



# **PANCAP GFR9 Project**

## **End of Project Report**

**Medical Laboratories Component**

**Implemented by Caribbean Med Labs Foundation  
(CMLF)**

31 March 2016

# **Strengthening Caribbean Laboratory Networks**

## **Overall Objective:**

"A regional network for provision of laboratory testing to support HIV/AIDS, Sexually Transmitted Infections (STIs) and Opportunistic Infections (OIs) (including support for monitoring of Haematology and Biochemical parameters) established in the region".

Implemented in all sixteen participating countries



## TABLE OF CONTENTS

<b>1.0 BACKGROUND</b> .....	1
1.1 <i>CARIBBEAN MED LABS FOUNDATION (CMLF)</i> .....	1
1.2 <i>CMLF'S WORK</i> .....	2
<b>2.0 THE GFR9 LABORATORY COMPONENT</b> .....	3
2.1 <i>LABORATORY COMPONENT OBJECTIVES AND STRATEGIES</i> .....	3
<b>3.0 PROGRAMME ACHIEVEMENT</b> .....	6
3.1 <i>INDICATOR ACHIEVEMENT</i> .....	10
<b>4.0 FINANCIAL REPORT</b> .....	12
<b>5.0 SUSTAINABILITY PLAN</b> .....	13
5.1 <i>CMLF FUNDING INITIATIVES</i> .....	14
<b>6.0 LESSONS LEARNED AND CHALLENGES</b> .....	15
6.1 <i>GRANT IMPLEMENTATION ARRANGEMENTS</i> .....	15
6.2 <i>PARTNERSHIPS</i> .....	16
6.3 <i>PR FUNCTIONING AND OVERSIGHT</i> .....	17
<b>7.0 CONCLUSIONS AND RECOMMENDATIONS</b> .....	18

### APPENDICES:

Appendix 1 – Regional Framework for National Laboratory Policy

Appendix 2 – End of Project Indicator Monitoring Report and Matrix

Appendix 3 – CMLF GF R9 Matrix of Activities by Beneficiary Country

## LIST OF ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
ALT	Alanine Aminotransferase (enzyme)
ARV	Antiretroviral (treatment)
AST	Aspartate Aminotransferase (enzyme)
BUN	Blood Urea Nitrogen
CARICOM	Caribbean Community
CARPHA	Caribbean Public Health Agency
CBC	Complete Blood Count
CCAS	Caribbean Cytometry & Analytical Society
CD4	T-helper lymphocyte (Cluster of differentiation antigen 4)
CDC	(United States) Centers for Disease Control and Prevention
CMLF	Caribbean Med Labs Foundation
CMO	Chief Medical Officer
COHSOD	Council (of Ministers) for Human and Social Development
COIN	Centro de Orientacion E Investigacion Nacional
CROSQ	CARICOM Regional Organisation for Standards and Quality
CRSF	Caribbean Regional Strategic Framework on HIV and AIDS
CSO	Civil Society Organization
CVC	Caribbean Vulnerable Coalition
DNA PCR	Deoxyribonucleic Acid Polymerase Chain Reaction
EQA	External Quality Assessment
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HAPU	HIV AIDS Project Unit
HIV	Human Immunodeficiency Virus
ISO	International Organization for Standardization
LIS	Laboratory Information Systems
LQMS-SIP	Laboratory Quality Management Systems - Stepwise Improvement Process
M&E	Monitoring and Evaluation
MOH	Ministry of Health

NAP	National AIDS Program
NGO	Non-Governmental Organization
OECS	Organization of Eastern Caribbean States
OECS PPS	OECS Pharmaceutical Procurement Service
OI	Opportunistic Infections
PAHO	Pan American Health Organization
PANCAP	Pan Caribbean Partnership Against HIV/AIDS
PT	Proficiency Testing
STI	Sexually Transmitted Infection
TB	Tuberculosis

# 1. BACKGROUND

## 1.1 CARIBBEAN MED LABS FOUNDATION (CMLF)

The Caribbean Med Labs Foundation (CMLF) is a non-governmental, not-for-profit, organization, established in May 2008 in response to the urgent need to build on the significant interventions initiated and gains made in improving the quality of medical laboratory operations under the guidance of the EU funded “Strengthening of Medical Laboratory Services in The Caribbean” Project. This project was implemented by the Caribbean Epidemiology Centre (CAREC) in 23 English, Dutch, Spanish and French-speaking Caribbean territories from 2002-2007. It was initiated against a background of evidence of unacceptably high levels of error from Caribbean medical laboratories, the absence of regulation and legislation in most of the Project countries and the fact that very, very, few Caribbean laboratories were accredited - accreditation being the only proof of competence and reliability. Beneficiary countries included CARIFORUM countries and the British and Dutch Overseas Territories.

