

Republic of Zambia

FY2016 Ex-Post Evaluation of Technical Cooperation Project (SATREPS<sup>1</sup>)

“Establishment of Rapid Diagnostic Tools for Tuberculosis and Trypanosomiasis and Screening of Candidate Compounds for Trypanosomiasis”

External Evaluator: Miho Kawahatsu, OPMAC Corporation

## 0. Summary

The objective of this project is to perform the research and development needed for a rapid diagnostic method for sustained use in identification of tuberculosis (TB) and trypanosomiasis,<sup>2</sup> and screening of candidate compounds for improvement of the treatment of trypanosomiasis, in Zambia. The diseases of concern, TB, and Trypanosomiasis, one of the Neglected Tropical Diseases (NTDs), are assigned high importance in Zambia’s national development plans, and in the field of public health, they have had consistently high priority in health-related policies. Further, both infectious diseases are hence of great concern in connection with the issue of public health, and there has been a consistent need for rapid and accurate diagnosis in order that it can be controlled and treated is amply evident. In addition, concerning Japanese development assistance policy, this project is consistent with the public health concerns addressed in the Japanese Assistance Program for Zambia, Japan Action Plan in Combating Infectious Diseases in Africa, and the Tokyo International Conference on African Development (TICAD). Thus, relevance is high. Regarding effectiveness, it is believed that the project achieved advances in the capability for research and development needed for rapid diagnosis, but because no actual activities were implemented on the screening of candidate compounds for the treatment of trypanosomiasis, this latter objective was not achieved. Concerning impact, while work on improvement of a rapid diagnostic method is being continued in the laboratory of implementing agencies, progress has not been made in obtaining official approval of the method<sup>3</sup> by the Ministry of Health (MOH). However, because there has not been an overall goal assigned to this project, this has not been used in the evaluation of impact. As collateral impacts, research

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<sup>1</sup> Science and Technology Research Partnership for Sustainable Development.

<sup>2</sup> Trypanosomiasis is a zoonotic disease, common to cattle, sheep and other animals as well as humans, and development of diagnostic techniques and therapeutic drugs for it are lagging compared to other infectious diseases. The protozoa causing the disease is parasitic, and transmitted by the tsetse fly. It is found in 36 African countries and it is thought that 50,000,000 persons are at risk of contracting the disease. Infection causes lymph node swelling, hepatosplenomegaly, headaches, deteriorating consciousness, lethargy, and anemia, and physical weakening through these effects can cause death. Many cases have been reported of misdiagnosis of malaria as having caused superinfection. Because this project targeted trypanosomiasis in human, the disease is properly called Human African Trypanosomiasis (HAT). In Africa, two parasites in different regions have been identified as the cause; in eastern and southern Africa including Zambia, following infection with the parasite *Trypanosoma brucei rhodesiense* the disease spreads to the nervous system, causing acute symptoms. As the project is concerned with trypanosomiasis in humans, it is called “trypanosomiasis” here.

Source: [http://www.who.int/trypanosomiasis\\_african/country/HAT\\_rh\\_2014.png?ua=1](http://www.who.int/trypanosomiasis_african/country/HAT_rh_2014.png?ua=1).

<sup>3</sup> By international and/or national laboratory or public research institute in the fields of analytic chemistry and microbiological culturing, a method corresponding to or equal to specifications for qualitative analysis, quantitative analysis, culture and detection of microorganisms is determined as standard.

Source: [https://www.jica.go.jp/topics/notice/20150318\\_01.html](https://www.jica.go.jp/topics/notice/20150318_01.html).

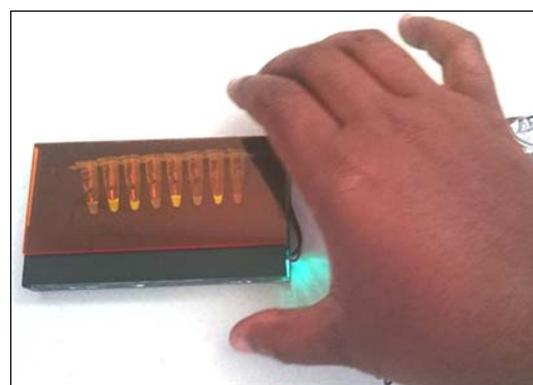
achievements have been made by the University of Zambia School of Veterinary Medicine (UNZA-SVM), that the World Bank has designated as a center for advanced education in zoonotic diseases prevalent in Eastern and Southern Africa. It is expected to contribute to the advancement of education and research, and to the expansion of international collaborative research efforts in the center. Thus, the effectiveness and impact of the project are judged to be fair. Because the project was completed within the planned time frame and budget, it is judged to be highly efficient. As for sustainability, while the necessary policy and institutional measures for the continuation of the effect of the project are assured, there are issues remained in terms of organizational technical, and financial matters to specifically engage the utilization of research outcome in this project so that its sustainability is evaluated as fair.

In light of the above, this project is evaluated to be satisfactory.

## 1. Project Description



Project Location



A Rapid Diagnosis Toolkit (RDT)  
developed by the project

### 1.1 Background

There has been a grave concern about the resurgence of TB as a superinfection accompanying the increase in the number of people with HIV/AIDS, and the rampancy of hard-to-treat multidrug-resistant and extensively-drug-resistant TB in Zambia and other African nations. Besides, as infection with TB transmitted to humans from animals has been widely reported in Africa, the transmitting path of the pathogen has been important to unravel to develop an effective control of TB as a zoonosis disease.

Moreover, malaria is the most serious disease affecting Zambia, and trypanosomiasis, a protozoan infection<sup>4</sup>, is often diagnosed as malaria that has symptoms similar to those of that disease, delaying treatment of trypanosomiasis; once the pathogen has spread to the spinal cord the situation is extremely serious and likely to cause death. The drug generally used to treat

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<sup>4</sup> Infectious disease caused by protozoa, including trypanosomiasis and borreliosis, brucellosis, and leptospirosis. Many of these are zoonosis diseases.

trypanosomiasis contains an organic arsenical compound, that has side effects that can be grave in the case of extremely ill patients, so that there is a need for a safer drug for treating this disease.

This project is a joint-research attempt to apply a high-sensitive as well as simple Loop-Mediated Isothermal Amplification (LAMP)<sup>5</sup> technique for diagnosis of TB and trypanosomiasis, for development of a sustainable method of rapidly diagnosing trypanosomiasis that can be used in rural Zambia, and, at the same time, to discover a candidate compound for improvement of the medication used to treat trypanosomiasis. The project also had the purpose of enhancing the research and development capabilities of UNZA-SVM and the University Teaching Hospital (UTH), the University of Zambia.

This project has been adopted as an undertaking in the SATREPS program and was implemented with participation by the Japan Science and Technology Agency (JST)<sup>6</sup> and the Japan International Cooperation Agency (JICA). This program is to promote joint research with developing countries on global issues such as the environment, energy, disasters, and on measures to combat infectious disease, with the associated objective of contributing to the improvement of the capabilities of those institutions.

## 1.2 Project Outline

At the time of the ex-ante evaluation, preparation of a Project Design Matrix (PDM) was not required for SATREPS projects, but for this project, with the exception of an overall goal, project purpose, outputs, and indicators were specified and set for agreement with the implementing agencies. At the time of the mid-term review, the timing of achievement of output was specified by the PDM thereby agreed by the implementing agencies. Thus the ex-post evaluation was done on the basis of the PDM of the mid-term review. In the ex-post evaluation, ascribing the contents of the lessons learned reported at the time of the terminal evaluation, to the basis of shared views of related personnel, the status of the overall goal was provisionally taken as of the “expected impact” and it was verified accordingly. However, as above mentioned, because no overall goal was agreed on with implementing agencies achievement status of “expected impact” is not used in evaluation judgment.

