The lab is already built, so how can it be maintained?”. These two tools could conceivably be used by country governments, donors and partners to address all laboratory capacity building activities that they wish to implement, with the aim of implementing laboratory biosafety and biosecurity in a sustainable manner.

The FAO Laboratory Mapping Tool was presented by Ms Beatrice Mouillé. The tool was developed in 2010 to aid in veterinary laboratory project assessment by mapping key operational and technical elements. The tool measures strengths and weaknesses and allows countries to prioritize actions for improvement. The Group agreed that there were linkages to explore but highlighted that the costing nature of the PVS Sustainable Laboratories Tool made both tools inherently different but complementary.

Each of the WHO tools was presented by Dr Lisa Stevens. The International Health Regulations (IHR) Joint external evaluation (JEE) Tool is used to evaluate the capacities required under the IHR to prevent, detect, and respond to IHR related hazards. The WHO Laboratory Assessment Tool is a supplement to the IHR tools used to identify priorities and standardize ways to assess laboratories capacities. The tool gathers qualitative & quantitative data on a range of technical laboratory capacity. The WHO Laboratory Test Costing Tool, the Group agreed, is the tool most like the PVS Laboratory Sustainability Tools. It was developed by
WHO EURO as a part of the Better Labs for Better Health regional initiative and builds on the premise that sustainable laboratory services require a rational approach to laboratory system strengthening.

3. Overall Vision of the PVS Sustainable Laboratories Tool Enhancement

The overall vision of the PVS Sustainable Laboratories Tool enhancement, to add value and benefit for OIE Members, to increase impact, and to better communicate on the benefits of laboratories’ financial sustainability on biosafety and biosecurity, was presented by Ms Lasley. The name of the mission has been changed from “PVS Pathway Laboratory Mission” to the “PVS Sustainable Laboratories Mission” to better reflect the objective, methodology, and conduct of the missions and better differentiate it from other tools with focus on technical evaluation and audit. With respect to the name change of the PVS Sustainable Laboratories Tool, the Group determined it was important to define sustainable laboratory networks to ensure a common understanding and better frame the problem and objectives of the mission. Based on group discussion, the following working definition, aligned with the Sustainable Development Goals, was determined: “a system of laboratories that can maintain appropriate safety, security, and quality on a path towards compliance with OIE International Standards, taking into account social, environmental, and economic factors in its day to day operations for the benefit of the health system.”

There will be 3 parallel work streams in the project: Analyse, Streamline, and Enhance. The OIE, along with laboratory and economics experts, will analyse the data from the 15 missions and use it to inform the Investment Needs Advocacy Paper and other supporting documentation of the PVS Sustainable Laboratories Tool and to inform the streamlining and enhancement of available tools by late 2021. The tools will be streamlined to make them more effective and efficient in the short-term. Modifications will be made to each tool and will be rolled out as beta versions during upcoming missions. The enhance stream includes the development of new tools, specifically the mission report, to add additional benefit for Member Countries and PVS Laboratory Experts and to increase impact. The target date for enhancements is mid-2021.

Many common business tools exist but have different components based on source information. Common business tools were reviewed to compare components to those used in the PVS Sustainable Laboratories Mission. The business tools reviewed were: business planning, business case, business model, strategic planning, market analysis, opportunity cost, strategic planning, scenario planning, and detailed cost analysis by disease. Each of the tools was briefly discussed with more detailed presentations on cost-benefit analysis and return on investment.

Ms Valsa Shah discussed a case study on a cost benefit analysis (CBA) model for sustainable laboratories. The Group recommended repackaging the current PVS Laboratory Mission report according to a narrative CBA format with all benefits, from commercial for laboratories, to societal benefits, and to incorporate benefits as a larger component of the mission and report. The current PVS laboratory mission report also does not include costs outside the laboratory and therefore reference to these costs could also be made to support the sustainability argument. The Group agreed that the current approach of providing different options with costing and benefits should be preserved in the future, but better highlighted in the report as noted.

