

# **SIAPS TB Core End-of-Project Report**

**December 2017**



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## **About SIAPS**

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

## **Recommended Citation**

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## ACRONYMS

aDSM	active drug safety management and monitoring
Bdq	bedaquiline
CHAI	Clinton Health Access Initiative
Dlm	delamanid
DUR	drug use review
EWS	early warning system
GDF	Global Drug Facility
DR-TB	drug-resistant TB
ECSA HC	East, Central and Southern Africa Health Community
KNCV	The Netherlands TB Foundation
MDR-TB	multidrug-resistant TB
MIS	management information system
MSF	Médecins Sans Frontières (Doctors Without Borders)
MSH	Management Sciences for Health
NTP	National TB Program
PAHO	Pan American Health Organization
PSM	procurement and supply management
PSS	pharmaceutical systems strengthening
PV	pharmacovigilance
PViMS	Pharmacovigilance Information Management System
PY	project year
SAE	serious adverse event
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
TB	tuberculosis
UNOPS	United Nations Office for Project Services
USAID	US Agency for International Development
USG	United States Government
WHO	World Health Organization

## OVERVIEW OF SIAPS TB CORE PROGRAM

### Background

Despite the availability of highly effective treatment, tuberculosis (TB) remains a critical global health problem that is hindered by a number of pharmaceutical management issues. In 2016, approximately 1.3 million people died of TB, including 374,000 who were HIV-positive.<sup>1</sup> Of the 10.4 million cases of TB estimated to have occurred in 2016, national TB programs (NTPs) were notified of only 6.3 million, leaving a gap of approximately 4.1 million people who were either not diagnosed or not reported.<sup>1</sup> A gap between evidence-based pharmaceutical management-improvement practices and their application in global initiatives resulted in inefficient global TB medicine supply mechanisms and highlighted the need to strengthen governance, leadership, and coordination within and between global initiatives. Human resource capacity and leadership for pharmaceutical supply management and services within TB programs, specifically with regard to forecasting and quantification, inventory management, and supply planning, are big challenges. Without institutional improvements in capacity, short-term gains in pharmaceutical management will not be sustained.

Besides human resources, other health-systems building blocks in many high-burden TB countries require individual strengthening and improved synergy, particularly in management information systems (MIS) (including data quality assurance and impact assessment), definition of standards, and delivery of pharmaceutical services. Without a concerted effort to bolster these foundational elements, global investments in the development and promotion of new tools for TB control may be used ineffectively. Adding to these issues is the fact that there is a dearth of research documenting the outcomes and impacts of pharmaceutical interventions in low- or middle-income countries (LMICs), which have the greatest burden of TB. This gap may result in part from limited pharmaceutical research expertise at the country level, lack of supportive infrastructure, or limited funding for research in the face of competing priorities. However, such research promotes inclusivity in the design and implementation of interventions and is necessary to generate data for strategic decision-making.

Adding to these challenges is the rapid emergence of drug-resistant (DR-TB) forms of TB. In 2016, approximately 490,000 people worldwide developed multidrug-resistant (MDR)-TB, with only 22% of those enrolled in treatment in 2016. Globally, the treatment success rate for MDR-TB treatment in 2015 remained low at 54%.<sup>1</sup> New tools to combat the challenge of DR-TB, the first new TB medicines in more than 40 years—bedaquiline (Bdq) and delamanid (Dlm)—were released onto the market. Since then, these medicines have also been used to treat TB patients who have experienced life-altering side effects or developed intolerance or resistance to some second-line TB medicines. In 2015, USAID and Janssen Pharmaceuticals announced a donation of 30,000 treatments of Bdq to treat DR-TB patients. WHO also issued guidance documents to help countries quickly introduce these medicines. However, uptake has been slow by countries for many reasons, including a lack of expertise, infrastructure, and appropriate systems to monitor the efficacy, safety, and potential adverse effects. Consequently, there is an increased

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<sup>1</sup> Global Tuberculosis Report 2017. Geneva: World Health Organization; 2017.



demand from countries for knowledge on how to manage patients on these new TB medicines and regimens and for technical assistance on overall programmatic implementation.

All of these challenges are compounded by limited access to and improper use of quality assured TB medicines in many high-burden countries. Limited access to medicines stems in part from a lack of valid quantification information and supply chain bottlenecks at the country level. In addition, access to quality TB diagnosis, treatment, and pharmaceutical services in the private sector remains limited and is often substandard. With regard to improper use of TB and DR-TB medicines, a lack of monitoring of drug utilization and management of adverse reactions can result in poor treatment outcomes and foster the development of drug resistance. Patient-centered TB diagnosis and treatment relies on the capacity of health staff to track and assess patient data and ensure implementation of evidence-based care. Concurrent treatment of co-morbidities, such as TB/HIV and TB/diabetes, results in greater risk of adverse events, which may contribute to treatment interruptions and poor patient outcomes. With the introduction of new tools in the fight against TB, including Bdq and Dlm, pediatric formulations, short-course treatment regimens, and new diagnostic tools, SIAPS built country capacity to improve access to life-saving medicines and technologies for TB patients.

## **Program Objectives and Results Framework**

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is a major US Agency for International Development (USAID)-funded mechanism (annex 1) for providing technical leadership in TB pharmaceutical management to global TB initiatives, donors, Stop TB partners, and NTPs. In the early project years, SIAPS addressed the objectives of the Global Plan to Stop TB 2006–2015 by focusing primarily on strategic components related to increasing the availability of, and ensuring access to, quality assured first- and second-line TB medicines and related pharmaceutical services. In 2014, the World Health Assembly of the 194 member states approved the End TB strategy (2016-2035)<sup>2</sup> developed under the leadership of WHO. This strategy was strongly supported by the United States Government's (USG) strategic framework envisioning a world free of TB with zero deaths, disease, and suffering.<sup>3</sup> SIAPS activities specifically contributed to the three key pillars of the strategy: (1) integrated patient-centered care and prevention, (2) bold policies and supportive systems, and (3) intensified research and innovation.

The primary goal of the SIAPS TB Core portfolio was to ensure the availability of quality pharmaceutical products and support the implementation of effective pharmaceutical services for achieving global and USG TB program targets; also represented in the USG health goals were protecting communities against infectious diseases, fostering an AIDS-free generation, and strengthening health systems. SIAPS built on many years of experience, methodologies, and tools developed and tested by Management Sciences for Health and its different USAID

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<sup>2</sup> World Health Organization. 2015. Brochure "Gear up to End TB, Introducing the WHO End TB Strategy". Assessed from [http://www.who.int/tb/End\\_TB\\_brochure.pdf?ua=1](http://www.who.int/tb/End_TB_brochure.pdf?ua=1)

<sup>3</sup> United States Government. Global Tuberculosis Strategy: Reach, Cure, Prevent 2015-2019. Assessed from <http://www.usaid.gov/sites/default/files/documents/1864/Reach-Cure-Prevent-2015-2019-TBStrategy.pdf>

programs. As a result, SIAPS has at its disposal an array of instruments to address TB pharmaceutical management gaps within the health system.

The four key strategies employed by the TB portfolio address 1) pharmaceutical governance for TB at global and country levels; 2) capacity for TB pharmaceutical supply management and services; 3) utilization of information for TB control decision making; and 4) pharmaceutical services and access to TB products for achieving global and country goals. The SIAPS TB Core results framework is presented in figure 1.