Under the guidance and management of the ‘Med Labs Project’, implemented from 2002 -2007, Caribbean networks of laboratories, tertiary institutions, standards bureaus, procurement and maintenance providers and information technology professionals were developed and operationalised. Under the Project’s guidance, regional Governments during this period accessed advice and training to support development of their national medical and public health laboratory services; national laboratory advisory committees were established; national quality coordinators/focal points were designated; national laboratory strategic plans were drafted; draft legislation for regulating medical laboratories was developed & circulated; a standard for regional medical laboratory operations was agreed; a guidance document for the implementation of standards was developed and published; a mechanism/model for a Caribbean Laboratory Accreditation Scheme (CLAS) was developed and agreed and this was subsequently initiated under the Caribbean Regional Organisation for Standards and Quality (CROSQ); a competency profile for regional technologists was developed and published; a revised and harmonized curriculum for technologists was drafted and initiated in some institutions; national data management teams were initiated; over 1000 persons from 23 Caribbean countries were trained in quality management, the ISO 15189 standard, accreditation requirements, laboratory assessments, procurement, maintenance, proficiency testing, microbiology, cytology and curriculum development. Awareness, momentum and the many tangible improvements brought about by Project interventions were welcomed by Governments,

laboratory staff and stakeholders and highly commended by the European Union evaluators who noted the Project's unique successes (<http://cmedlabsfoundation.net/>).

The Project's management team and Ministers of Health recognized, however, that while significant progress had been made in many Project countries and awareness of the need to implement quality and standards in medical and public health labs was high, in the absence of a force to drive continued improvements, momentum would eventually die and the strides made could even be reversed. More importantly, the rising global concern over the growing evidence of medical laboratory error even in the more regulated environments such as the USA, reinforced the critical need to aggressively continue the lab strengthening effort. These concerns led to the establishment of the Caribbean Med Labs Foundation in 2008.

## 1.2 CMLF's WORK

CMLF's mission is to promote and support the achievement of quality laboratory services in accordance with appropriate standards, through advocacy, resource mobilisation, collaboration, research and education.

The broad objectives of the CMLF include:

- Continued development of the supportive environment for the rapid expansion of high quality regional laboratory services
- Advocacy at the highest levels for the implementation of relevant laws, regulation and accreditation of regional laboratories
- Mobilisation of resources for lab strengthening efforts
- Mapping of a regional coordinating strategy to ensure sustained lab strengthening efforts

CMLF's roles and functions include partnering with a wide range of key lab stakeholders – Ministries of Health, insurance companies, tourism industry, training institutions, standards bureaus, and partners working on laboratory strengthening regionally.

## 2.0 THE GFR9 LABORATORY COMPONENT

The Global Fund to Fight AIDS, Tuberculosis and Malaria GFATM Agreement MAC-910-G02H entitled “Fighting HIV in the Caribbean: a Strategic Regional Approach” was signed on behalf of the CARICOM Caribbean Community on 5 October 2010, for implementation over a period of five years (2011-2015) which was implemented over two phases. Development and implementation of the Grant was guided by the Caribbean Regional Strategic Framework on HIV and AIDS (CRSF) 2008-2012.

The objectives of the project were:

- *An enabling environment that fosters universal access to HIV services;*
- *Reduced HIV transmission in vulnerable populations;*
- *Lower people living with HIV (PLH) morbidity and mortality in the small islands that make up the Organization of Eastern Caribbean States (OECS);*
- *Improved human and laboratory resources (health systems strengthening);*
- *Better information on the epidemic and the response; and*
- *Build capacity and promote sustainability (added in Phase II).*

The project benefitted 16 countries including Antigua and Barbuda, Belize, Bahamas, Barbados, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, Montserrat, St Kitts & Nevis, Saint Lucia, St Vincent & The Grenadines, Trinidad & Tobago, and Suriname.

## 2.1 LABORATORY COMPONENT OBJECTIVES AND STRATEGIES

CMLF was the Sub-Recipient (SR) charged with the responsibility for implementation of the laboratory component of this PANCAP R9 Grant, with the objective of forging a regional network to provide the critical support required from Caribbean medical and public health laboratories. Increased access to quality, affordable and sustainable laboratory services required to effectively support national HIV treatment and care programmes has been among the key challenges faced by regional Governments over the past two decades.