Dr Salama Al Muhairi provided a presentation on the return on investment of implementing ISO 17025. The costs of accreditation were compared to the returns to determine the overall efficiency of the investments. The Group agreed that Dr Muhairi’s approach would add value to the PVS Sustainable Laboratories mission report in that it represents many commercial and societal benefits of implementation of quality management systems. The Group agreed it is useful to incorporate a narrative cost benefit analysis (narrative CBA) of a quality management system to the return on investment of the overall contribution to society of the veterinary laboratory.
Mr David Korcal provided an overview of IT infrastructure, how to make the user experience better, and improve data management. The flow of data was diagrammed before, during, and after the mission. Data issues expressed by Member Countries and Laboratory Experts were then summarized. The IT plan is being developed to ensure online and offline accessibility, data security, rapid data visualization, and improved access to data in the report. In addition, an overview of the process for streamlining and enhancing tools was provided.

4. Streamlining the Existing PVS Sustainable Laboratories Tool

The Group agreed with the OIE Members and PVS Laboratory Experts surveyed that the core approach used in the PVS Sustainable Laboratories mission adds value for Members and should be maintained. In addition, the Group agreed that the PVS Sustainable Laboratories Tool contributes to a better understanding of the dynamics leading to financial sustainability and efficient resource management at the laboratory level. The Group agreed that there were small improvements that could be made in order to have significantly more impact for advocacy purposes with decision makers, Members, investors, and Partners.

The Group agreed that the most important audiences for the PVS Sustainable Laboratories body of work at the OIE are: OIE Members, PVS Laboratory Experts, and Partners. In addition, the Group agreed that the public facing documents (data collection and mission report) both merited significant focus in the streamline and enhance streams of the project in order to make the most impact in the shortest time. Most discussions and actions proposed revolved around these two outputs of the mission.

In order to address the comments made by the Members, PVS Laboratory Experts and the Group itself, the Group brainstormed additional tools to add value to the existing PVS Sustainable Laboratories method and made the following suggestions, in particular the development of:

- a starter kit for Member Countries. The kit should target veterinary services (VS) and national veterinary laboratory management and should explain the purpose of the mission, the concepts underpinning the mission’s approach, the mission process, the mission’s benefits, and data collection guidance. The kit could also include communication and advocacy materials that could be used independently.
- a pre-mission interview template to determine mission objectives prior to the mission data collection begins. The template should be flexible enough to use it during face to face meeting, phone calls, or webinars.
- a toolbox approach where materials are available online with necessary guidance documents. Each new tool should add significant value to the approach with the aim of making the mission easier to accomplish by experts and easier to use and act by Members.
- a Mission Evaluation that would gather feedback from Member Countries and Laboratory Experts. Consider using a tool that allows data to be collated for future analysis in a follow-up mechanism.
- a Monitoring and Evaluation framework that would be completed by Member Countries and reviewed by Laboratory Experts to assess progress and determine if follow-up missions could be scheduled.
- a mechanism to monitor the mission process, output, and outcome indicators in order to prioritize necessary mission process changes in the future.
- a variety of promotional materials targeted to specific audiences, adapted to the audience needs, and with compatible terminology.

In addition, the Group suggested other possibilities for changes to and uses for the PVS Laboratory Tool such as:

- Conduct a return on investment analysis/narrative CBA on the implementation of biological risk management, like the one conducted by Dr Muhairi for QMS.
- Explore adapted methodology of the PVS Sustainable Laboratories mission to benefit OIE Laboratory Twinning Project Candidate Laboratories, following suggestions of better harmonising and linking the laboratory targeted support under the PVS Pathway by PVS experts of the PVS Think Tank in 2017.
- Explore linkages and possibilities for implementation with the OIE Reference Centres and determine methodologies for different uses.
- Explore methods to calculate how to budget and plan for emergencies, in the context of surge capacity/change in demand due to endemic outbreaks or exotic/natural disasters.
- Ensure that biosafety, biosecurity, biological risk management, biological threat reduction, etc. are included sufficiently throughout the PVS Lab tools and inextricably linked to sustainability.