## Approach

The SIAPS TB Core systemic approach to stronger pharmaceutical systems for universal access to TB commodities and rapid introduction of new TB medicines, regimens, and diagnostics was built upon key public health and pharmaceutical sector functions, including governance, pharmaceutical services delivery, management information, and human resources.

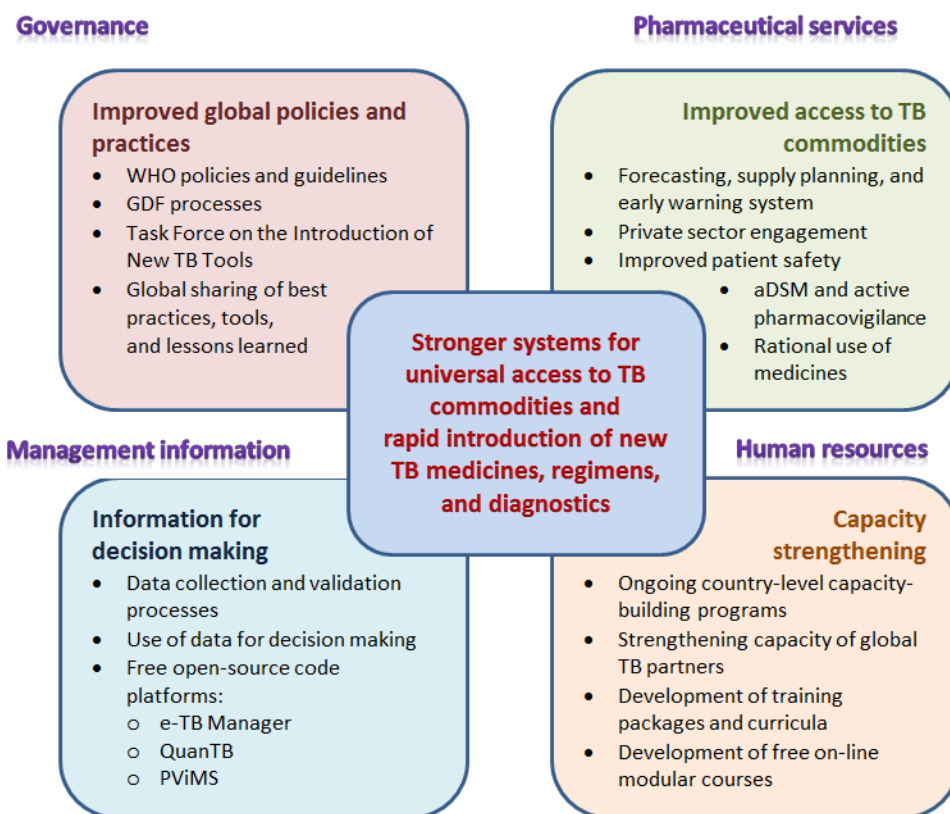


Figure 1. TB Core results framework

## Countries Supported by the TB Core Portfolio PY1-PY6

Throughout the life cycle of the project, SIAPS TB Core was utilized to support TB programs in 26 countries in Africa and the Central and South East Asia regions: Armenia, Azerbaijan,

Bangladesh, Burma, Cambodia, DRC, Ethiopia, Georgia, Kenya, Malawi, Mozambique, Burma, Namibia, Nigeria, Pakistan, Philippines, South Africa, South Sudan, Swaziland, Tajikistan, Tanzania, Turkmenistan, Uganda, Ukraine, Uzbekistan, Zambia, and Zimbabwe.

## **Pharmaceutical Systems Strengthening Interventions and Achievements**

### ***Pharmaceutical Governance for TB Strengthened at the Global Level***

One of the goals for SIAPS was to advance good pharmaceutical governance principles and practices and maintain them on the global TB agenda. This goal was achieved by applying a system strengthening approach to the development of global policies and guidelines, disseminating best practices and lessons learned, and providing direct technical leadership and technical assistance (annex 4) to donors, global and regional initiatives, implementing partners (annex 2), and NTPs.

#### *Global TB Policies for Introduction of New TB Medicines and Regimens Developed*

SIAPS made considerable contributions to global TB policies by providing technical leadership in pharmaceutical management to the Stop TB Global Drug-Resistant TB Initiative and WHO during the development of key policy documents and TB guidelines, especially those related to the introduction of new TB medicines and regimens. These key policy documents include:

- *WHO Policy Implementation Package for New TB Tools* (2014); SIAPS Chapter: “Systems approach for ensuring uninterrupted supply of new and existing quality-assured medicines”
- *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis* (2014)
- *WHO Treatment Guidelines for Drug-Resistant Tuberculosis. 2016 Update*
- *Digital Health for the End TB Strategy: An Agenda for Action* (2015)
- *Active Tuberculosis Drug-Safety Monitoring and Management (aDSM). Framework for Implementation* (2015)
- *Implementing the End-TB Strategy: The Essentials. WHO* (2015)

#### *Global TB Supply Mechanisms Strengthened*

By far, one of SIAPS’ most prominent achievements was its continuous<sup>4</sup> technical support to the Stop TB/Global Drug Facility (GDF), an international procurement and technical assistance mechanism currently housed in the United Nations Office for Project Services (UNOPS) in

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<sup>4</sup> USAID provided continuous technical support to GDF since its inception in 2001 through several projects, all managed by MSH, including Rational Pharmaceutical Management Plus, Strengthening Pharmaceutical Systems, and SIAPS.

Geneva. GDF was established in 2001 as a mechanism for providing donor-supported grants of first-line TB medicines to countries; it evolved into a procurement and supply mechanism for all TB medicines and diagnostic products and a provider of technical assistance services.

The technical support of GDF was multifaceted, ranging from technical assistance in organizational management and developing processes to assistance to GDF's client countries in strengthening procurement and supply management (PSM) practices. SIAPS' support has included the development of GDF strategies, position papers, concept notes and market-shaping approaches, operational management through direct technical assistance, and leadership through the GDF Technical Review Committee. Following the GDF management and supply crisis in 2012, USAID requested that SIAPS lead the establishment of a Stop TB advisory board to develop GDF strengthening strategy and second a full-time manager to lead GDF operations in 2012–2015. During that time, GDF significantly improved its supply indicators, successfully passed the audit, and extended its ISO 9001/2008 certification, which is “designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product or service.”<sup>5</sup> (List of stakeholders can be found in annex 3.) In 2014, Stop TB's hosting arrangement with WHO expired; moving to the new host, UNOPS, required revising all standard operating procedures related to the GDF functioning as a procurement and supply entity. With the help of the SIAPS-seconded manager, this transition was successfully performed without any interruptions in TB medicine supply.

SIAPS and the GDF established collaboration aimed at zero tolerance for TB medicine stock-outs/overstock, an approach based upon cooperation between SIAPS regional activities portfolio consultants and GDF regional support officers, and utilization of QuanTB<sup>6</sup> as a common quantification and early warning tool. SIAPS staff conducted over 30 technical missions in conjunction with GDF in over 20 countries, including Bangladesh, Burma, Cambodia, DRC, Ethiopia, Georgia, Kenya, Kyrgyzstan, Malawi, Mozambique, Nigeria, Philippines, South Sudan, Tajikistan, Tanzania, Uganda, Uzbekistan, Vietnam, Zambia, Zimbabwe, and others.