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<sup>5</sup> For this project, the RDT was developed based on the LAMP method patented by the Eiken Chemical Co., Ltd.. LAMP uses loop isothermal amplification of DNA. It does not require special equipment, and easily facilitates the speed of amplification of target genes. This genetic testing method for TB developed by the company was recognized by the WHO in 2016.

Source: <http://apps.who.int/iris/bitstream/10665/249154/1/9789241511186-eng.pdf>.

<sup>6</sup> The Japan Agency for Medical Research and Development (AMED) was established in April 2015 and from fiscal 2015 onward AMED has replaced JST to be the counterpart of JICA in work related to infectious diseases in the SATREPS program.

Overall Goal	Not specified	
Project Purpose	Research and development capacity of Zambian research institutes for rapid diagnostic tools and screening of candidate compounds for new drugs for trypanosomiasis are improved through collaborative research activities	
Output(s)	Output 1	Rapid diagnostic tools including a drug susceptibility test (DST) for tuberculosis to be developed as methods for practical use in laboratories in Zambia
	Output 2	A rapid diagnostic tool for trypanosomiasis is developed as a method for practical use in laboratories in Zambia
	Output 3	Candidate compounds for non-clinical trials are produced with diversity-oriented synthesis method for trypanosomiasis
	Output 4	Research system for the development of rapid diagnostic systems for tuberculosis and trypanosomiasis and screening of compounds for new drugs for trypanosomiasis are streamlined
Total cost (Japanese Side)	332 million yen	
Period of Cooperation	November 2009-November 2013	
Implementing Agency	Ministry of Health (MOH) / the University of Zambia School of Veterinary Medicine (UNZA-SVM) / University Teaching Hospital (UTH)	
Supporting Agency/Organization in Japan	Supporting Organization in Japan: Hokkaido University, Cooperating Institution: Tottori University	
Related Projects	<p><u>Technical Cooperation Project</u> [UTH]</p> <ul style="list-style-type: none"> <li>• The University of Zambia, School of Medicine Project (1980-1989)</li> <li>• Infectious Diseases Project (1989-1995)</li> <li>• Infectious Diseases Control Project (1995-2000)</li> <li>• HIV/AIDS and Tuberculosis Control Project (2001-2006)</li> </ul> <p>[UNZA-SVM]</p> <ul style="list-style-type: none"> <li>• The University of Zambia: Veterinary Education Project (I) (1985-1992)</li> <li>• The University of Zambia: Veterinary Education Project (II) (1992-1997)</li> <li>• Project for Surveillance of viral zoonoses in Africa (2013-2018)</li> </ul> <p><u>Grant Aid</u> [UTH]</p> <ul style="list-style-type: none"> <li>• Project for Improvement of the Department of Pediatrics and Child Health of the University Teaching Hospital (January 1996)</li> <li>• The Project for the Improvement of the Medical Equipment of the University Teaching Hospital (December 2009)</li> </ul> <p>[UNZA-SVM]</p> <ul style="list-style-type: none"> <li>• Construction of The School of Veterinary Medicine at the University of Zambia (for building construction G/A in August 1983, for ancillary facilities and main equipment G/A in July 1984)</li> </ul>	

	<p><u>Other Japanese institutions</u></p> <p>Ministry of Education, Culture, Sports, Science and Technology, Japan (MEXT)</p> <ul style="list-style-type: none"> <li>➤ Program of Founding Research Centers for Emerging and Reemerging Infectious Disease (2005-2009) <ul style="list-style-type: none"> <li>• Hokkaido University Center for Zoonosis Control in Zambia (collaboration with UNZA-SVM)</li> </ul> </li> </ul> <p>MEXT/ Japan Agency for Medical Research and Development (AMED)</p> <ul style="list-style-type: none"> <li>➤ J-GRID<sup>7</sup>: Japan Initiative for Global Research Network on Infectious Diseases (2010-2014) <ul style="list-style-type: none"> <li>• International collaborative research for zoonosis control (Joint research with UNZA-SVM)</li> </ul> </li> <li>➤ International Collaborative Research Program for Tackling the NTDs (Neglected Tropical Diseases) Challenges in African countries (2015-2020) <ul style="list-style-type: none"> <li>• Establishment of the model for controlling neglected tropical diseases based on the development of rapid diagnostic methods and risk analysis<sup>8</sup> (collaboration with UNZA-SVM)</li> </ul> </li> </ul>
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### 1.3 Outline of the Terminal Evaluation

#### 1.3.1 Achievement Status of Project Purpose at the Terminal Evaluation

On the basis of achievement status of outputs at the Zambian research centers at the time of the terminal evaluation, the judgment was that project purpose would be achieved in that research capabilities for a rapid diagnostic method for TB and Trypanosomiasis had been improved, except for screening of a candidate compound for the treatment of trypanosomiasis. During the project implementation, Zambian researchers benefited from their work done for the project and from training received in Japan, thereby adding to their knowledge and skills. Equipment provided as part of the project was fully utilized, and results of the research were made available to others through international scientific meetings and other means, indicating that research capability had been improved.

#### 1.3.2 Achievement Status of Overall Goal at the Terminal Evaluation (Including other impacts)

In view of this project not having specified an overall goal, and at the time of terminal evaluation merely “scientific output” was insufficient, a practical or tangible product had been sought. As such, at the time of terminal evaluation, the following three points have been taken as representing expected impact with the outlook for achievement. Although the status of

<sup>7</sup> J-GRID is an international research program for infectious diseases control and strategic framework for reinforcement by Japan Agency for Medical Research and Development (AMED).

<sup>8</sup> This research project of Hokkaido University, adopted by the international joint research program, is concerned with trypanosomiasis and Hansen’s disease, and has the status of being largely a follow-up and most relevant undertaking of the project. As the cause of Hansen’s disease, mycobacterium leprae is closely related to that of TB, developments in research on TB are known to be relatively easily applicable to Hansen’s disease.

achievement should be duly reconfirmed at the time of the ex-post evaluation based on the outlook for achievement at the time of terminal evaluation, it was not considered in determining the sub-rating or overall evaluation.

#### **Practical use of the LAMP Tuberculosis Rapid Diagnostic Tool (LAMP-TB RDT)**

On the basis of scientific evidence of sensitivity and specificity, a swift, accurate, easy-to-use, low-cost Point of Care (POC)<sup>9</sup> was developed by improving the testing for diagnosis applicable in rural Zambia where there are many suspected infections. However, as test results using a preprocessing method for sputum were still numerically low, it was recommended to continue tests after project completion, in order to accumulate scientific evidence of the efficacy of the diagnosis performance.

#### **Practical use of the LAMP Trypanosomiasis Rapid Diagnostic Tool (LAMP-Tryps RDT)**

LAMP-Tryps RDT had already been in use for diagnosis of trypanosomiasis, as in the case of TB, it was recommended that tests would continue after the project completion, in order to acquire scientific evidence of the tool's value.

#### **Other impact**

Through the development of drug susceptibility testing in TB during this project, a discovery was made of drug-resistance the tubercle bacillus that was expected to have a positive impact in optimizing TB treatment. Further, both LAMP-TB RDT and LAMP-Tryps RDT were intended to be developed as methods for diagnosing disease in humans. It was deemed to be possible that it can be applied also in surveillance of animal disease conducted at UNZA-SVM.

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<sup>9</sup> Defined as an examination at a medical and health care facility at the home or nearby to it. Rapid diagnosis at such examinations facilitates early treatment of disease, and help prevent infections.