Private and public sector medical and public health laboratories in the Caribbean have struggled to both achieve and sustain the required levels of quality functioning outlined in the ISO 15189 standard<sup>1</sup> the recognised international benchmark for laboratory practice and the standard adopted by the region under the EU-funded Project “Strengthening of Medical Laboratory Services” (2002-2007) implemented by the Caribbean Epidemiology Centre (CAREC).

Ensuring adequate and appropriate laboratory diagnostic capacity for HIV/AIDS control and prevention efforts is critical to the delivery and sustainability of relevant, responsive and reliable clinical and other key services. Developing a network that leverages the collective national and regional resource to support the provision of comprehensive and cost-effective laboratory services at all levels of the healthcare system is an essential strategy in the Caribbean HIV control and prevention effort.

The stated project objective is as follows:

*“A regional network for provision of laboratory testing to support HIV/AIDS, STIs and OIs (including monitoring of haematological and biochemical parameters), established in the region”.*

The major objective of the GFR9 project’s laboratory component was thus to **strengthen national and regional laboratory networks** to support HIV/AIDS care and treatment programmes. This intervention was designed to build on the progress already made within the Caribbean region through the CAREC EU-funded medical laboratory strengthening project and to collaborate with other partners within the Caribbean region such as the Pan American Health Organisation (PAHO) and the US Centers for Disease Control and Prevention (CDC PEPFAR), with the objective of building organised networks of laboratories to support HIV, STI, and OI testing including services to monitor patients on treatment.

Project strategies sought to first identify the gaps in national and regional infrastructures that are currently impacting laboratory services and in collaboration with national and regional stakeholders and partners, to identify and support implementation of feasible solutions. Towards this end the GFR9 project strategies included:

- *Conducting baseline and repeated annual laboratory surveys in 16 project countries*
- *Identifying gaps and barriers in national and regional laboratory structures, systems and capacity*
- *Identifying laboratories that have the potential to provide a national and/or regional reference service and providing support for strengthening their capacity to provide these services*
- *Facilitating the development of national strategic and action plans to strengthen laboratory networks that will more effectively provide high quality HIV, STI, OI services*
- *Providing periodic monitoring oversight for implementation of plans*

- *Development of National Laboratory Policy Regional Framework – advocacy for its endorsement and facilitation of its adaptation at national level.*
- *Upgrading quality management systems and relevant techniques within national networks in collaboration with other regional partners*
- *Facilitating implementation and/or improvement of laboratory information systems (LIS) to encourage effective sharing of laboratory information across the network*
- *Providing support for laboratory participation in proficiency testing (PT) programmes for external quality assessment.*

Packages of tests were defined by regional stakeholders (clinicians and laboratory professionals) as the tests that were critical to effective management of HIV/AIDS patients. There was common agreement among regional stakeholders in Project countries about the core lab support needed as follows:

1. *Ready access to HIV screening and confirmatory testing; viral load and DNA PCR diagnosis and CD4 testing.*
2. *Ready access to a basic complement of tests for evaluating liver and kidney functions and a Complete Blood Count (CBC) analysis.*
3. *Ready access to TB diagnosis and common STIs such as syphilis and gonorrhoeae.*
4. *A preliminary complement of opportunistic infections (OIs) to be addressed was developed by a multi-stakeholder group but recommendations were that decisions on an appropriate complement would have to be confirmed at the national level.*

### **3.0 PROGRAMME ACHIEVEMENTS**

The major achievements of the laboratory component of the GFR9 grant are outlined below.

#### **Laboratory Services Assessment and Monitoring**

1. Collection and analysis of baseline information on the regional situation with respect to laboratory services to support HIV/AIDS programmes was a key aspect of determining the strategies necessary to support the laboratory intervention.
2. CMLF promoted and assisted countries to establish formats for recording sample information and monitoring turnaround times for the defined packages of services. Establishment of systems for ongoing collection and monitoring of laboratory network data was critical – including identification of major packages of service required to support HIV programmes, national structures for quality of laboratory services, and key indicators of laboratory network performance – specifically, turnaround time (TAT), proficiency testing performance and surveillance reporting.