### *Global TB Policy Dialogue Enhanced*

SIAPS significantly contributed to the global TB dialogue by providing technical leadership and expertise in pharmaceutical management for TB, presenting at conferences, and producing publications.

SIAPS contributed to the Unitaid and USAID TB Market Forum in 2013 by leading a dialog on improving forecasting and quantification of second-line TB medicines (first global presentation of SIAPS' QuanTB tool), and contributed the PSM perspective to the Global Fund Sourcing and Market Dynamics meetings in 2014 and 2015 for discussions on streamlining the demand for TB medicines. (Unitaid is a global health initiative to end the world's TB, HIV/AIDS, and malaria epidemics.)

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<sup>5</sup> [Wikipedia](#)

<sup>6</sup> QuanTB is a SIAPS-developed tool for forecasting, quantification, supply planning, and early warning currently used in all high-burden TB countries.

Annual Union World and Regional Conferences on Lung Health are major international events that bring together all TB donors, global initiatives, implementing agencies, and NTPs to strategize and share best practices to end the TB epidemic. With TB Core funding, SIAPS took the lead in the technical area of pharmaceutical management for TB at all Union world conferences from the 43rd in 2012 to the 47th in 2016. In conjunction with donors like USAID and Unitaid and technical partners like GDF, WHO, The Netherlands TB Foundation (KNCV), MSF, and Partners in Health, SIAPS developed and facilitated workshops, including the topics of transitioning to sustainable pharmaceutical management systems, universal access to internationally quality assured TB medicines, global supply chain mechanisms and early warning systems (EWSs), active pharmacovigilance (PV) for new TB medicines and regimens, MDR-TB patient information and adherence counselling, lessons learned from increasing access to Bdq and Dlm, and digital health technology for the End TB strategy.

To extend the outreach for TB policy dialog, SIAPS conducted three conferences, in conjunction with WHO and Stop TB/GDF, focused on best governance and PSM practices for TB and the development of countries' PSM strengthening action plans. These conferences were SIAPS' second Africa TB Regional Conference on Management of TB Medicines for 20 countries (2012); SIAPS' first Regional Conference on Novel Approaches to Pharmaceutical Management for TB and MDR-TB in the Europe-Eurasia Region for 16 countries (2013); and Building the Post-2015 Agenda: Novel Approaches to Improving Access to TB Medicines and Pharmaceutical Services in Bangkok, Thailand for 22 countries (2015). Country action plans developed during these conferences became part of national TB strategic plans and proposals for Global Fund support.

### ***Capacity for TB Pharmaceutical Supply Management and Services Increased and Enhanced***

The demand for pharmaceutical management expertise, best PSM practices, and efficient tools has grown considerably as new TB medicines and regimens were adopted and introduced. SIAPS focused on key global initiatives and targeted these efforts at NTP managers and TB medicine coordinators; managers engaged in programmatic management of DR-TB; and implementing technical agencies. The SIAPS approach included formal face-to-face and on-line training, training of trainers, follow-up trainings, and hands-on capacity strengthening and mentoring. SIAPS developed training modules that can be adapted to country-specific needs that cover the following topics: systemic and managerial issues of policy and regulations, supply chain management, quality assurance management, rational selection and use of TB medicines, forecasting and quantification, introduction of new medicines and regimens, EWSs, and PV. All SIAPS trainings include practical field exercises and development of individual improvement work plans.

### ***Capacity at the Global Level Strengthened***

At the global level, SIAPS focused on the development of organizational capacity of global donors and initiatives, such as the Global Fund, GDF, and WHO, and their staff and consultants, to monitor access to TB medicines, develop rapid interventions for accelerated uptake of new medicines, and prevent stock-outs and treatment interruptions.

SIAPS conducted comprehensive trainings for GDF staff and consultants, Global Fund portfolio managers, and KNCV consultants on quantification of medicines and QuanTB. The GDF staff and consultants then used SIAPS materials to conduct more capacity-building exercises at the regional level (Francophone African and Latin American countries and India, Pakistan, Ukraine, and Ghana).

On the request from the Pan American Health Organization (PAHO), SIAPS conducted two trainings on forecasting, quantification, supply planning, and early warning with QuanTB in Latin America in 2015, first for PAHO staff and future trainers, followed by training of national TB medicine coordinators from Central American countries. As a result, PAHO adopted QuanTB as its tool for validating and quantifying country orders that go through its Strategic Fund for procurement. Nine countries started using QuanTB after the first SIAPS training. Additional regional trainings were delivered by GDF in 2016 and 2017, expanding the QuanTB capacity to all Latin American country subregions.

SIAPS developed the capacity of the East, Central, and Southern Africa Health Community (ECSA HC) staff to monitor and coordinate access to TB medicines in the region; SIAPS conducted and published *Rapid Situation Analysis of the Five East, Central, and Southern Africa Countries on TB Data and Commodity Management*, developed and trained users, and handed over to ECSA HC the TB Commodity Monitoring Dashboard (2014).

SIAPS continued to contribute to capacity-building programs and curricula of WHO Collaborating Centers in Riga, Latvia (2012 -2014), and Tradate, Italy (2012-2016). Both collaborations go back to 2001. SIAPS developed 1–2-day PSM training sessions for the centers' annual courses focusing on improving participants' skills in pharmaceutical management for TB, MDR-TB, and TB/HIV, including forecasting, supply planning, quantification, and early warning for stock-outs. Since 2014, special focus was on the introduction of new TB medicines and regimens. Participants of these courses included national TB managers, donors, and technical agencies, such as KNCV, Project HOPE, Clinton Health Access Initiative (CHAI), Union, and individual consultants. After the end of SIAPS funding, the PSM sessions at these courses were picked up by SIAPS-trained consultants (Latvia) and GDF (Italy).

Throughout the project, SIAPS invited other projects and technical agencies to its trainings and capacity-building exercises at the global, regional, and country levels. This included ChallengeTB Project and KNCV, Project HOPE, CHAI, Union, and others. SIAPS PSM training materials and tools, such as QuanTB, are now being used by all these partners in their regional and country trainings.

### *Capacity at the Country Level Strengthened*

SIAPS addressed PSM capacity-strengthening needs at the country level through regional trainings and transfer of best practices and tools to countries and implementing partners; country-specific capacity strengthening interventions included trainings, follow-up technical assistance, and mentoring.

Prior to 2014, SIAPS relied on regional workshops to promote best practices and tools, inviting NTP representatives and technical agencies that were implementing bilateral USAID projects in target countries. To promote QuanTB as a tool for streamlining PSM and improving access to TB medicines, SIAPS conducted two regional trainings in the Europe-Central Asia region in 2013. As a result, SIAPS methodology and QuanTB for quantification and early warning were accepted in most countries, and SIAPS provided additional assistance to Ukraine and the Central Asia region. As an additional milestone, QuanTB was accepted and continuously used in non-SIAPS-supported countries, such as Belarus, Moldova, and Russia.

After 2014, SIAPS began developing a capacity strengthening and technical assistance program for selected priority countries to streamline their PSM and accelerate the introduction of new TB medicines and regimens. The selected countries included Burma, Cambodia, DRC, Kenya, Mozambique, Nigeria, Philippines, South Sudan, Tanzania, Uzbekistan, Zambia, and Zimbabwe. SIAPS built the PSM capacity-strengthening approach on QuanTB and skills in forecasting, quantification, supply planning, and early warning. Key staff in all priority countries went through formal trainings followed up by technical assistance missions and direct mentoring. As of December 2017, all these countries routinely generate early warning reports and place and monitor orders via QuanTB.