### 1.3.3 Recommendations from the Terminal Evaluation

<b>Use of the target Two RDTs in the project as national standards</b>	
Zambia MOH	The MOH, together with UTH, UNZA, and other relevant institutions, should prepare and implement an action plan for approving the RDTs as national standards and putting them into practical use to serve the entire population.
<b>Detection and reporting of cases of trypanosomiasis</b>	
Zambia MOH	The MOH should enhance training of health care workers, raise awareness of residents, and strengthen the surveillance system for better detection and reporting of the cases of trypanosomiasis.
<b>Identification of candidate compounds for a new drug of Trypanosomiasis</b>	
Hokkaido Univ. and UNZA-SVM	With regard to how to carry out collaborative research on the subject after the project completion, the details of collaboration should be discussed thoroughly between Hokkaido University and UNZA-SVM.
<b>Budget for the BSL-3<sup>10</sup> laboratory</b>	
Zambia MOH	The necessary budget for using and maintaining the BSL-3 laboratory must be continuously secured by the Government of Zambia. The MOH should take note of the need to utilize it for detection and diagnosis if and when serious infectious diseases emerge, and prioritize budget allocation to the laboratory in the annual budget formulation process.
<b>Further academic development of Zambian researchers</b>	
Related Ministries (MOH, Ministry of Higher Education, Ministry of Agriculture and Livestock, etc.)	In order for Zambian researchers to sustain the outputs of the project after the project completion, relevant ministries should consider providing opportunities for Zambian researchers at UTH and UNZA-SVM to obtain degrees at the graduate school level.

## 2. Outline of the Evaluation Study

### 2.1 External Evaluator

Miho KAWAHATSU, OPMAC Corporation

### 2.2 Duration of Evaluation Study

This ex-post evaluation study was conducted within the following schedule.

Duration of the Study: September 2016 to January 2018

Duration of the Field Study: January 29, 2017 to February 14, 2017

May 21, 2017 to May 30, 2017

<sup>10</sup> An abbreviation of Bio-Safety Level 3, that is also referred to as physical containment (P3). Depending on the risk level at the relevant pathogen there are four levels for the specifics of facilities handling it. WHO guidelines are very strict for levels 3 and 4; handling in an enclosed environment is required.

### 3. Results of the Evaluation (Overall Rating: B<sup>11</sup>)

#### 3.1 Relevance (Rating: ③<sup>12</sup>)

##### 3.1.1 Consistency with the Development Plan of Zambia

At the time of the ex-ante evaluation, measures to counter TB had high priority in the health policy of the Fifth National Development Plan (FNDP; 2006-2010) adopted in 2006. Further, on the basis of the specific purpose of the National TB Control Programme (NTP), various measures were taken, notably by means of Directly Observed Treatment, Short course (DOTS),<sup>13</sup> measures for drug-resistant TB, and superinfections with HIV/AIDS, and support for research and development. Regarding trypanosomiasis, one of the NTDs, similar to instances of other parasitic diseases, measures for diagnostic techniques and therapeutic drugs were lagging and were on the priority agenda in the FNDP mentioned above.

At the time of project completion, among the objectives of the Sixth National Development Plan (SNDP, 2011-2015), improvement of the people's access to TB care was included in the strategy for "supply of highly cost-effective, high-quality health and medical care services." Further, as quantified targets in the National Health Strategic Plan (2011-2015), the government called for diagnosis of 70% of all persons suffering from TB, and target cure rate should be 85% of those diagnosed. Further, it was reported that in the southwestern regions of Zambia the incidence rate of trypanosomiasis was deemed to be as high as 25%. To tackle this, it was mentioned to reduce the incidence rates of major NTDs as its strategic target. Also, epidemiological mapping and improvement of clinical management and training for disease prevention of health care workers were covered as a part of the strategy in Zambia.

From the above, it is evident that the strategic priority of TB programs, and the needs of related research and development, are consistently high. Also in the case of trypanosomiasis, although no quantitative target was set, it presents a serious problem in that the disease is misdiagnosed as malaria especially in rural areas where there are few medical facilities. Further, there have been reports of incidence of the disease not only in Zambia but also in neighboring countries, making it imperative to take an international approach as the region-specific disease.

From the time of the ex-ante evaluation to project completion, TB and NTDs have been high-priority agenda in Zambia's national development plans, so this project is highly consistent with Zambia's national policy.

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<sup>11</sup> A: Highly satisfactory, B: Satisfactory, C: Partially satisfactory, D: Unsatisfactory.

<sup>12</sup> ③: High; ②: Fair; ①: Low.

<sup>13</sup> DOTS, refers to the overall therapeutic strategy for TB (for 2006-2015) as indicated by the WHO as necessary for strengthening the national public health system. (the Japan Anti-Tuberculosis Association; Source: [in Japanese] <http://www.jata.or.jp/rit/rj/gtc99.html>)

### 3.1.2 Consistency with the Development Needs of Zambia

At the time of the ex-ante evaluation TB was spreading in Africa as an opportunistic infection accompanying the spread of HIV/AIDS, and in Zambia, in particular, the HIV/AIDS infection rate of TB patients was 70% -- a serious issue of public health. As for trypanosomiasis, although the number of patients was low relative to TB, in rural areas the potential number of sufferers of the disease was believed to be high. Thus, trypanosomiasis was one of the NTDs, characterized by lagging development and use of diagnostic techniques and therapeutic medicine. Further, need for the development of a high-specificity method of diagnosis of the disease was particularly high because of a high rate of misdiagnosis of other parasitic diseases.

At the time of the project completion, as well superinfection of TB and HIV/AIDS was recognized as a serious problem in Zambia, and need was perceived for a method of rapid diagnosis that could be used as a POC testing at local laboratories in the rural regions. Further, because of failure to administer or take proper dosages for TB patients undergoing treatment, the danger of multi-drug-resistant TB and super-multiple-resistant TB would emerge. Thus, development of a simple, easy-to-use test for drug susceptibility was also needed. Regarding trypanosomiasis, one of the NTDs, existing method of diagnosis was sputum smear microscopy, but this often resulted in misidentification of another disease-causing parasite such as malaria. In addition, there had been limited drug options, because the side effect of using a conventional drug-containing organic arsenical compound was oftentimes too severe to continue the treatment, there was an urgent need for the development of an effective, safer new drug for it.

From the time of the ex-ante evaluation to project completion, drug-resistance of TB patients became more serious and the importance of a method of accurate and rapid diagnosis was consistently high as a result of increased superinfection of HIV/AIDS patients, while in the case of trypanosomiasis although the number of cases was low relative to the incidence of TB, as morbidity was highly concentrated in rural areas, the cause of infection was difficult to accurately determine, and the disease was often misdiagnosed as malaria. These conditions indicate that there had been a high development need for acquiring and using a method of accurate and rapid diagnosis, that could enable better control and treatment of the disease.

### 3.1.3 Consistency with Japan's ODA Policy

In the Country Assistance Program for Zambia, issued in October 2002, improving the cost-benefit ratio and the high quality of health and medical services was a priority area for address control of infectious diseases. Notably, TB was one of the cross-cutting issues from perspectives of the nation's human resources and social capital. Further, in June 2005, the Japanese government announced the Health and Development Initiative (HDI) in the context

of which the Action Plan in Combating Infectious Disease in Africa was formulated as a specific plan for assistance in May 2006, and this led to the promotion of concrete measures for combating Africa's three major infectious diseases and parasitic issues through South-South or Asia-Africa cooperation. Further, at the TICAD IV conference in May 2008 and after that the Toyako Summit, it specifically identified the need for TB countermeasures, as well as support for fighting NTDs. Therefore, at the time of the ex-ante evaluation, the project was consistent with Japanese development assistance policy.

From the above, the implementation of the project is judged to be highly consistent with development policy of Zambia, its public health and public health development needs, and Japanese development assistance policy. Thus, the relevance of the project is high.

### 3.2 Effectiveness and Impact<sup>14</sup> (Rating: ②)

#### 3.2.1 Effectiveness

##### 3.2.1.1 Project Output

As a result of compilation of answered questionnaires and examination of information obtained at hearings at the implementing agencies, the status of achievements at project completion was found to be as follows.