#### **Advocacy and Policy Support for Laboratory Networks**

1. Data collected and observations made of laboratory service gaps were used to advocate for the necessary support from key stakeholders including clinicians, laboratory management and staff, Ministers and Ministries of Health and Programme Managers for establishment and sustainability of regional and national laboratory networks.
2. Technical and financial support was provided by CMLF for the annual HIV Laboratory Network meeting as part of the CCAS Annual meeting from 2011 to 2015. In 2011 this resulted in a Declaration being issued by the CCAS meeting for the first time, with respect to important policy issues for laboratory services in the region.
3. Data collected by CMLF in assessing laboratory services and the CCAS Declaration was used to obtain the COHSOD Decision in 2012, committing Ministers of Health support for establishment of national and regional networks, policy and regulatory support for laboratory services and support for the development of transitional plans to ensure sustainability of laboratory quality interventions through a smooth handover of resource responsibilities from donor to national governments.
4. Development of a Regional Model Framework for National Laboratory Policy was undertaken by CMLF in collaboration with a regional group of experts to advance the process of policy formulation. Endorsement and support from Ministers of Health and Chief Medical Officers in 2014, for adaptation and adoption at national level was

obtained through advocating at regional meetings and in national fora. The Model Framework, which is based on WHO guidance, and meets the requirements of International Health Regulations that all countries have signed on to meet by 2016, is attached as **Appendix 1**, and includes requirements for:

- a. *Governance and Co-ordination of laboratory services (including establishment of National Focal Point, National Laboratory Advisory Committee, provision of financial resources, competencies of staff)*
  - b. *Quality Management Systems (including legislation for regulation and licensing, and training of laboratories to meet QMS requirements)*
  - c. *Support Systems including Procurement and Inventory, Safety and Biosafety and Maintenance.*
  - d. *Laboratory Information Management – integration with Health Information Systems.*
5. Model legislation to support the implementation of the National Laboratory Policy was drafted for sharing with countries. It is expected that the Ministries of Health will continue to drive towards the final approval and implementation of laboratory legislation.
  6. CMLF website was upgraded and regular website and social media updates used to inform stakeholders <http://cmedlabsfoundation.net/>
  7. Publication of semi-annual Caribbean Med Lab News was initiated electronically and in hard copy with the objective of providing stakeholders with updates on issues of importance to laboratory services within the Caribbean region. In particular, the newsletter has highlighted issues challenging sustainability of laboratory services within the region with the objective of sensitizing stakeholders to the support necessary for sustaining laboratory services.
  8. In collaboration with UNAIDS, an animation video was produced to advocate with policy makers and administrators for the necessary policy and financial support to ensure sustainability and improvement of laboratory services. This animation video can be viewed on CMLF website at <http://cmedlabsfoundation.net/>

### **Quality of Services**

1. CMLF facilitated the development of National Laboratory Policies based on Regional Framework in 13 of the 16 participating countries. CMLF did not facilitate development of these policies in the Dominican Republic due to challenges posed by language differences and access to the Ministry of Health and in Haiti and Trinidad and Tobago

since both these countries had initiated development of a national laboratory policy prior to the CMLF intervention.

2. CMLF was included in collaboration with PAHO/WHO, US Centers for Disease Control and Prevention, the CARICOM Regional Organisation for Standards and Quality (CROSQ) and Regional Accreditation Bodies to develop the Laboratory Quality Management Systems - Stepwise Improvement Process (LQMS-SIP). In developing the National Laboratory Policy Regional Framework, Tier 1 of the LQMS-SIP was included as the requirement for licensing of laboratories.
3. In collaboration with COIN, another SR on this PANCAP GF Project, CMLF conducted training within the Dominican Republic (DR) for improving the quality of services provided by laboratories serving key populations within Civil Society Organisations (CSOs) in the DR.
4. Training was conducted for laboratory network supervisors in Haiti to improve the quality and monitoring of the public laboratory network.
5. Proficiency testing programmes were provided to participating laboratories in 15 countries in the areas of HIV, Haematology and Biochemistry, STI and OI testing. Countries were provided with guidance and models for analyzing and undertaking corrective actions to improve their performance. CMLF also advocated with participating countries to secure the necessary funding to sustain PT programmes and conducted online training in partnership with the PT provider for quality improvement based on PT programme results.
6. Periodic monitoring of laboratory quality systems and the reliability of laboratory performance, through online surveys and external quality assessments (EQA), served to identify existing quality and technical gaps.