Regarding data collection, the Group advised the following:

- Develop tools for web-based data collection but ensure that there is a mechanism to collect for those with no or unreliable web access.
- Use multiple language formats to improve country understanding.
- Simplify data required prior to mission.
- Improve the usability of both online and offline data collection tools.
- Consider phasing country input to ensure critical information is provided to the mission team prior to the mission.
- Automate calculations.
- Lock formula cells.
- Develop a mechanism to regularly update prices for diagnostic tests and test mechanisms.
- Review diagnostic test costs by region and compare results to determine if the costs of diagnostic tests should be regionalized.
- Facilitate regular updating of tools.
- Focus data collection on key performance indicators.

The Group also made the following recommendations related to the mission report:

- Automate report generation.
- Modify report to list “benefits” instead of “advantages” from commercial to societal benefits.
- Format the mission report in a narrative cost benefit analysis format for more impact.
- Include recommendations about next steps and suggestions on future actions to take and how to proceed.
- Automate graphics in order to facilitate data visualization with charts and graphs.
- Use semi-quantitative visual representations of benefits from commercial to societal, and over time.
- Maintain strategic options with standard format and more images/less words.

Regarding the data analysis, the Group recommended the following:

- Develop an infographic/dashboard with 1-2 concise, visual key messages for advocacy purposes.
- Develop diagrammatic representations of the data and options for ease of communicating the results during final briefing sessions, as well as for incorporation in the report.
- Automate data aggregation.
- Ensure data are readily exported to the report.
- Ensure data from all missions are collated and available to be used to appraise country and regional status and priorities.
- Develop a web-based portal for data visualization.
- Focus data analysis and visualization on key performance indicators.
- Include real time data visualization in offline tools.

5. **Work plan development**
The timeline and short-, mid-, and long-term goals were reviewed by the Group. Progress will occur in 3 parallel work streams described above, with action items delegated to Group members who volunteered for assignments to ensure goals are met. Work will advance among subcommittees of Group members through the next meeting of the Group.

The next meeting of the *ad hoc* Group is tentatively targeted to be held 28-30 April 2020.
MEETING OF THE OIE AD HOC GROUP ON SUSTAINABLE LABORATORIES

Paris, 8–10 October 2019

List of Participants

MEMBERS

Dr Ana Maria Nicola (Chair)  Dr Heather Sheeley  Dr. Salama Al Muhairi
Talcahuano 1660  Workplace Health and Safety Lead  Director of Veterinary Laboratories Division
Código Postal 1640  Public Health England  Animal Wealth Sector
Martinez  UNITED KINGDOM  Heather.Sheeley@phe.gov.uk  52150, AD
Buenos Aires  UNITED ARAB EMIRATES  salama.almuhairi@adfca.ae
ARGENTINA  anicola@senasa.gob.ar

Dr. Natalie Bloch  Dr Andre Menconça de Oliveira
20 Gundara st  Coordenador
The Gap 4061  Laboratório Nacional Agropecuário -
Queensland  Ministério da Agricultura, Pecuária e
AUSTRALIA  Abastecimento
natalie.bloch.equipage@gmail.com  Rua Raul Ferrari S/n, Jardim Santa Marcelina,
Buenos Aires  PMB 24 Geelong 3220
ARGENTINA  andre.mendonca@agricultura.gov.br

OBSERVERS

Dr Lisa Stevens  Ms Beatrice Mouillé
Technical Officer  EMPRES Laboratory Unit Deputy Coordinator
Laboratory Strengthening & Surveillance (CPI/PCB/WHE)  Animal Health Services (AGAH)
WHO Lyon Office / Bureau OMS de Lyon  Emergency Centre for Transboundary Animal Diseases (ECTAD)
Immeuble Tony Garnier  Viale delle Terme di Caracalla
24 rue Jean Baldassini  00153 Rome, ITALY
69007 Lyon, France  Beatrice.Mouille@fao.org
stevensl@who.int

CONSULTANTS

Ms Barbara Martin  Mr David Korcal
Executive Director  Diagnostic Center for Population and Animal Health
World Association of Veterinary Laboratory Diagnosticians  Michigan State University
2503 Eisenhower Ave Iowa 50010  Lansing, Michigan 48910
UNITED STATES OF AMERICA  UNITED STATES OF AMERICA
Martin.barbara.m@gmail.com  korcal61@gmail.com