#### **< Output 1. Rapid diagnostic tools including drug susceptibility test (DST) for tuberculosis and developed as methods for practical use in laboratories in Zambia. >**

Successfully achieved in terms of introducing a technique of drug susceptibility testing at UTH. Although actual use of a rapid diagnostic method has been introduced, at the time of project completion, a result of comparative testing of the method suggested a need for further study, development of a practical-use method was not completed. It is noteworthy, in connection with the introduction of BSL-3 that was added to the research plans during the project, that UTH established a system for TB testing by a bio-safety standard manual drafted on schedule. Therefore, it is judged that Output 1 was mostly achieved.

#### **< Output 2. A rapid diagnostic tool for trypanosomiasis is developed as a method for practical use in laboratories in Zambia. >**

During the project implementation, the effectiveness of LAMP-Tryps RDT was verified and developed as a practical method; thus, Output 2 is judged to be achieved.

#### **< Output 3. Candidate compounds for non-clinical trials are produced with diversity-oriented synthesis method for trypanosomiasis. >**

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<sup>14</sup> Sub-rating for Effectiveness is to be made with consideration of Impact.

UNZA-SVM has a chemical library of candidate compounds and is in the process of registering additional candidate compounds, but because no compound has yet been found to be sufficiently active in the stage *in vitro* prior to non-clinical trial *in vivo*, the tests have not been performed. Output 3 thus was not achieved.

**< Output 4. Research system for the development of rapid diagnostic systems for tuberculosis and trypanosomiasis and screening of compounds for new drugs for trypanosomiasis are streamlined. >**

Apart from the Standard Operation Procedures (SOP) for the screening of candidate compounds for the treatment of trypanosomiasis, both UNZA and UTH have introduced, implemented, and put in place SOP for rapid diagnostic tools for TB and trypanosomiasis. It is recognized that through project implementation, research management capability has improved and is anticipated to contribute to effective performance in following research projects and daily research tasks. Therefore, Output 4 was mostly achieved.

3.2.1.2 Achievement of Project Purpose

At the time of the ex-post evaluation, having reexamined outputs of the project their relations to the project purpose are shown in Fig. 1. Regarding the project purpose of developing a rapid diagnostic tool for TB and trypanosomiasis, respectively, judgment was made based on the achievement status of Outputs 1, 2 and 4. Regarding development of a drug to treat trypanosomiasis, achievement was judged on the basis of Output 3 and the existence of Standard Operating Practices (SOP) related to its pertinent part of Output 4.

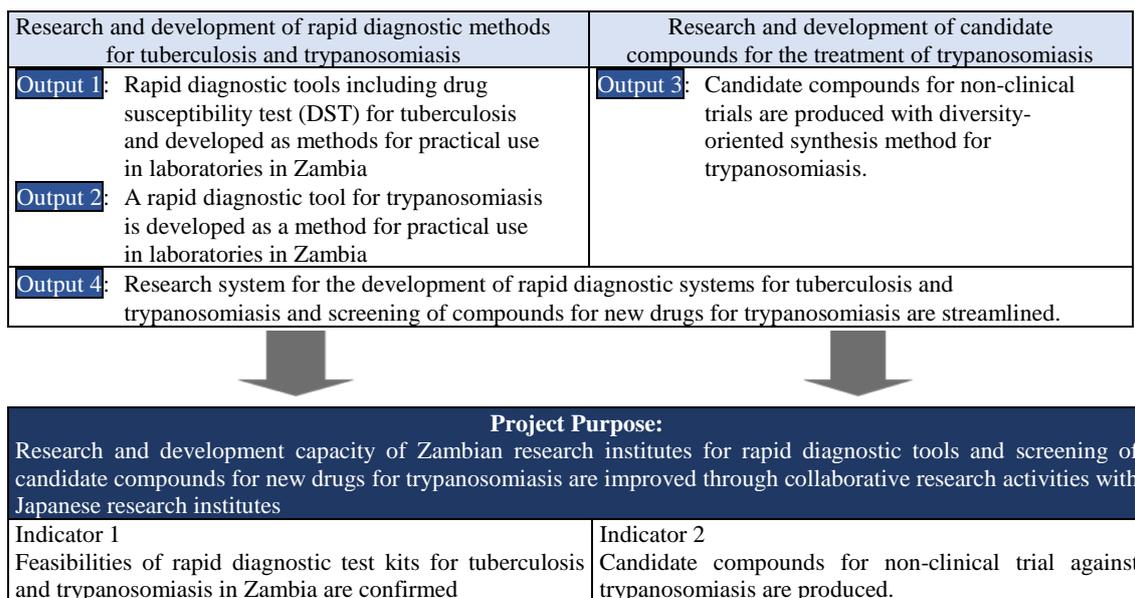


Figure 1: Relationship Diagram of Each Output and its Project Purpose of the Project

As for research activities for Indicator 2 it was confirmed at the time of hearings at UNZA-SVM that this component of the research was planned as a two-step process of screening whereby research at Hokkaido University was supposed to identify candidate compounds that can show anti-trypanosomal activity that was proved to be effective and safe *in vitro*, and then as a basis of the result, UNZA-SVM was to conduct further screening by using an animal model to ascertain activity and cytotoxicity of the candidate compounds *in vivo*. The results of JST-supported research conducted in Japan were on a critical path for determining whether it was possible to do further research in Zambia. Therefore, research activities in Zambia of this matter were inevitably postulated by reference to the result of preceding research in Japan. It was therefore considered inadequate to evaluate this component on a par with the achievement status regarding the development of rapid diagnostic methods.

Therefore, in this evaluation, in judging the achievement of the project purpose, the emphasis was given to the status of the rapid diagnostic methods as noted in Indicator 1, in view of the research activity that has taken place, and the outlook for an early contribution of the utilization of research outcome to countermeasures for infectious disease.

Table 1: Achievement of Project Purpose

Project Purpose	Indicator	Actual
Research and development capacity of Zambian research institutes for rapid diagnostic tools and screening of candidate compounds for new drugs for trypanosomiasis are improved through collaborative research activities with Japanese research institutes	1. Feasibilities of rapid diagnostic test kits for tuberculosis and trypanosomiasis are confirmed	<p>◆ Accomplished by project completion</p> <p>&lt;LAMP-TB RDT&gt;</p> <ul style="list-style-type: none"> <li>• The reagent for the RDT proposed by this project was inexpensive, at 1USD, and it did not require a large investment in production equipment, so this was financially better than the existing method.</li> <li>• The detection rate was about 40% higher than in the case of smear microscopy, due to its higher sensitivity</li> </ul> <p>&lt;LAMP-Tryps RDT&gt;</p> <ul style="list-style-type: none"> <li>• Practicality was confirmed with respect to technical and cost aspects.</li> <li>• Because susceptibility was higher relative to the conventional parasitological methods, the detection rate of infection got higher.</li> <li>• The test results got more stable relative to those from conventional microscopy.</li> </ul>
	2. Candidate compounds for non-clinical trial against trypanosomiasis are produced.	<p>◆ Not accomplished by the project completion</p> <p>Because progress regarding the identification of compounds targeted in the project was not observed, no substantial research activity was done.</p> <p>◆ Issues remained at the project completion</p> <p>There was a necessity to replicate evaluation of the candidate compound for non-clinical testing using infected mice and undertake evaluations of efficacy and safety in infected animals in UNZA-SVM, but by the time the project was completed no compound had been identified as being effective and safe at Hokkaido University.</p>

As shown in Table 1, by the time of project completion, improvement of research and development capabilities was achieved through the work done on rapid diagnostic methods for the two diseases, TB and trypanosomiasis, but with regard to the component of screening candidate compounds for trypanosomiasis treatment, it was not achieved as no related research activity was conducted in Zambia, because in preceding research in Japan, it was impossible to discover any compounds that could considerably show anti-trypanosomal activity.