### **Laboratory Information Systems**

1. Assessments were conducted of laboratory information management systems within participating countries.
2. Based on the outcomes of the baseline assessment in which 11 national laboratories indicated that they managed their data manually, the CMLF Electronic Logbook was designed and developed to facilitate tracking of turnaround times and other key indicators, as well as surveillance reporting by laboratories without Laboratory Information Management Systems (LIMS). The CMLF Electronic Logbook was piloted in two laboratories in Suriname.

3. CMLF provided Technical Assistance and established a User Group to assist countries with LIMS to better utilize their capabilities and to extract data for surveillance and indicator monitoring.

### **Access to Services – National and Regional Reference Nodes**

1. CMLF facilitated the development of National Laboratory Network Plans in 10 participating countries. These network plans included structuring of the national network to provide access to levels of service – based on the regional model agreed and endorsed at the CCAS meeting of the HIV Laboratory Network, including clinicians and programme managers.
2. Identification of regional reference nodes for provision of reference services for:
  - a. *Molecular diagnostics – Barbados and Jamaica*
  - b. *Validation of HIV test kits - Jamaica*
  - c. *Proficiency testing and Quality Control models – Belize and Suriname.*
3. A QMS Costing framework was developed to guide governments and laboratories in planning and costing their QMS implementation.
4. Support was provided to selected reference laboratories:
  - a. *Barbados Lady Meade Reference Laboratory to improve efficiency and cost recovery systems with a view to ensuring sustainability and quality of service to OECS countries.*
  - b. *Belize and Suriname for improving and/or establishing national PT and Quality Control programmes.*

### **Sexually Transmitted Infections and Opportunistic Infections**

1. Based on gaps identified in baseline assessments, a regional training workshop for Diagnosis of Opportunistic Infections (OIs) and Sexually Transmitted Infections (STIs) was conducted for participants from 15 countries.
2. Standard Operating Procedures for OI and STI testing and a Plan of Action were produced as outputs of the regional training workshop.

### **Procurement and supply chain management**

1. CMLF, in partnership with the OECS HIV AIDS Unit, another SR on this PANCAP Project, initiated negotiations with suppliers of HIV rapid test kits to determine the cost savings which could be achieved through joint negotiation and/or purchasing of test kits.

Through this initiative, cost savings of 14-30% per country were negotiated, and the arrangements for the OECS Pharmaceutical Procurement Service (PPS) to undertake purchasing of laboratory supplies on behalf of the OECS countries was agreed.

### 3.1 Indicator Achievement

The indicator established for the laboratory services component of this project was:

The number and percentage of countries where laboratories provide a defined set of quality-assured laboratory services through national and regional networks. Ten (10) countries achieving this outcome were set as the target for the end of project. **Eleven (11) of the sixteen (16) countries participating in the project were able to successfully achieve the target at the end of project.** These countries were **Antigua, Bahamas, Barbados, Dominican Republic, Grenada, Haiti, Jamaica, St Kitts, St Lucia, St Vincent, Suriname.**

Indicators included the timely and reliable provision of a defined package of HIV/AIDS lab diagnostic services. Services selected were HIV serological, viral load and PCR testing; syphilis and GC testing as indicators of STIs; TB testing, Gram stain and Wet preparations as indicators of OIs; AST, ALT and Bilirubin as measures of liver function; BUN and Urine Dipsticks as indicators of Kidney function and CBCs. Indicators also included the provision of regular and reliable surveillance reports for HIV, GC, Syphilis and TB as required by the national epidemiologists, and participation of laboratories in proficiency testing for these analytes, as a measure of accuracy of testing.

#### Basic Package of Services

While at least **15 of the 16 project countries** continued to offer a comprehensive package of laboratory services, in 2015, funding challenges periodically impacted access to the viral load and PCR services provided by the LRU reference laboratory in Barbados to OECS countries. These services were previously supported by donor funding and when this support ended, countries were forced to transition these expenditures to the national health budgets in a time of severe economic challenges. National labs, continued, however, to provide over 95% of the tests required to effectively support national HIV/AIDS treatment and care programmes, either providing the required diagnostic services directly or facilitating access to these services from a regional reference facility. Reduction in donor funding from PEPFAR in Haiti also impacted on the ability to provide continuous laboratory services to support HIV/AIDS programmes.