Overall, the TB Core portfolio trained 3,755 people in aspects of pharmaceutical system strengthening (PSS). The SIAPS capacity-building approach, materials, and tools are being widely used by partners, including Stop TB/GDF, KNCV, Project HOPE, Union, and others.

### *Access to e-Learning Inaugurated*

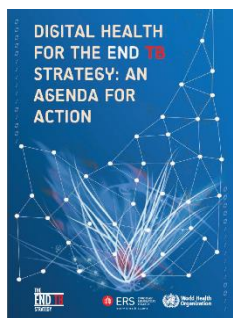
To enable access to the SIAPS-developed tools and best practices, SIAPS launched two eCourses for the public that are hosted on the MSH platform LeaderNet (Leadernet.org). Following the release of QuanTB v4 at the 47th Union Conference in Liverpool, SIAPS updated the training modules and videos and made available a free, self-paced QuanTB course for health professionals on LeaderNet. The goal of this course is to strengthen learners' skills for appropriate quantification of first- and second-line medicines and other TB commodities to ensure an uninterrupted supply in NTPs. The course includes two modules on quantification methods and assumptions and use of the tool, with interactive video demonstrations and knowledge checks. The full course takes approximately five hours to complete and a certificate is provided to those who complete the full course. As of December 1, 2017, 168 health professionals subscribed to the course.



The second eCourse launched by SIAPS is entitled “Using New TB Medicines and Regimens,” a free, self-paced course for health professionals on new TB medicines, such as Bdq and Dlm, and the responsible use of new regimens, such as the nine-month regimen, for the treatment of MDR-TB. This course is intended for physicians, nurses, pharmacists, and all health care workers currently engaged in the management of MDR-TB patients. Workers in NTPs, MOHs, and nongovernmental organizations who are looking to introduce new TB medicines and regimens in their countries will also greatly benefit from this course. The information in this course was

developed from publicly available resources from the World Health Organization (WHO) and elsewhere. It has been taught via in-person workshops to hundreds of health care workers in five countries. The course includes eight modules with interactive case studies. Learners can choose to review all the modules or simply pick the ones that are most relevant to their practice setting. A certificate is provided for those who complete the full course. As of December 1, 2017, there were 194 subscribers to the course.

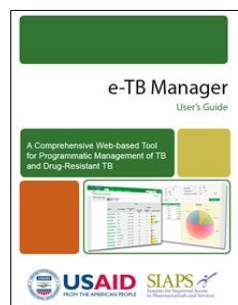
### **Utilization of Information for Better Decision Making Improved**



The collection, analysis, and use of health and pharmaceutical management information drive better decision making at all levels of a health system. This information, when used through efficient systems for decision making, ensures an uninterrupted supply of medicines; provides insights into the factors that enable patients to adhere to treatment regimens; provides evidence for development and revision of national treatment protocols; facilitates better quantification, procurement, and costing for medicines and other health supplies; and ultimately contributes to stronger health systems and better health outcomes. SIAPS worked to improve information for

decision making through the availability and interoperability of electronic tools combined with systems strengthening. The WHO publications *Guide on Electronic Recording and Reporting for Tuberculosis Care and Control* (WHO 2012) and *Digital Health for the End TB Strategy* (2016) were, in part, based on the SIAPS experience with electronic tools, such as e-TB Manager and QuanTB; these publications recommended these tools for implementation by NTPs.

### **e-TB Manager**



One of SIAPS's successes has been e-TB Manager, a comprehensive platform that addresses key management information needs of NTPs. This tool integrates diverse aspects of TB control, such as diagnosis, treatment, medicines, and outcomes. Consequently, e-TB Manager allows for a holistic approach that avoids the common disconnect between activities focused on various types of TB and comorbidities, and inventory management for first- and second-line TB medicines. The tool has been adapted to specific country requirements, implemented, and is operational in 10 countries, including Armenia, Azerbaijan, Bangladesh, Brazil,

Cambodia, Indonesia, Namibia, Nigeria, Ukraine, and Vietnam. e-TB Manager is fully owned by the countries, with the last handover completed in Bangladesh in the summer of 2017.<sup>7</sup> As of July 2017, over 650,000 TB and MDR-TB cases were managed globally via e-TB Manager.

Working to expand the knowledge base of pharmaceutical best practices and improve utilization of information for TB control decision-making, SIAPS published two peer-reviewed journal articles related to e-TB Manager. The first article was published in the *European Respiratory Journal Open Research*; it presented results of an in-depth analysis of Ukraine's experience

<sup>7</sup> e-TB Manager was adapted for Turkmenistan, the implementation technical assistance was provided by SIAPS, and the tool has been handed over to the government. The current status, however, is not known as Turkmenistan is not sharing this information.



implementing e-TB Manager as a nationwide TB registry based on the responses from 565 users in the country; users gave high ratings to the registry's ability to improve case management (the number of active users increased to 1,319 by 2017 since the study was done in 2016).

The study demonstrated that Ukraine expanded use of e-TB Manager countrywide for patient care and decision making, down to the rayon (district) level, despite what once seemed to be insurmountable obstacles to using the tool. Figures in the article illustrated the use of the registry against the total TB burden in the country. Furthermore, the quantitative analysis showed that registry users can find the information they need to care for patients and improve their workplace productivity. The open access article is under a CC BY-NC license and can be freely shared and distributed from <http://openres.ersjournals.com/content/3/2/00002-2017>.

The second peer-reviewed study was published by the *International Journal of Medical Informatics*. SIAPS received 1,753 responses with a completion rate of 86% from 9 participating countries. The average response rate of 76% among the 9 countries significantly exceeded expectations. Key results of the survey include that 81% of users agree that e-TB Manager improves patient case management, 80% find e-TB Manager reliable, and 75% agree that they have the capacity to use all of e-TB Manager's features. This open access article is under a CC BY-NC-ND 4.0 license and can be freely shared and redistributed from <http://www.sciencedirect.com/science/article/pii/S1386505617300783>.

### QuanTB



QuanTB was developed by SIAPS in 2013 as a free downloadable tool for forecasting, quantification, supply planning, and early warning for TB medicines. Four updated versions had been developed in the course of the SIAPS Project, with the latest, QuanTB-4, made available for download in the summer of 2017, with a new supply scheduling functionality, improved dashboards, and increased computation speed. The tool is available in six languages: English, French, Russian, Chinese, Spanish, and Portuguese. As of September 2017, QuanTB had been downloaded more than 2,500 times

worldwide by 136 countries or almost 70% of all countries in the world, showing widespread interest in the tool. QuanTB is being widely used by TB partners, such as KNCV and the Union, in their field projects. It is an official forecasting and quantification tool of PAHO for countries that procure using its strategic fund, and of GDF, where all of its 28 Tier 1 priority countries are mandated to use QuanTB for placing and monitoring TB medicines orders.<sup>8</sup> Overall about 50 of the GDF client countries are using the tool for quantifying TB medicine orders. QuanTB makes data collection and utilization easier and more efficient for decision making, allowing rapid informed response to avoid stock-outs or overstocks by playing supply scenarios and using dashboards.