As indicated above, the project purpose was partially achieved.

### 3.2.2 Impact

As stated above in 1.2, Project Outline, evaluation was attempted making reference to the content regarding lessons learned as given in the terminal evaluation and the understanding shared by related personnel, with the external evaluator using “expected impact” as a substitute for the overall goal and used the manifestation of impact according to information obtained during field research for the evaluation. Since an overall goal was not set in this project, the degree to which the “expected impact” was achieved was not included in the evaluation judgment.

According to the above-mentioned lessons learned SATREPS projects, in addition to obtaining scientific results from the implementation of research and development are also to seek utilization of research outcome as an overall goal or expected impact; that is, it is to aim at yielding some sort of practical result. However, in the planning stage for the project, it was difficult to forecast the duration of time needed for verification and a validation period during the research and development phase, or for producing a tangible result, thus, at the time of the ex-post evaluation scheduled to be carried out three years after project completion, likewise, it made it difficult to make a judgment on whether it is possible to judge the impact to the extent of being validated as an overall goal. Moreover, in the actual process of utilization of research outcome, it may require, in addition to the implementing agency, participation by the government and the private-sector which are outside of the research institute, in such a transition phase.

As stated in 1.2, Project Outline, there was no overall goal assigned to this project. Nevertheless, the project was implemented in a consistent manner with the need for future utilization of research outcome in mind, and with awareness of the intent of realization of rapid diagnostic methods that could be available to TB and trypanosomiasis patients at medical facilities close to their homes, and the intent of developing a new therapeutic preparation for trypanosomiasis. Further, it was presumed that subsequent to project completion, the actual application of the RDTs for TB and trypanosomiasis will take place throughout the nation and that a discovery of candidate compounds will contribute to the development of a new drug for

treating trypanosomiasis. For the utilization of research outcome to take place it was believed that the control of subsequent work must have been assumed by the MOH, that research results be re-examined from a public viewpoint so that official approval can be granted. Depending on the status of progress in actual utilization of research outcome, the impact of the project would be assumed in various ways, ranging from an improvement in the diagnosis rate of patients in rural areas to improvement of the cure rate by early diagnosis, but because this prerequisite is dependent upon MOH's approval as an official method, the impact was not able to be explicitly expressed as an overall goal.

However, noting too that in the ex-post evaluation, as stated in 1.3.2, at the time of terminal evaluation, the three items were described to be the impacts to be accomplished, (1) development of a rapid diagnostic method for TB, (2) development of a rapid diagnostic method for trypanosomiasis, and (3) discovery of a candidate compound for clinical testing for the development of a new drug for treatment of trypanosomiasis, were used for verification of an overall goal of the project on a trial basis.

### 3.2.2.1 Achievement of Overall Goal (for reference)

As stated above, whereas there had not been an overall goal for this project, the expected impact at the time of the terminal evaluation was taken as being equivalent to an overall goal and used provisionally to gauge the achievement.

Table 2: Degree of Achievement of Expected Impact

Expected impact	Status	Degree of accomplishment
Practical use of the LAMP-TB RDT as a diagnosis tool for TB	<ul style="list-style-type: none"> <li>• It was confirmed that the MOH did not take any concrete action for establishing it as an official method.</li> <li>• In use as a test kit at the level of the UTH lab.</li> <li>• The opinion of UTH technical staff is that processes are fewer than those of the previous method and steps requiring manipulation skill are not complicated, so that a long training period is not needed, and results can be obtained quickly and accurately at rural medical facilities where there is only limited testing equipment.</li> <li>• During the project period, there was a transfer of technology to the UTH lab regarding domestic production and distribution, and it is already possible for UTH technical staff to produce the kit. Further, in anticipation of actual use in rural areas a high-volume production system has been almost completed and is expected to be introduced from Hokkaido University in the coming fiscal year.</li> <li>• In expectation of distribution and storage of the reagent which is a consumable material for the test kit used at rural medical facilities, Hokkaido University is now studying and testing for prolongation of the shelf life of the reagent.</li> </ul>	In use on a lab base. In absence of approval as an official method, the range of beneficiaries is limited.

Expected impact	Status	Degree of accomplishment
	<ul style="list-style-type: none"> <li>During the project period a study was initiated to target urine as a specimen for childhood TB testing, but because good data were not obtained, at the time of the ex-post evaluation, simplification of processing of sputum is being studied at Hokkaido University instead.</li> </ul>	
Practical use of the LAMP-Tryps RDT as a diagnosis tool for trypanosomiasis	<ul style="list-style-type: none"> <li>It was confirmed that the MOH did not take any concrete action for establishing it as an official method.</li> <li>Transfer of technology was completed during the project period, and upon request by patients, the diagnosis service has been properly provided. Thus, the test kit has been utilized at the level of the UNZA-SVM lab.</li> <li>Interest has been regionally shown principally by neighboring Malawi and Zimbabwe because trypanosomiasis is an NTD existing in this region of Africa, there is no competing method of a diagnosis like other diseases, and the RDT is highly innovative.</li> <li>Although it has been thought that the habitat of the tsetse fly which is the carrier of trypanosomiasis was limited to rural river regions in the eastern part of the country, researchers at UNZA-SVM believe that surveillance through the use of the test kit is needed to verify the actual situation of the infection, as there have been unexpected diagnoses of serious cases in the central region and in the southern border region with Zimbabwe.</li> <li>UNZA, as a higher education and research institution, is not regulated by the MOH, and medical institutions providing therapy such as UTH and hospitals are under the MOH, it is recognized that an inter-ministerial cooperative arrangement is needed for smooth execution of diagnoses and treatment of trypanosomiasis.</li> </ul>	In use on a lab base. In absence of approval, the range of beneficiaries is limited.
A discovery of a candidate compound for new drug therapy of trypanosomiasis	<ul style="list-style-type: none"> <li>Progress has not been confirmed for development of a candidate compound for non-clinical testing of anti-trypanosomal activity in Zambia.</li> </ul>	Not achieved

Source: Questionnaires returned from the implementing agencies, and interviews

Although no confirmation with regards to the processes and procedures for granting official approval by the MOH for LAMP-TB RDT and LAMP-Tryps RDT, as for the expected impact, appropriate diagnostic service has been provided at the level of the research lab, and development is continuing, with production and acquisition and other aspects of sustained use in rural medical facilities in mind, and it is thought that the stage prior to actual use for POC testing at local laboratories has been reached. Regarding development of a drug for treatment of trypanosomiasis, however, there has been no change in status since project completion and further development was not confirmed.

As shown above, part of the provisionally set overall goal has not been achieved.

### 3.2.2.2 Other Positive and Negative Impacts

#### (1) Impact for natural environment

At both the times of terminal evaluation and the ex-post evaluation no impact on the environment was confirmed.

(2) Relocation of residents; acquisition of land

The project was implemented on the existing premises of the implementing agencies and hence there was no relocation of residents or acquisition of land. Therefore, at both time of termination and the ex-post evaluation, no impact was confirmed.

(3) Research capacity development and sophistication of university education

In 2016, UNZA-SVM was designated as a center for higher education and research on the zoonotic disease, in ACE-II<sup>15</sup>: The Eastern and Southern Africa Higher Education Centers of Excellence Project supported by the World Bank<sup>16</sup>. The background of selection included the evaluation of accomplishments ranging from a high number of international joint research undertakings including the project, the publication of research papers, to the operation of BSL-3-enabled facilities and precision equipment for gene sequencing, where JICA assistance was used to improve the center's scientific analysis of pathology and disease transmission.

The evolution of UNZA-SVM as an emerging center of higher-education and research institution in southern Africa is noteworthy for the following reasons. It had Zambian researchers who were dedicated to and proud of making international contributions. When grant aid was provided by the Japanese government and Hokkaido University in the 1980s, it enabled establishing its school of veterinary medicine for the first time. Since then, an all-Japan approach, notably backed by JICA and the department of veterinary medicine of Hokkaido University has constantly provided technical assistance and help in education for about three decades. Both of recent domestic training under the aegis of SATREPS as well as the preceding acceptance of Zambian students over years in Japan have helped establish a foundation for the comprehensive development of human resources for research<sup>17</sup>.