## **Turnaround Time**

**Eighteen (18) respondent laboratories** surveyed in 15 of the 16 Project countries used either a manual or electronic system or a mix of both to record dates of sample receipt, dates that results were completed and approved and the dates that samples were dispatched. **National laboratories in 9 countries** (Bahamas, Barbados, Belize, Dominica, Grenada, Jamaica, St Lucia, St Vincent, Suriname), now have some type of electronic system to assist with data management. In-country visits indicated that electronic systems ranged from simple excel spreadsheets to more sophisticated LIMS. Only 4 laboratories – the hospital laboratories in St Kitts, Antigua & Barbuda, Montserrat and Montego Bay Jamaica - reported the sole use of a manual system. CMLF has recommended a transition to a simple electronic system such as the electronic logbook for these laboratories and in 2015 information systems assessments were conducted by CMLF in Antigua & Barbuda, St Kitts and Montserrat and recommendations made for updating their information systems.

## **Surveillance Reporting**

By the end of December 2015, national laboratories in **sixteen countries** continued to provide disease information for HIV, Syphilis, GC and Tb to the MOH either weekly, monthly or quarterly.

## **Proficiency Testing**

In 2015, the Project laboratories in **14 countries** – Antigua & Barbuda, Bahamas, Barbados, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, St Kitts, St Lucia, St Vincent, Suriname and Tobago - were participating in PT for over 90% of the basket of tests required to support HIV/AIDS treatment and care programmes (**Appendix 2**). As a result of the variability in lab PT performance in 2014 and 2015, CMLF arranged for the PT Provider, One World Accuracy, to provide online training in November 2015, to train lab staff to better interpret PT reports and apply more effective troubleshooting approaches to address performance errors. The challenge for countries will be how PT participation is to be sustained once extra-budgetary funds are no longer available. CMLF continued at all policy level and laboratory stakeholder fora to advocate for the continued funding of PT participation.

Additional indicator detail is included at **Appendix 2**.

The matrix attached as **Appendix 3** outlines the activities conducted by CMLF by beneficiary country.

## 4.0 FINANCIAL REPORT

<i>GF Phase I (2011-2012) and II (2013-2015)</i>							
	<i>Phase I Budget 2011-2012</i>	<i>Phase I Expenditure 2011-2012</i>	<i>Phase II Budget 2013-2015</i>	<i>Phase II Expenditure 2013-2015</i>	<i>Budget 2011-2015</i>	<i>Expenditure 2011-2015</i>	<i>Variance 2011-2015</i>
<b>Human Resources</b>	406,152	365,829	716,632	717,422	1,122,784	1,083,251	39,533
<b>Infrastructure and Equipment</b>	12,600	8,768	13,341	7,586	25,941	16,354	9,587
<b>Overheads</b>	4,896	4,194	134,799	119,135	139,695	123,329	16,366
<b>Planning and Administration</b>	113,136	92,118	63,051	37,492	176,187	129,610	46,577
<b>Technical Assistance</b>	84,946	37,428	88,648	152,332	173,594	189,760	(16,166)
<b>Training</b>	85,354	99,218	158,735	167,072	244,089	266,290	(22,201)
<b>Communication Materials</b>			44,580	16,914	44,580	16,914	27,666
<b>Monitoring &amp; Evaluation</b>			64,090	64,498	64,090	64,498	(408)
<b>Health Products and Health Equipment</b>			130,000	124,372	130,000	124,372	5,628
<b>TOTAL</b>	707,084	607,555	1,413,876	1,406,823	2,120,960	2,014,378	106,582

## 5.0 SUSTAINABILITY PLAN

The sustainability of this intervention will require **political** support and engagement of **laboratory and administrative managers** at the national level. A critical success factor will be the adoption and implementation of the draft national policies and supporting legislation, which provide overall guidance for the effective and quality assured functioning of laboratory services. The function of the National Laboratory Advisory Committee established for the implementation of the National Laboratory Policy and National Network Plan developed under this project is a critical component that must be endorsed and made accountable under the Ministry of Health within each country. Support for the necessary legislative adaptation and adoption will also be critical.