To determine key achievements, experiences, and perspectives of in-country and global beneficiaries and challenges and lessons learned, SIAPS conducted a review of the impact of the

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<sup>8</sup> These include all USAID TB priority countries; <https://www.usaid.gov/what-we-do/global-health/tuberculosis/where-we-work>

QuanTB implementation and related TB PSM technical assistance in 12 countries<sup>9</sup>—Bangladesh, Burma, DRC, Kenya, Nigeria, Philippines, South Sudan, Tajikistan, Tanzania, Uganda, Zambia, and Zimbabwe. The review was conducted by using data collected from background documents, reports, interviews with SIAPS staff and country beneficiaries, and online satisfaction and experience surveys. Key themes that arose from the analysis included high satisfaction and confidence with QuanTB; a high level of perceived strengthening of the overall supply chain system for TB as a result of the tool and technical assistance; manageable costs of implementing the tool; improved decision making for quantification and supply planning as a result of the EWS and related SIAPS technical assistance; and reductions in wastage, expiries, and stock-outs of medicines.

Key achievements of SIAPS technical assistance and the implementation of QuanTB included:

- Countries' NTP institutional and staff capacity was improved, leading to better quantification, coupled with vigilant stock management, which resulted in improved availability of medicines to meet the evolving needs of NTPs.
- EWS data and dashboards on the availability of TB commodities significantly improved access to TB medicines by documented reductions in stock-outs and waste of medicines.
- The logistics management information systems (LMIS) and data quality and reporting were improved for better decision making.
- Significant financial savings resulted from timely, informed PSM decisions.

### PViMS



The Pharmacovigilance Information Management System (PViMS) was the last electronic tool developed by SIAPS in response to the need for efficient and user-friendly active drug safety monitoring and management (aDSM) tools for safe introduction of new TB medicines and regimens. PViMS makes it feasible to implement active surveillance activities in LMICs by addressing the entire data collection and analysis process to identify signals for improving the safety of patients undergoing treatment. When used for spontaneous reporting, PViMS provides a comprehensive PV solution for LMICs.

PViMS was adopted by and handed over to NTPs in Georgia, Swaziland, and Philippines where the NTP trainers and staff were trained, and national implementation guidelines for PViMS were finalized.

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<sup>9</sup> Goredema W, Sawyer K, Mwatawala S, and Owunna C. 2017. Implementing an Early Warning System for TB Medicines: Global Report. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

### *SIAPS e-Tools in Open-Source Code Repository*

In 2017, SIAPS released all SIAPS-developed electronic tools to the public in the open source code format, including e-TB Manager, QuanTB, and PViMS. All these tools, along with relevant documentation for users and programmers, can be accessed by any country, partner, or individual at GitHub, a web-based version-control repository hosting service.

In November 2017, Uzbekistan became the first country to independently access e-TB Manager documentation and source code via GitHub to implement e-TB Manager as the national TB MIS.

### ***Pharmaceutical Services and Access to TB Products Improved***

The SIAPS interventions to improve access to TB diagnosis and treatment included three primary efforts—improving access to medicines by strengthening EWS and supply planning, strengthening linkages between the private and public sectors, and improving medicine use and patient safety.

#### *EWS and Supply Planning Strengthened*

As part of its mission to improve the availability of TB medicines, SIAPS provided technical assistance to NTPs in selected USAID-priority countries<sup>10</sup> to improve TB PSM. SIAPS strategy for technical assistance in PSM strengthening was implemented by three regional technical advisors (Africa, South East Asia, and Central Asia/Europe) who managed country-based technical advisors in key countries, such as Kenya, Nigeria, and Burma, and a pool of technical consultants. The technical approach included rapid needs assessments in targeted countries, development of individual intervention plans, and the use of the QuanTB EWS to improve forecasting, supply planning, and monitoring of availability, stock-outs, and expiries. To ensure country ownership and sustainability, SIAPS employed a systems strengthening approach that included obtaining the buy-in of country NTPs; building their institutional and human resource capacity to improve data collection and quality and to regularly monitor stock status and supply chain risks by using QuanTB; and strengthening the communication and coordination of NTP counterparts with local and global stakeholders in disseminating and using EWS information. Implementation of the tool was complemented by other SIAPS TB technical assistance activities, such as quantification capacity-building training and participation in country monitoring missions.

SIAPS conducted a review<sup>10</sup> of the impact of TB Core PSM technical assistance and QuanTB implementation on improved access to TB medicines in 12 countries—Bangladesh, Burma, DRC, Kenya, Nigeria, Philippines, South Sudan, Tajikistan, Tanzania, Uganda, Zambia, and Zimbabwe. The review was conducted using data collected from background documents, reports, interviews with SIAPS staff and country beneficiaries, and online satisfaction and experience surveys. Objectives of the review included determining key achievements, experiences, and perspectives of in-country and global beneficiaries and challenges and lessons learned from the

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<sup>10</sup> Tanzania, Uganda, Ethiopia, Malawi, Swaziland, Kenya, DRC, Nigeria, Zambia, Zimbabwe, South Sudan, Mozambique, Burma, Philippines, Cambodia, and Afghanistan; additionally, through USAID Mission support, Tajikistan and Uzbekistan

intervention. The review demonstrated improved access to TB medicines within the first two years of implementation: the percentage of countries with at least one first-line medicine out of stock decreased from 80% in the quarter ending April 2014 to 18% by May 2016. The percentage of countries with at least one second-line medicine out of stock decreased from 67% in the quarter ending April 2014 to 30% by May 2016.

SIAPS PSM interventions also improved the financial management of the supply of TB medicines by optimizing procurement and reducing waste resulting from overstock and expiry. For example, Bangladesh saved approximately \$900,000 by cancelling and deferring shipments<sup>11</sup> in 2015. By postponing pending shipments of supplies, Ethiopia, Nigeria, Tanzania, Kenya, and Zimbabwe saved more than \$7.1 million between December 2014 and June 2016. By transferring excess stock at risk of expiring to other countries in need, these five countries saved an additional \$1.4 million during the same period.<sup>12</sup> This allowed the NTPs to redirect saved resources to fund and improve other services, such as case finding, diagnosis, and treatment.

### *Linkages between Public and Private Sectors Strengthened*

According to the WHO end-TB strategy, engagement of communities, civil society organizations, and public and private care providers is one of the essential elements of success in combating the global TB epidemic. One of SIAPS' efforts to improve the quality and accessibility of TB diagnosis and treatment was to strengthen linkages between the public and private sectors. In accordance with the global strategies of the Stop TB Partnership and the USG, SIAPS developed a strategic approach that began with compiling in-country information on the TB/DR-TB situation in the private sector. SIAPS then collaborated with key stakeholders to design environment-specific interventions on the basis of data collected in Kenya. In these interventions, the NTP and private physicians used drug use reviews (DURs) to focus on containing MDR-TB and patient safety. In Tanzania and Pakistan, the focus was on engaging private drug sellers in referring presumptive TB cases to the NTPs. SIAPS tested several models, including engaging the pharmacy school, the medical representative model, and the dedicated community health officer model to reach out to private pharmacies. On the basis of the number of referrals and the cost of implementation, engaging the pharmacy school and its students proved to be the most effective strategy.