In light of the above, with regards to the project purpose, it was confirmed that upgrading of the capability of research and development concerning rapid diagnosis of the two diseases had been achieved, however with regard to the screening of candidate compounds for the

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<sup>15</sup> This World Bank program adopted higher education centers at 24 universities in eight countries in the region. Its scope covers priority areas such as industry, agriculture, public health, education, and applied statistics. It is involved in promotion of higher education and practical applied research that matches the needs of domestic labor markets and in cooperation with domestic and foreign research institutions, domestic institutions, and private industries. It is expected to generate role models as top-class institutions of higher education. Institutions in the program are entitled to maximum of 600 million USD of low-interest financing over a period of five years.

Source:<http://documents.worldbank.org/curated/en/105551478248187571/pdf/109745-BRI-ACEII-finalOct-PUBLIC.pdf>.

<sup>16</sup> The World Bank project that UNZA-SVM is active in is called ACEEZD, or Center of Excellence for Emerging and Zoonotic Diseases.

<sup>17</sup> See Hiroshi Kanekawa, "Creation of the Veterinary Medicine Faculty of the University of Zambia – An Education Project for Building Africa's Future (in Japanese)." *Journal of International Cooperation for Agricultural Development*, 12 (March 2012), p. 65-71.

treatment of trypanosomiasis this was not achieved as a candidate compound for non-clinical testing was not identified by the preceding research in Japan. Due to these results, the effectiveness of the project is judged to be fair.

As an impact, exclusive of the evaluation judgment on the accomplishment of an overall goal, research accomplishments have been recognized internationally, and the institution that produces the research has been designated as a center for higher education and research in zoonotic diseases, in the World Bank's ACE-II program. Therefore, research capacity development and its upgrading was confirmed as a positive impact.

In the event that achievement of an overall goal is considered as an impact, while the rapid diagnosis method has been used in the lab of the implementing agencies, and the MOH should begin procedures to put them through an examination process for official approval, it was not confirmed that any such action has been taken by the MOH. Further, as per the related activity on a discovery of a candidate compound for the treatment of trypanosomiasis, it was not implemented in Zambia, inevitably, an impact was not achieved. Therefore, with consideration made for the achievement, although it would be comparatively higher in evaluation based on confirmed impact, there are many items related to achievement of an overall goal that has not been concretely confirmed. Thus, it hardly can be judged as being high, effectiveness and impact are judged to be fair.

In as much as effectiveness and impact had not been set as the overall goal of the project, they are not considered in evaluating the degree of accomplishment. As a result, it is judged that implementation of the project has shown a certain degree of effects, thus effectiveness and impact are fair.

### 3.3 Efficiency (Rating: ③)

#### 3.3.1 Inputs

Inputs of the project were as shown in the table below.

Table 3: Inputs of the Project (Plan and Actual)

Inputs	Plan	Actual
(1) Experts	3 long-term experts 1-2 short-term experts (Chief advisor/ Development of diagnostic method for Tuberculosis/ Development of diagnostic method for Trypanosomiasis/ Screening of a candidate compound for trypanosomiasis)	2 long-term experts (74.0MM*) (Development of genetic diagnostic methods for Tuberculosis and Trypanosomiasis / Project Coordinator) 52 short-term experts (31.0 MM)
(2) Trainees received	2 persons	7 persons (Genetic diagnosis for TB, Genetic diagnosis for Trypanosomiasis, Chemosynthesis of anti-trypanosomal candidate compound(s))
(3) Equipment	*Although there was no specific description of equipment to be provided, in special remarks, noted a need to consider the improvement of facilities as a BSL-3 laboratory because it was planned to handle pathogens that may affect the human body.	143 million yen (Genetic analyzer, Ultracentrifuge, Ultra-deep freezer, thermal cyclor, BSL-3 compliant container testing laboratory Electric generator for BSL-3 Lab)
(4) Local Activity Cost	n.a.	43 million yen
(5) Third country training	n.a.	1 person (UTH), 1 person (UNZA-SVM)/ Total 2 persons (Trained in the USA regarding maintenance technique of safety cabinet, change of filters, and safety evaluation method)
Japanese Side Total Project Cost	Total 350 million yen	Total 332 million yen
Zambian side Total Project Cost	1. Allocation of Counterpart Personnel - 8 persons (researchers) 2. Equipment and Facilities - UTH: Office space in TB lab - UTH: Research space in TB lab - UNZA-SVM: Research Space in UNZA-SVM - Existing equipment for research activities 3. Local cost - Running costs for research activities	1. Allocation of Counterpart Personnel - MOH: 3 persons - TB Research Team: 13 persons - Trypanosomiasis Research Team: 12 persons 2. Equipment and Facilities - UTH: Office space in TB lab - UTH: Research space in TB lab - UNZA-SVM: Research Space in UNZA-SVM - Existing equipment for research activities 3. Local cost - Running costs for research activities (e.g. costs for water, electricity and landline phone)

\* MM stands for man-months.

Source: Ex-ante evaluation sheet (Oct. 2009), Terminal Evaluation Report (Aug. 2014) and hearing survey result from the implementing agency

### 3.3.1.1 Elements of Inputs

There was a substantial increase relative to plans for the number of short-term-dispatch researchers. This was necessary due to the number of new issues that emerged in connection with the improvement of the rapid diagnosis method during the project and action taken to deal with them. As for the introduction of equipment, UTH began use of the newly installed BSL-3 facility at the end of 2012 and made use of it during the latter half of the project. After

beginning its efficient use of the equipment, it succeeded in achieving the project purpose related to drug susceptibility testing by the project completion. Moreover, it was confirmed at the time of the ex-post evaluation that it was being used on a daily basis in two lines of testing for TB drug susceptibility and cultivation at the containerized lab. In addition, the researchers who received training in Japan, who had the opportunity to acquire advanced techniques of molecular biology analysis<sup>18</sup> and through that became more skilled in pathological research or acquired higher university degrees.



### 3.3.1.2 Project Cost

Project cost had been planned at 350 million Japanese yen, while it was actually totaled 332 million Japanese yen, it was within the plan (95% of the plan).

### 3.3.1.3 Project Period

As the project period was from November 2009 to November 2013 it was implemented as planned (100% of the plan). As stated above, the start of operations of the BSL-3 facility at UTH was in the latter part of this period but this did not cause any delay in the project activities.

Both the project cost and project period were realized as planned and therefore efficiency of the project is high.

## 3.4 Sustainability (Rating: ②)

As stated in the section of effectiveness and impact above, as a matter of the utilization of research outcome after the project completion, proactive efforts of the MOH, as the authority governing pharmaceutical affairs in Zambia, are indispensable. As such, it was necessary to confirm the status of institutional improvement with regards to the current approval process of pharmaceutical affairs together with the organizational continuation status of research implementation.

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<sup>18</sup> Specifically, polymerase chain reaction (PCR) and spoligotyping. PCR involves selectively amplifying a target segment of DNA sequencing by an enzyme reaction. Spoligotyping is used to genotype clinically isolated mycobacterium tuberculosis because of the necessity to clarify the infection pathway as to how it infects people. It is a method to investigate the presence or absence of 43 spacer sequences (DNA sequences linking structural genes) on the genome, and it is said to solve the drawbacks of the conventional method.

### 3.4.1 Related Policy and Institutional Aspects for the Sustainability of Project Effects

In terms of policy arrangements, it is significant to have maintained its policy towards serious diseases, notably TB as well as a representative NTD, trypanosomiasis in Zambia.