At the regional level, CMLF will undertake the development and implementation of a supporting and accountability strategy in collaboration with CARICOM/PANCAP and CARPHA for following up on implementation of the COHSOD decision of 2015 which should be included within regional meetings. At the September 2015 COHSOD, Ministers of Health:

- (i) **Noted and Congratulated** countries for the progress made in developing national laboratory policies with facilitation by CMLF;
- (ii) **Committed** to provide leadership at the national level to support adoption and implementation of the National Laboratory Policy – critical to ensuring reliable and sustainable national laboratory services and to meeting IHR requirements.
- (iii) **Recognised** the current operational challenges being faced by national regional laboratories and agreed to **address with urgency**, the allocation of the minimum quantum of human and financial resources required to secure consistent, uninterrupted, reliable testing and information generation by laboratories, given the evidence that while only approximately **5% of the national health budget** in most countries is expended on laboratory services, **laboratory data influences 70% of clinical decisions and a significant percentage of public health decision-making.**

Collection and use of data on network performance must be continued through to ensure continued functioning of the network and to provide the information necessary to secure the political, administrative and technical actions to support and improve the networks.

## 5.1 CMLF Funding Initiatives

Though its advocacy and networking with partners, CMLF has negotiated the following arrangements to ensure continued support to countries and key civil society partners in achieving **sustainable access to quality laboratory services**:

- 1. CMLF has been included as a Sub-Recipient in the OECS GF R10 Project. Under this OECS Project, CMLF will provide support to the OECS countries for adoption of national laboratory policies and regulatory legislation developed under this GF R9 project. These policies will be reviewed to ensure that they address the needs of key populations. In addition, CMLF will undertake training of trainers to facilitate training of CSOs for provision of rapid testing services for HIV and STIs, and inclusion of these services for monitoring under the national laboratory structures. CMLF will also liaise with the OECS-PPS to improve the procurement of laboratory supplies for OECS laboratories under this joint government funded arrangement.*
- 2. CMLF has been included as a Sub-Sub-Recipient under the PANCAP GF R10 Project. Under this PANCAP Project, CMLF will undertake to provide support to non-OECS countries for the adoption of national laboratory policies and regulatory legislation developed under this GF R9 project – including review to ensure that they address the needs of key populations. In addition, CMLF will undertake training of Laboratory and Quality Managers who will undertake key roles at the national level to ensure quality oversight and training of other laboratorians.*
- 3. CMLF has been included as a partner under the Caribbean Vulnerable Communities (CVC) GF R10 Project. Under this CVC Project, CMLF will undertake training of CSO personnel who provide laboratory services to key populations, to improve the quality and access to services for key populations, and to improve the supply chain management to ensure sustainability of services. CMLF will also work within the national structures to ensure that these testing services are included under the national laboratory monitoring structures.*

## 6.0 LESSONS LEARNED AND CHALLENGES

CMLF's experience in the implementation of this GF project highlighted some major successes and challenges. These are outlined below.

### 6.1 Grant Implementation Arrangements

1. *CMLF's active linkages with Ministries of Health and their laboratories for the conduct of this programme within countries was a critical success factor in facilitating access for implementation. The introduction of SRs to participating countries by the PR at the start of the grant would have been beneficial and should be considered in the start-up phase of new grants.*
2. *The development of a Regional Model Framework for National Laboratory Policy and obtaining of endorsements from Ministers of Health and Chief Medical Officers at their regional meetings, was an effective method for fast-tracking the development of policies at the national level.*
3. *The involvement of PANCAP-CARICOM in this project presented major opportunities for impact on regional policy formulation. Through the linkages with CARICOM and PANCAP access to Regional Meetings of Ministers of Health and annual reports to the Council of Ministers (COHSOD), support for the policy initiative and advocacy for appropriate support for laboratories was facilitated.*
4. *The inclusion of clinicians within the annual CCAS meeting presented a great opportunity to include their input in development of critical aspects of the laboratory network's services e.g. establishment of levels of laboratory services, indicators of success for the network, etc.*
5. *Resources for the implementation of the PANCAP project's activities and desired outcomes were extremely limited and success was dependent on the commitment of country stakeholders in complying with agreed deliverables in a timely manner. This required significant follow-up by CMLF to ensure that the mechanisms for follow-up monitoring and implementation in country were actively undertaken.*
6. *Some occasional tardiness in receipt of funding allocations impacted negatively on implementation of project activities. This led to some challenges with meeting timelines, but overall activity and outcome targets were met.*