Ms Valsa Shah
VSC-Economics Ltd.
London
UNITED KINGDOM
valsashahconsulting@gmail.com

OIE HEADQUARTERS

Ms Jennifer Lasley  Mr Benjamin Nyange
Programmes Department  Programmes Department
12 rue de Prony  12 rue de Prony
75017 Paris  75017 Paris
FRANCE  FRANCE
j.lasley@oie.int  b.nyange@oie.int
Ad hoc Group on Sustainable Laboratories
Paris, OIE HQ, 8-10 Oct 2019

Agenda

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Day 1 10am

Item 1  Welcome, introductory remarks, and adoption of agenda
  
  • Objectives, Deliverables, & Vision – J Lasley
    o Timeline through Oct 2021 – J Lasley
    o Project logic model – J Lasley
  
  • Mini PVS Lab Tool Training – J Lasley, A Nicola, N Bloch, A Mendonca
    o What does the PVS Sustainable Laboratories Tool currently do?

Item 2  Learning from experience and similar work

  • Member Country Survey on PVS Lab tools – J Lasley
  
  • PVS Lab Experts’ Survey – B Martin

  • Existing Tools for laboratories
    o Chatham House Prior Assessment Tool – E Ross
    o FAO Laboratory Mapping Tool – B Mouillé
    o WHO Laboratory Assessment Tool – L Stevens
    o WHO Lab Test Costing Tool – L Stevens
    o IHR Joint evaluation (JEE) – L Stevens

Item 3  Overall Vision of the PVS Sustainable Laboratories Tool enhancement

  • Discussions on the overarching approach and assumptions
    o What indicators/statistics on laboratory sustainability are needed? (e.g., in order to better demonstrate the problem, to convince decision makers to pay attention, to advocate for appropriate resources, etc.)
    o How can this mission have more impact? - J Lasley

  • Alignment to common business tools
    o Definitions of common business tools, examples and potential application to labs – B Martin, J Lasley, V Shah
    o Case Study: CBA model for sustainable laboratories – V Shah
    o Return on investment of implementing ISO 17025 – S Al Muhairi
Prioritization exercise – B Martin and J Lasley
• IT infrastructure and how to make the user experience better – D Korcal and B Nyange
• Data management – D Korcal and B Nyange

Day 2  9am

Item 4  Streamlining Existing PVS Sustainable Laboratories Tool

• New tools to be developed – B Martin and J Lasley
  o Starter Kit for country - B Martin
  o Post-request/Pre-mission interview template - J Lasley
  o Toolbox approach - J Lasley
  o Supporting Documents – J Lasley
  o Mission Evaluation - B Martin
  o Performance monitoring tool - B Martin
• Prioritization ranking exercise – B Martin and J Lasley
• Streamlining the existing PVS Lab tools
  o Demand Tool - D Korcal

Day 3  9am

Item 5  Work plan development

• Planning of future work
  o Upcoming Missions and targets - J Lasley
  o Classification of short-, mid-, and long-term actions in order to assign work – A Nicola
• Detailed Timeline through Oct 2021 - J Lasley

Item 6  Other matters – Any other business
MEETING OF THE OIE AD HOC GROUP ON SUSTAINABLE LABORATORIES

Paris, 8 – 10 October 2019

Terms of Reference

Background

Access to laboratory diagnosis, laboratory infrastructure and quality assurance are crucial to understanding the ability of an OIE Member to implement and comply with OIE standards and to provide valid results to the Veterinary Services as the basis for decision making. Chapter 1.1.1 “Management of veterinary diagnostic laboratories” of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals outlines the range of issues to be addressed if laboratories are to meet international standards, including key elements of staff safety, biocontainment, biosecurity and quality assurance as vital and essential components of good governance and management of a veterinary diagnostic laboratory for the safe, sustainable and effective delivery of diagnostic services and towards the objective of reducing biological risks. The OIE international standards further state that “the governance and management of these aspects are as important as the delivery of the actual diagnostic service”.

The OIE has developed several tools to support strengthening of veterinary services under the umbrella of its overarching Performance of Veterinary Services (PVS) Pathway. This includes support to national, regional, and global laboratory networks. In 2013, the OIE launched the PVS Pathway Laboratory Tool, with 14 missions completed to date.