The Revised Sixth National Development Plan (R-SNDP; 2013-2016)<sup>19</sup> adopted in 2014, was in effect at the time of the ex-post evaluation, and among high priority items of health policy was targeted treatment rate of 80% for TB in 2016. Also, the grave importance of improving the accuracy of diagnosis and treatment rates is indicated by the overall trend for the sufferers being superinfected with HIV (70% of TB patients as of the end of 2010) to increase annually, as a bit less than 50,000 persons were reported TB infected for 2008 to 2010. An update of the National Health Strategy Plan had not been released as of the time of the ex-post evaluation but because the implementation of the plan was being continued to be effective, it is thought that no major change would be made after the project completion. The National Strategic Plan for Tuberculosis Prevention, Care, and Control (2017-2021) was in the final stage of preparation and not yet announced. However, through hearings at the MOH, it is deemed that high importance in policy will be assigned to the rapid diagnosis method.

At the time of the ex-post evaluation, there had not been a great change in the importance in the policy of TB and NTDs, and it is assumed that the policy necessary for sustaining the effects of the project is mostly continuing in force.

### 3.4.2 Organizational Aspects for the Sustainability of Project Effects

As for organizational aspects, it is significant that the project resulted in a research organization for authorization and improvement of rapid diagnostic methods, and improvement of the MOH as a regulatory body that can process drug approval that is necessary for the utilization of research outcome.

At the time of the ex-post evaluation, the organization for research at UTH and UNZA-SVM was as follows.

UTH is not a research organization but a hospital that also provides clinical education/training, where the TB laboratory section, where work on behalf of the project was conducted, was at the time the major place for TB exams. As a consequence of the project, UTH acquired BSL-3 and thereby improved its holdings of equipment. It has secured laboratory technicians with a high level of knowledge and techniques regarding drug susceptibility and cultivation. It is believed that the strengthening of this group of permanent staff was part of the improvement of the TB laboratory system and the establishment of the basic arrangement for research improvement of LAMP-TB-RDT.

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<sup>19</sup> The draft Seventh National Development Plan (2017-2021) was still being drafted and not available at the time of the ex-post evaluation.

Table 4: Trend of the number of researchers at UTH TB laboratory

	Actual									Plan
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Permanent researcher/ Laboratory technician	-	-	-	-	14	14	14	14	14	14
Contract researcher/ Contract staff	-	-	-	-	0	0	0	0	0	0
Total	-	-	-	-	14	14	14	14	14	14

Source: UTH TB laboratory's response to the questionnaire

Note: no answer was given regarding data from 2007 to 2010.

In a subsequent new project at UNZA-SVM<sup>20</sup>, based on the experience of streamlining research system through the project, they are extending further lab research in order to secure government approval of the LAMP-Tryps RDT for reliable surveillance of trypanosomiasis that had diagnosed only to the extent of a few cases in the past. Note however that it is recognized that as UNZA-SVM is under the administrative control of the Ministry of Higher Education, further cooperation with the MOH should be enhanced concerning diagnosis and therapy for trypanosomiasis infections in humans.

Table 5: Trend of the number of researchers at UNZA-SVM

	Actual									Plan
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Permanent researcher (Ph.D.)	3	3	7	7	7	7	7	5	5	5
Part-time researcher	0	0	0	0	0	0	0	0	0	0
Total	3	3	7	7	7	7	7	5	5	5

Source: UNZA-SVM's response to the questionnaire

As for regulatory arrangements of the MOH for approval of pharmaceutical affairs, according to hearings at the ministry, despite the value of an RDT is strongly recognized, neither the RDTs by the project nor any other new RDT are in process for approval, and no specific plans or budget allocation have been engaged. For it to be approved, actually applied and disseminated it inevitably requires add-on tests and its validation in the approval process. Furthermore, assuming the expansion of diagnostic examinations in rural areas, careful planning is needed for related activities at various levels including initiation of domestic production of the RDT kits along with the creation of a distribution scheme. Therefore, additional support from foreign donors is much needed.

On the basis of the above review, at the time of the ex-post evaluation, there was no existing

<sup>20</sup> This is a research program that is one of Hokkaido University's international joint research projects, is titled Creation of a Neglected Tropical Disease Countermeasures Model Based on Development of a Rapid Diagnostic Method and Risk Analysis. It has the major objectives of (1) determining the status of Hansen's disease and trypanosomiasis in Zambia, (2) development and actual utilization of an RDT for Hansen's disease and trypanosomiasis, and (3) proposing a package plan for fighting Hansen's disease and trypanosomiasis.

system at the MOH that would permit the utilization of research outcome, but the implementing agency now possesses a systematic research structure for further improvement of the RDT, through the implementation of subsequent research projects by fully utilizing facilities and equipment procured by the project.

### 3.4.3 Technical Aspects for the Sustainability of Project Effects

Regarding technical aspects of the project, it is important that the implementing agencies can continue research and improvement of capabilities in order to achieve the objective of utilization of the research outcome of the project.

Reports indicate that as a consequence of the project development of human resources at UTH, one of the implementing agencies under the MOH, some staff members of higher ability are seeking to pursue doctor's degree Further, through the substantial improvement of facilities and equipment and of skilled lab techniques by the project, it has enabled the TB laboratory at UTH to become better at functioning as a lab performing high-accuracy culture inspections, ranked after WHO certified top referral labs in Zambia, such as Chest Disease laboratory (CDL) and a Tropical Disease Research Center (TDRC).

As for UNZA-SVM, Zambian researchers there are proceeding with studies at their own initiative and have used a random sample of 100 residents of Mwenya Village in Mambwe, an area where the tsetse fly breeds, for diagnoses of trypanosomiasis and malaria using LAMP-Tryps RDT, and when test results were negative by conventional microscopy, retesting with LAMP-Tryps RDT was performed. Further, the quality of their research papers has improved as a result of the improvement of facilities and equipment procured by the project.



Table 6: Number of academic articles concerning Trypanosomiasis by UNZA-SVM

	Before the project		Project Period					After the project		
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
International academic journals	0	0	0	0	0	2	2	1	5	2
Domestic academic journals	0	0	0	0	0	1	0	0	0	0
Total	0	0	0	0	0	3	2	1	5	2

Source: UNZA-SVM's response to the questionnaire

An official mechanism at the MOH for issuing accuracy certification of any domestically developed medical product, as well as validating and authorizing as an official method does not exist. There is thus no other alternative but to conform to accepting WHO-certified products. Therefore, there is a gap in the technology and knowledge needed to construct such a mechanism for official approval of the RDTs developed by this project.

As indicated above, at the time of the ex-post evaluation, although there is not sufficient technology and knowledge at the MOH for constructing an official mechanism for certifying the accuracy of the RDTs, UTH and UNZA-SVM have achieved the level of technology for validating the diagnostic performance of RDTs for TB and trypanosomiasis.

#### 3.4.4 Financial Aspects for the Sustainability of Project Effects

Turning to financial matters, as disease-related policy, activities are continuing with the ultimate objective of the perfection and dissemination of RDTs suitable for practical use, and hence it is important that funds be budgeted for further research and activities regarding utilization of the research outcome.

Among the facilities and equipment provided under the project, BSL-3 facilities that were newly installed at UTH TB laboratory were indispensable to maintain the system of the research implementation. It has also required the operation and maintenance conducted by the implementing agency itself. At the time of the ex-post evaluation, the BSL-3 facilities were functioning for daily examination tasks without any serious problem in operation and being used effectively. Further, maintenance service for the incidental safety cabinet is being obtained through an outsourcing contract with a specialty company in South Africa and since 2014 the annual cost of 20,000 USD has been continually provided for this. Separate budget funds are allocated to purchase needed spare parts. Note, however, that as stated above UTH is considered by the MOH as the proper authority, to be the entity for TB exams, thus UTH is not supposed to undertake research activities and hence research funding per se is not provided.