The most successful intervention was SIAPS' unique public-private partnership activity in Pakistan<sup>13</sup> to explore the potential of increasing TB case finding. SIAPS spearheaded assessments of knowledge, attitudes, and practices of private pharmacies and medicine shops and then used the findings to develop interventions to educate medicine sellers and establish referral

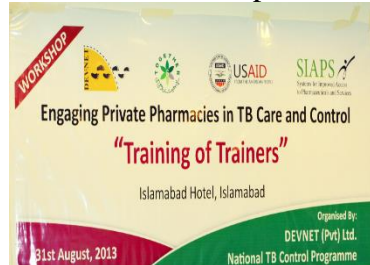
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<sup>11</sup> Goredema W, et al. 2016. Implementing QuanTB to Improve Forecasting, Supply Planning and Early Warning System for TB Medicines: Bangladesh Report. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

<sup>12</sup> Mwatawala S, et al. 2016. Benefits of Implementing Early Warning System in Improving Information for Decision Making in Five African Countries. Poster presented at the 47th Union World Conference on Lung Health, Liverpool, UK: October 26–29, 2016.

<sup>13</sup> Malik M, Rutta E. Engaging private sector pharmacies in Pakistan to increase early TB case detection. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health; 2016.

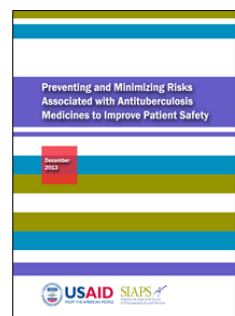
mechanisms between private retail outlets and TB diagnostic centers under the leadership of the NTP. Overall, 502 pharmacies in 6 major cities were part of the intervention. These trained



pharmacies referred 1,071 presumptive TB cases to public-private-mix general practitioners and public-sector basic health units over a period of 8 months. Of these, 829 (77%) were traceable and 198 (18%) of the total referred were confirmed as having TB. In December 2015, a national-level dissemination meeting was held with 25 participants from donor agencies, the NTP, implementing partners, and pharmacy schools. As a result of the pilot study and this meeting, the NTP made a policy decision to include private

pharmacies in the 2020 national strategic plan for TB control. SIAPS supported the NTP in the development of a concept note and tentative budget. In 2016, with support from the Global Fund, the NTP and the provincial TB control program and partners began implementing the project on a national scale with a phased approach.

### *Medicine Use and Patient Safety Improved*



SIAPS developed a number of tools and approaches to mitigate the risks associated with TB medicines for MDR-TB treatment. Monitoring the use of medicines can be done through a DUR, a systematic process designed to promote the safe and effective use of TB treatment. Risk management algorithms have been designed to help health care workers identify and promptly address known side effects of TB treatment, and active pharmacovigilance activities allow health systems to proactively identify and manage side effects that result from the combination of medicines for TB and HIV.

To improve patient safety, SIAPS worked with NTPs and appropriate national regulatory bodies to establish or strengthen active surveillance systems to determine the real-life frequency, risk factors, and impact of clinically significant adverse medicine events on treatment outcomes. SIAPS focus countries included Kenya, South Africa, Philippines, and Swaziland. In Kenya, a series of trainings and technical assistance to strengthen DUR practices led to the revision of national treatment guidelines for MDR-TB and establishment of an ongoing DUR process that ensures patient safety. This work in Kenya also linked the NTP and private physicians by engaging the Kenya Association for the Prevention of Tuberculosis and Lung Diseases and developing a consensus policy document on DUR and patient safety. DUR methodology was also introduced in South Africa and Ukraine.



In the Philippines, through training of trainers, cascade trainings, and direct technical assistance, SIAPS established a national active PV system for TB medicines based on PVIMS, a web-based application used by clinicians, regulatory bodies, and implementing partners to monitor the safety and effectiveness of medicines, including new TB medicines. In October 2017, PVIMS was adopted as a national PV system, managed by the Food

and Drug Administration and Department of Health in the Philippines. PViMS was also introduced in Swaziland, Ukraine, and Georgia.

### ***Rapid Introduction and Adoption of New TB Medicines and Regimens***

The first new TB medicines in more than 40 years—Bdq and Dlm—were released onto the market for the treatment of MDR-TB in 2013 and 2014, respectively, immediately followed by WHO guidelines on their use. In March 2015, USAID and Johnson & Johnson affiliate Janssen Therapeutics signed an agreement to donate 30,000 free treatment courses of Bdq to qualifying countries through the Bedaquiline Donation Program. In April 2015, SIAPS was tasked by USAID with providing technical assistance to five countries to adopt, expedite the introduction and use of, and monitor the effects of Bdq and other new TB medicines/regimens. The countries were Georgia, Kenya, Philippines, Swaziland, and Uganda. SIAPS used a system strengthening approach that involved engaging and coordinating stakeholders, building upon existing systems or establishing new ones where appropriate, strengthening human resources via trainings and direct mentoring, strengthening PSM planning and practices for new TB medicines, and using validated information for reporting and decision making. The main focus of the SIAPS work, however, was on two technical areas—improving access to medicines through better quantification, supply planning, and early warning using QuanTB and improving patient safety through the introduction of aDSM using PViMS.

To make the SIAPS experience and expertise in the introduction of new TB medicines and regimens available to a broad audience, SIAPS developed open resources and training materials, including a website ([www.newTBdruginfo.org](http://www.newTBdruginfo.org)) with information for program managers, MOH staff, and health care workers and an eCourse on the use of new TB medicines and regimens available on <https://leadernet.org/>.

Since the start of the activity in March 2015, most success was achieved in Georgia, Philippines, and Swaziland. All three countries have been using QuanTB for phasing-in supply planning for new medicines and regimens, and all three have implemented PViMS as a tool for WHO-required aDSM. Georgia enrolled 415 patients on Bdq and Dlm, with 240 still on treatment as of September 2017, and was reporting serious adverse events (SAEs) via PViMS. SIAPS contributed to aDSM cascade training in Georgia in August–October 2017, which resulted in 79 SAEs reported after the training, compared to 37 SAEs reported since the new medicines were released in 2014. Doctors have become much more aware of adverse events that would have been missed before training and underreported.

In Philippines, SIAPS partnered with the Department of Health’s Pharmaceutical Division, Food and Drug Administration, and the NTP to adopt and implement PViMS as a national PV tool. SIAPS supported the development of guidelines and standard operating procedures; established a national database; and conducted a training workshop in September 2017 for 63 health professionals from 9 regions and from government partners, including all 10 health facilities that are piloting use of a shorter treatment regimen, Bdq, and Dlm. SIAPS consultants also provided on-site hands-on mentoring for the staff at seven health facilities in seven regions that are implementing a shorter treatment regimen, Bdq, and Dlm.

Swaziland was the first country to field-test and adopt PViMS as an aDSM tool. As of September 2017, the country had received 235 treatment courses of Bdq and is steadily enrolling eligible patients.

In Uganda, SIAPS provided technical assistance on revising the supply plan for Bdq and companion medicines for 20 patients undergoing treatment with Bdq and helped the NTP review recording and reporting forms and processes for SAEs.

In Kenya, the uptake of new medicines was slow because of the country's weak capacity to diagnose and select patients for treatment. SIAPS helped Kenya adjust the country's procurement and supply plan to reflect the realities of slow uptake.

None of the five countries where SIAPS provided assistance in the introduction of new TB medicines and regimens experienced stock-outs of these vital products or delays in the enrollment of patients because of unavailability of medicines.