## 6.2 Partnerships

1. Partnerships with other SRs proved highly beneficial and added to the benefits and sustainability of project outcomes. CMLF was involved in the following collaborations:
  - a. *Conduct of training for CSO laboratories serving key populations within the DR through collaboration with COIN. This training proved highly beneficial to the desired outcomes in supporting the treatment cascade for these key populations. As a result of this successful collaboration, CMLF was included as a partner to support improvement of laboratory services serving key populations in the COIN proposal to the GF R10.*
  - b. *CMLF undertook, at the request of the OECS HIV/AIDS Unit, an initiative to explore opportunities for cost savings through joint negotiation and/or purchasing of laboratory supplies. CMLF successfully negotiated a reduction in the price of HIV Rapid Test kits at the end of 2014, and the initiative for inclusion of purchasing of laboratory supplies under the OECS PPS arrangement with support from CMLF has been included in the OECS GF R10 grant.*
  - c. *CMLF participated with CARPHA in the conduct of the evaluation of the HIV/AIDS Strategic Plan of The Bahamas in 2015.*
2. Given the other partners working on laboratory strengthening initiatives within the region, there were possible perceptions of duplication. Partnership with PAHO and CDC PEPFAR has been important in several initiatives including for example the development of the laboratory quality management systems stepwise improvement process (LQMS-SIP) initiative. Countries who have been assisted by both CDC and CMLF have reported that they have benefitted in different ways from the interventions of the two organisations in support of their laboratory services. For example, the policy initiative undertaken by CMLF on this grant has supported the LQMS-SIP through inclusion of Tier 1 of the LQMS-SIP as a requirement for licensing of laboratories.
3. It was critical to ensure that linkages were made between the objectives of the GF R9 laboratory initiatives with CARICOM, PAHO and CDC initiatives for:
  - a. *Development of the Caribbean Public Health Agency (CARPHA)*
  - b. *Integration of HIV into the health sector including policy dialogue*
  - c. *Stepwise process for Quality Management Systems implementation toward Accreditation within the Caribbean.*

As a measure of the success and sustainability of these collaborations, CMLF and CARPHA signed an MOU in January 2016 to continue working collaboratively on laboratory strengthening within the Caribbean region.

### 6.3 PR Functioning and Oversight

1. The supportive and solution-oriented approach of the PR as represented by the PMU within CARICOM served as a major source of guidance and support for the implementation of this project and was a key success factor for its success. For example, the flexibility and understanding of the PMU was critically important for undertaking the funding re-allocations necessary to facilitate the policy initiative which was not initially included within the project design, but became evident as a major gap when the baseline assessments were undertaken.
2. Meetings of SRs arranged by the PR were highly beneficial in ensuring that SRs were informed of the work of other SRs on the project, and also served as a major encouragement to SRs to seek out opportunities for collaboration. As a result, CMLF was able to undertake partnership with other SRs noted in **Section 6.2**.
3. Monitoring visits by the PR served to ensure that grant progress was assured and accountability systems were in place. The monitoring visits also served the very important purpose of detailed discussions between the PMU and staff of CMLF with respect to proposed activities and outcomes, and assisted in determination of the way forward.

## **7.0 CONCLUSIONS AND RECOMMENDATIONS**

Even as the PANCAP Round 9 Grant comes to a close, laboratory services continue to play a key role in the Caribbean's ability to meet global targets for HIV/AIDS, while significant deficiencies in laboratory support continue, despite the laboratory strengthening efforts undertaken under this and other regional and international programmes. Regional and international targets to reduce HIV infections by 2020 include the goal that 90 per cent of those with HIV will be aware of their status, 90 per cent of those who are HIV positive will receive treatment, and 90 per cent of those on treatment will have undetectable viral loads. At each step, laboratory services are fundamental to providing the necessary information to facilitate - diagnosis, treatment and confirmation of treatment success. When this three-part target is achieved, at least 73% of all people living with HIV worldwide will be virally suppressed, representing a two- to three-fold increase over current rough estimates of viral suppression.

Critical laboratory strengthening initiatives, including the establishment of national policies, plans and legislation for laboratory regulation, national structures for monitoring of laboratory quality and standards implementation, upgrading skills of laboratory personnel, improving supply chain management and ensuring the availability of key critical tests through further development of national and regional networks, will serve, not only the needs of HIV/AIDS programmes, but also needs for other communicable diseases (such as dengue and Chikungunya) as well as non-communicable diseases (such as diabetes, heart diseases and cancers). The role of laboratory services in the fight against HIV/AIDS and other diseases of public health importance remains a critical one, and the necessary political support for laboratory service improvements within the Caribbean is key, if laboratory services are to be sustained and reliable, and success of the health targets adopted by Caribbean governments are to be achieved. Continued work by CMLF in partnership with CARPHA, PANCAP and CARICOM will be critical to successful advocacy and implementation of these objectives.