These activities are linked to the mandate of the OIE and the Sixth Strategic Plan for the period of 2016 – 2020. Specifically, the Sixth Strategic Plan takes into consideration the changing global environment and its associated new challenges, and focuses on multiple areas including reducing biological risks, whether they are of natural, accidental, or intentional origins. This approach is consistent with and supported by the OIE’s Strategy for Biological Threat Reduction.

In September 2018, the OIE received financial support from Global Affairs Canada to further develop the PVS Sustainable Veterinary Laboratories Tool (i.e., 2nd Edition of the PVS Pathway Laboratories Tool) to rationalise laboratory networks, increase sustainable laboratory biosafety and biosecurity, all with the aim to reduce the risk of accidental or intentional release of dangerous pathogens.

To achieve this, an ad hoc Group on Sustainable Laboratories will be convened (8 – 10 October 2019) to examine the existing PVS Sustainable Laboratories Tool to explore where it can be further enhanced and developed.

Scope

The OIE Consultation on sustainable laboratory biosafety and biosecurity held 1-2 March 2018, provided important feedback in the aspects to consider in the future work on the Tool.

The current Tool aims to provide Members with knowledge, arguments and tools to advocate for internal and external support to meet their needs and assist them in understanding and delivering on their long-term commitments to operate, maintain and sustain laboratories’ capacities. However, this Tool and its related materials and training need to be updated according to the experience that the OIE has cultivated over the past five years through country missions, and based new demand and new users – this information will be used to enhance PVS Sustainable Laboratories along with the Mission Manual and Tools. All this will be undertaken in a
One Health approach working with public health partners so that the tool can be used in any health laboratory setting.

The main components of this project are:
1. 3 ad hoc Group meetings on Sustainable Laboratories through 2021
   a. 8 missions through 2021, to pilot new uses (CBA, ROI, business case development, business plan, business model, etc.) and with new users (Twinning Projects & OIE Reference Centres)
2. Enhancement of the PVS Sustainable Laboratories Tool
3. Expert training workshop in 2021

Terms of Reference
1. Conduct a review of the current PVS Sustainable Laboratories Tool and best practices for good laboratory management, taking into account current and future needs as presented in collected data;
2. Develop, integrate, and/or restructure new tools according to new audiences, uses, users, applications, and outcomes into the Mission Manual and Tools, based on the first five years of implementation and new demand for the approach;
3. Determine the desirable form, structure and content to conduct the PVS Sustainable Laboratories Mission and Tool; and
4. Provide advice to the OIE, as appropriate, on other issues related to sustainable laboratory biosafety and biosecurity that may present opportunities for additional guidelines or standards development for veterinary diagnostic laboratories.

Expected Minimum Outputs
1. Report of the ad hoc group meetings
2. Detailed plans for the entirety of the activity
   a. Plan for analysis on collected data relevant to this activity
   b. Plan for enhancement of the PVS Sustainable Laboratories Tool, in the short-, mid-, and long-term
3. Enhanced PVS Sustainable Laboratories Toolbox
   a. Streamlined existing tools
   b. Development of new tools

In performing the above tasks, the ad hoc Group should review materials provided by the OIE Secretariat listed below.

List of documents to be provided over the course of the project
1. The PVS Sustainable Laboratories suite of tools:
   a. Supply Tool
   b. Demand Tool
   c. Calculation Tool
   d. Analytical Line Tool
   e. PVS Sustainable Laboratories Mission Manual
   f. PVS Sustainable Laboratories Mission Report Template
2. Chatham House Prior Assessment Tool
3. FAO Laboratory Mapping Tool (LMT) and Veterinary Laboratory Policy state of play
4. IHR Joint External Evaluation (JEE) Tool
5. WHO Laboratory Assessment Tool (LAT)
6. Summary of the analysis of PVS Laboratory missions conducted in 14 Members Countries
7. Summary of the analysis of equipment management of preventive and corrective maintenance and calibration
8. Summary of the analysis of PVS Evaluation and Gap Analysis missions conducted in OIE Member Countries
9. Summary of OIE Member Countries’ laboratory capacity reported to WAHIS