## SUSTAINABILITY OF SIAPS TB CORE INTERVENTIONS AND TOOLS

Sustainability of interventions and tools has been built into SIAPS TB Core activities throughout the life of the project, with the following results:

- Pharmaceutical system management for TB is now firmly on the global agenda; SIAPS contributed technical expertise on PSM to Stop TB and to regional (WHO) and national (NTP) groups. This expertise eventually became part of the guidelines on medicine supply management and part of TB strategies at the regional and national levels.
- SIAPS continuous technical support of GDF ensured its smooth transition from WHO to UNOPS and improved performance
- All SIAPS electronic tools, such as QuanTB, e-TB Manager, and PViMS, and all relevant documentation were made available to the public via the open-source code repository GitHub
  - QuanTB: Several international organizations, such as KNCV and Project HOPE, have adopted QuanTB as their tool for country programs and consultancies; GDF adopted it as its official tool, with over 30 countries using it for placing orders with GDF
  - e-TB Manager has been adopted, adapted, and institutionalized as a national TB MIS tool in 10 countries
  - PViMS has become the national PV tool in Swaziland and Philippines
- SIAPS trainings on forecasting, quantification, and early warning using QuanTB and on new TB medicines are available as free, on-line modular courses via MSH's LeaderNet website, with hundreds of health care professionals already accessing them
- These same training materials have been adopted and used by organizations such as Stop TB/GDF, the KNCV-managed Lilly Foundation's MDR-TB project, and several ChallengeTB field projects.
- SIAPS's approach to ongoing technical assistance and capacity strengthening of NTPs in procurement and supply planning has been adopted by Stop TB's GDF (including SIAPS-developed regional and country technical advisors and consultants)



## LESSONS LEARNED

- Throughout the SIAPS Project, as countries moved toward UHC, there was a clear need to develop a stronger understanding and support of PSS beyond logistics and medicines availability within the donor community (Global Fund, USAID, Unitaid, WHO). A lot of donor investment was going into global supply mechanisms, such as GDF or the Global Fund's Pooled Procurement Mechanism, that could deliver health commodities to countries, but little was invested in strengthening countries' capacity for medicines governance, proper PSM, pharmaceutical services, monitoring access, medicines use, and patient safety.
- SIAPS TB Core was successful in maintaining PSS issues on the global agenda through global and regional fora, such as the Union World Conferences on Lung Health, global TB working groups, and direct collaboration with WHO and the Global Fund and through building the PSS capacity of USAID-funded country technical advisors.
- A permanent annual global conference for PSS advocacy, best practices and lessons learned exchange, and ongoing global dialogue of technical and opinion leaders with donors and countries is required. Historically, the only global PSS conference was conducted in 2002 with the Bill and Melinda Gates Foundation and USAID funding (facilitated by MSH and KNCV); the conference focused on PSS issues in relation to the establishment of the GDF supply and technical assistance mechanisms and gave a significant boost to sharing best practices and strategies for improving country-level practices. SIAPS conducted three regional PSS-for-TB conferences (two in Africa in 2011 and 2012, one in Europe in 2014), which significantly improved country-level strategies and planning, but global conferences for all key stakeholders were not supported by USAID or donors such as the Global Fund.
- PSS requires an ongoing capacity-strengthening program for all stakeholders, including at the country (NTPs), regional (WHO regional), global (Global Fund, GDF), and technical-agency (KNCV, project HOPE) levels. Such a program should include formal trainings, training of trainers, platforms for knowledge and experience sharing, e-learning, hands-on training, follow-up, and direct technical assistance. SIAPS utilized all these approaches, but was not able to respond to all requests for PSS capacity building due to funding limitations. Challenges also include a fast-changing TB landscape and high turnover of staff at all stakeholders, thereby necessitating a lot of retraining.
- SIAPS' approach for providing rapid-response technical assistance and capacity strengthening for the introduction of new TB tools in priority countries via highly trained regional and country technical advisors proved to be very efficient. USAID TB funding allowed a degree of professional independence for these technical advisors in communicating with NTPs and addressing PSS gaps that other programs did not address. This SIAPS approach was picked up, along with the tools and technical advisors, by Stop TB/GDF and is now being applied for technical assistance to 56 USAID priority countries.
- A functional MIS with a strong early warning capacity is a key prerequisite for PSS interventions. Interventions can be efficiently built upon the introduction and implementation

of tools that structure the collection, validation, and analysis of data and the development of dashboards and information for decision making. Such tools must address data for both patients on specific treatments and medicine stock/availability, as e-TB Manager and QuanTB do. Collection, validation, and analysis of data and the development of management dashboards and information require interventions that permeate and cement all elements of pharmaceutical systems.

## **FUTURE OF PHARMACEUTICAL SYSTEMS STRENGTHENING FOR TB**

TB landscape is rapidly changing after decades of stagnation. New, game-changing molecular rapid diagnostic tools allow fast and precise diagnosis of specific types of TB and drug-resistance patterns, which in turn allow doctors to put their patients on tailored treatment regimens within days of diagnosis. New TB-specific medicines have been recently approved for treatment, and there are more diagnostic and treatment tools in the development and approval pipeline.

These changes multiply treatment options for better outcomes, but at the same time, require more agile and adaptable pharmaceutical systems and holistic approaches to strengthening them. Traditional procurement and supply systems that focus just on product availability may not cater to modern needs of TB control anymore.

Thus, future pharmaceutical systems will be multidimensional, built on constantly evolving modeling that provides decision makers with options for system architecture, tools, how-to guides, finance, hardware and human and resources requirements, built-in capacity development and strengthening tools, and management dashboards. The goal of PSS will be to link people with illnesses to best-practice pharmaceutical services throughout patient pathways—including access to specialized, standard, empirical, and individualized treatments; ancillary care; medicine safety; and palliative care. Key measurements of such PSS will be focused not only on products, but on patient safety and outcomes.

Good pharmaceutical systems will be smart and proactive and will anticipate the needs of the sector, producing models of options based on scientific evidence, experience, and target product and regimen profiles that allow proactive decision-making for rapid uptake and scale-up of new TB medicines and regimens coming out of the development pipeline.

After many years of vertical, donor-driven PSM systems for TB, there is a clear tendency at the country level for the integration of disease-specific pharmaceutical services into one agile and flexible pharmaceutical system. This is also reflective of a change in donor understanding of PSS needs and growing PSS investments, e.g. as defined in the Global Fund Strategy for Building Resilient and Sustainable Systems for Health.

PSS will include the development platforms for accessing best practices and models and obtaining rapid expert assistance, both virtual and hands-on.

## ANNEX 1. SIAPS TB CORE FUNDING 2012-2017

The SIAPS TB Core PY1-PY6 funding came from several USAID sources as illustrated below, with a total of \$16,250,000:

<b>Funding level</b>							
<b>USAID funding stream</b>	<b>PY1 (FY11)</b>	<b>PY2 (FY12)</b>	<b>PY3 (FY13)</b>	<b>PY4 (FY14)</b>	<b>PY5 (FY15)</b>	<b>PY6 (FY16)</b>	<b>Total funding</b>
<b>TB Core</b>	2,300,000	3,400,000	0	3,200,000	3,000,000	500,000	12,400,000
<b>TB/HIV add-on</b>	0	0	1,700,000	0	0	0	1,700,000
<b>TB PV</b>	0	0	0	0	2,000,000	0	2,000,000
<b>HIV</b>	0	150,000	0	0	0	0	150,000
<b>Total</b>	2,300,000	3,550,000	1,700,000	3,200,000	5,000,000	500,000	16,250,000

## ANNEX 2. SIAPS PROGRAM INDICATOR RESULTS BY PROGRAM IR AREA

Indicator	Baseline		End of PY indicator values						End-of-project target
	Value	Year	PY1	PY2	PY3	PY4	PY5	PY6	
<b>IR 1: Pharmaceutical sector governance strengthened</b>									
# of instances that USG-funded activities provided technical leadership to global TB efforts (USAID)	0	2011	12	16	12	14	11	2	12
% of SIAPS priority countries with prescription guidelines in line with WHO recommendations	0	2013	-	-	50%	70%	100%		100%
<b>IR 2: Capacity for pharmaceutical supply management and services increased and enhanced</b>									
# of participants trained in the components of the WHO STOP TB strategy with USG funding (# of persons trained in pharmaceutical management for TB) (USAID)	0	2011	1,521	448	692	388	706		2,000
# of SIAPS-supported local institutions or organizations providing training or technical assistance in pharmaceutical management	0	2013	-	-	32	32	32		12
# of e-learning pharmaceutical management programs developed with SIAPS assistance	0	2011	-	-	1	1	1		1
# of STOP TB partners utilizing SIAPS-developed training materials and tools for capacity development	0	2011	4	4	5	5	5		4
# of technologies under development (USAID)	0	2011	7	7	6	5	4	3	7
# of full-time SIAPS in-country consultants and regional advisors (against planned and budgeted for)	0	2013	-	-	3	4	7	-	6
<b>IR 3: Utilization of information for decision-making increased</b>									
# of countries with SIAPS-developed functional Pharmaceutical Management Information Systems that support both product and patient information	0	2011	9	10	11	12	13	-	12
# of instances of interventions being introduced or expanded in countries (USAID)	0	2011	18	30	50	58	63		16
% of priority countries that have adopted QuanTB via SIAPS support (or have other functioning system in place) and data are available	0	2013	-	-	40%	90%	90%		100% (10/10)
% of priority countries that have submitted at least 1 QuanTB (and/or GDF-type) quarterly report in the past 6 months	0	2013	-	-	40%	90%	90%		100% (10/10)
# of research/info gathering instances (USAID)	0	2013	-	-	12	17	9	3	10
# of countries using SIAPS-developed tools to regularly monitor the availability of essential TB medicines	0	2015	-	-	-	-	14	26	12

*Annex 2. SIAPS Program Indicator Results by Program IR Area*

Indicator	Baseline		End of PY indicator values						End-of-project target
	Value	Year	PY1	PY2	PY3	PY4	PY5	PY6	
<b>IR 5: Pharmaceutical services to achieve desired health outcomes improved</b>									
# of facilities in pilot countries where TB-HIV adverse drug reaction active surveillance is implemented	0	2011	-	-	5	5	5		5
% of priority countries without stock-outs at the central level	0	2014	-	-	100% (4/4)	66.67% (6/9)	72.73% (8/11)		100%
# of countries with SIAPS-supported TB patient safety measures in place	0	2013	-	-	4	4	5		6
# of countries that received SIAPS assistance to start patients on Bdq through USAID/Janssen Bedaquiline Donation Program	0	2015	-	-	-	-	7		5
# of SIAPS-supported priority countries reporting SAEs to global repository	0	2015	-	-	-	-	3		5

### ANNEX 3. IMPLEMENTATION PARTNERS

Implementing partner	Activity	PY1	PY2	PY3	PY4	PY5	PY6
<b>IR 1: Pharmaceutical sector governance strengthened</b>							
Stop TB/GDF	GDF management and operations strengthened ISO certification maintained PSM capacity built Uptake of SIAPS tools (QuanTB) improved Forecasting, quantification, supply planning, early warning processes instituted	X	X	X	X	X	X
WHO	DR-TB treatment guidelines updated by TB Guideline Development Group Global Task Force on Digital Health instituted Policy implementation package developed by Task Force on the Introduction of New TB Tools Evidence for new MDR-TB guidelines developed New DR-TB guidelines reviewed PSM perspective contributed to Global DR-TB Initiative	X	X	X	X	X	X
Global Fund	Sourcing and market shaping meetings held			X	X	X	
PAHO	Uptake of SIAPS tools (QuanTB) for streamlining PSM for the region improved			X	X		
Union	Best practices and tools shared through workshops, symposia, and poster sessions	X	X	X	X	X	X
Regional WHO offices, Global Fund, KNCV, Stop TB/GDF, NTPs	SIAPS-led global and regional conferences on management of TB medicines held	X	X	X	X	X	X
TB Alliance	Market and country preparedness survey for the introduction of new TB pediatric formulations created			X	X	X	
ECSA HC	TB commodities management and dashboard developed			X	X		
<b>IR 2: Capacity for pharmaceutical supply management and services increased and enhanced</b>							
WHO	Training sessions on pharmaceutical management for TB and introduction of new TB tools held (Cepina, Italy) for international consultants	X	X	X	X	X	
Global Fund	Training of Global Fund portfolio managers on forecasting, quantification, and supply country planning and monitoring based on QuanTB held			X	X	X	
GDF and WHO regional offices	Regional and country SIAPS workshops held	X	X	X	X		
NTPs	Country trainings held						
<b>IR 3: Utilization of information for decision-making increased</b>							
Primary health care	e-TB Manager implemented in Armenia	X					

*Annex 3. Implementation Partners*

<b>Implementing partner</b>	<b>Activity</b>	<b>PY1</b>	<b>PY2</b>	<b>PY3</b>	<b>PY4</b>	<b>PY5</b>	<b>PY6</b>
reform, Abt Associates							
MSF	e-TB Manager implemented in Armenia	X					
WHO	e-TB Manager implemented in Bangladesh	X	X				
TB Care-KNCV, HIPA Project, Palladium	e-TB Manager implemented in Cambodia	X					
TB Care 1 and Challenge TB, KNCV	e-TB Manager implemented in Nigeria, Indonesia, and Vietnam	X	X	X	X	X	
USAID's Strengthening TB Control in Ukraine, Chemonics	e-TB Manager implemented in Ukraine	X					
GDF	QuanTB (as GDF's standard tool) implemented and used	X	X	X	X	X	X
KNCV	QuanTB implemented and staff trained in 7 KNCV-Lilly MDR-TB Foundation-supported countries			X	X	X	
Global Fund	QuanTB introduced as the Global Fund HQ tool for country portfolio managers			X	X		
<b>IR 5: Pharmaceutical services and access to TB products to achieve TB goals improved</b>							
Hamdard University School of Pharmacy	Private sector research study in Pakistan performed Private pharmacies capacity for TB referrals built			X	X	X	
GDF	GDF monitoring and technical assistance missions conducted	X	X	X	X	X	
Accredited drug dispensing outlets	Outlets in Tanzania established	X	X	X			



#### **ANNEX 4. STAKEHOLDERS THAT SIAPS COLLABORATED WITH DURING PY1-PY6**

TB Alliance  
GDF  
Global Fund  
WHO  
USAID  
Unitaid  
CHAI  
MSF  
Partners in Health  
KNCV  
Lilly MDR-TB Foundation  
Hamdard University School of Pharmacy