Table 7: Maintenance expense for BSL-3 facilities at UTH TB laboratory

	2013	2014	2015	2016
Purchase of spare parts and consumables	--	459,620	600,000	873,330
Outsourcing for maintenance of safety cabinet	--	200,000	200,000	200,000

Unit: ZMK<sup>21</sup>

Source: UTH TB laboratory's response to the questionnaire

Continued research relying on the advances made through this project in research capability at UNZA-SVM has been subsequently included in another SATREPS project, Project for

<sup>21</sup> The exchange rate at the time of the ex-post evaluation: one ZMK was equal to about 0.1USD.

Surveillance of viral zoonoses in Africa (2013-2018) and International Collaborative Research Program for Tackling the NTDs Challenges in African countries (2015) by AMED. As shown in Table 7, funding for continuing the research has been secured. Further, as indicated in 3.2.2.2, Other Positive and Negative Impacts, it was adopted as a COE by World Bank's ACE-II program and the outlook is for research funds to be obtained from 2017 onward.

Table 8: Research funding and expenditure of UNZA-SVM

		Unit: ZMK			
		2013	2014	2015	2016
Research funding	Government	-	-	-	-
	Donors	2,595,540	2,993,150	5,955,057	4,928,893
	Other (private)	-	-	-	-
Research expenditure		2,486,772	2,713,863	5,008,213	4,819,761
Balance		108,768	279,287	946,844	109,132

Source: UNZA-SVM's response to the questionnaire

Add-on tests by a third-party institution being deemed as necessary for the MOH to certify the accuracy of diagnosis performance, need exists to objectively collect the requisite data and design the test to be conducted by that party, but there is no budget for such items.

It is concluded from the above that issues remain, such as lack of a budget allocation for the work needed for utilization of research outcome in the MOH, but the precision equipment provided to UTH and UNZA-SVM are being maintained and a budget allocation has been made for certifying the performance of the RDTs.

In light of the above, regarding institutional, technical and financial aspects, some issues exist. Thus, sustainability of the project effects is judged to be fair.

## 4. Conclusion, Lessons Learned and Recommendations

### 4.1 Conclusion

The objective of this project is to perform the research and development needed for a rapid diagnostic method for sustained use in identification of TB and trypanosomiasis, and screening of candidate compounds for improvement of the treatment of trypanosomiasis, in Zambia. The diseases of concern, TB, and Trypanosomiasis, one of the NTDs, are assigned high importance in Zambia's national development plans, and in the field of public health, they have had consistently high priority in health-related policies. Further, both infectious diseases are hence of great concern in connection with the issue of public health, and there has been a consistent need for rapid and accurate diagnosis in order that it can be controlled and treated is amply evident. In addition, concerning Japanese development assistance policy, this project is consistent with the public health concerns addressed in the Japanese Assistance Program for Zambia, Japan Action Plan in

Combating Infectious Diseases in Africa, and the TICAD. Thus, relevance is high. Regarding effectiveness, it is believed that the project achieved advances in the capability for research and development needed for rapid diagnosis, but because no actual activities were implemented on the screening of candidate compounds for the treatment of trypanosomiasis, this latter objective was not achieved. Concerning impact, while work on improvement of a rapid diagnostic method is being continued in the laboratory of implementing agencies, progress has not been made in obtaining official approval of the method by the MOH. However, because there has not been an overall goal assigned to this project, this has not been used in the evaluation of impact. As collateral impacts, research achievements have been made by the UNZA-SVM, that the World Bank has designated as a center for advanced education in zoonotic diseases prevalent in Eastern and Southern Africa. It is expected to contribute to the advancement of education and research, and to the expansion of international collaborative research efforts in the center. Thus, the effectiveness and impact of the project are judged to be fair. Because the project was completed within the planned time frame and budget, it is judged to be highly efficient. As for sustainability, while the necessary policy and institutional measures for the continuation of the effect of the project are assured, there are issues remained in terms of organizational technical, and financial matters to specifically engage the utilization of research outcome in this project so that its sustainability is evaluated as fair.

In light of the above, this project is evaluated to be satisfactory.

## 4.2 Recommendations

### 4.2.1 Recommendations to the MOH

In view of the purpose of implementing the project, it was intended to prevent the emergence of latent disease by application of a rapid diagnostic method developed for use on a sustained basis and in conformity with conditions prevalent in Zambia. In particular, it would facilitate diagnosis of people exposed to disease risk in rural areas, and early treatment of those patients. It is thus recommended that the MOH examine its capability for expediting the review of diagnosis performance and clarify issues related to the approval process for authorizing its qualification as an official method. As the rapid diagnostic method developed by the project is already in the stage of lab use, prior to actual use, the ministry should designate the responsible department and officials as soon as possible who would apply themselves to the scientific framework in terms of the necessary number of the specimen for testing and its performance to validate as an official method, confirm human resources and financial requirements for the regulatory arrangement, facilitate add-on tests by the CDL or TDRC under the ministry, and thereby begin the approval process. Moreover, diagnoses for trypanosomiasis using the rapid diagnosis method developed by this project are currently being made only by UNZA-SVM which is under the Ministry of Higher Education, so that it is

necessary to establish a working relationship with the MOH which is responsible for oversight of medical institutions that provide therapy.

#### 4.2.2 Recommendations to JICA

An interruption was found to exist in the stage of transitioning to the process of utilization of the rapid diagnostic methods, the results of the project. In the event that the MOH begins work for approval of the rapid diagnostic methods, it will be important to assure scientific objectivity by use of a third party, and support is deemed to be necessary for the formation of a scheme for official approval of actual use to be granted, that would enable guarantee of diagnosis performance, and because of this it is desirable as a follow-up undertaking to provide the assistance by training of pharmaceutical affairs or dispatch of expert(s) in the area. In the framework of review for official approval by a third-party committee, such as an ethical review committee, it should be on the premise of the dissemination and promotion in medical facilities in the rural area in Zambia. Thus, it is desirable to promote and support the effort from the viewpoint of the comprehensive infection control program, including financial and economic perspectives, with consideration given to incorporate the crucial prerequisites of production and procurement, its distribution cost, training etc. in the scope of the application plan.

#### 4.3 Lessons Learned

##### Good practice according to a versatile and consistent commitment to developing human resources

Zambia is an excellent example of how versatile Japanese grant aid, technical assistance, student exchange programs etc. over an extended period of time have developed a pool of researchers to the extent which they have become able to make internationally-recognized accomplishments in medical research concerned with disease prevalent in their own country. Further, the outlook is for contributions derived from the research capability that has been acquired in Zambia, contributions to be made to all of Africa. In particular, the outlook, as stated in the section on other impacts, at UNZA-SVM there have been the versatile underpinnings created through the exchange of personnel that represents a strong organizational commitment by Japan. In addition to general analytic ability including skill in using analytical equipment, it is vital to develop the ability to identify hitherto unknown scientific challenges. As the project was undertaken from such perspectives, it is deemed to result in sustainability of the research activities. Specifically, if we consider the case of the TB Laboratory at UTH and the balance of personal benefits accruing individuals desirous of receiving a higher degree, versus public benefit, the establishment of BSL-3 and day-to-day promotion of collaborative research work by technicians aspired for a higher degree have not only provided individual incentives to deepen proficiency of using the equipment but also has raised the overall level of the implementing agency itself. This is seen as a result of comprehensive support for research.

#### Necessity for long-term support in the field of medical and health-related research

Among SATREPS projects concerning the mode of utilization of research outcome in the field of infectious disease control, it is envisaged to aim at not only working on product development of new drugs and/or testing equipment but also making surveillance system to ensure higher accuracy in an inspection by incorporating newly developed research method. However, it is most commonly thought that in the field of medical and health research, it involves the product development of new drugs and/or vaccines accessible to ordinary people in developing countries. It requires a comprehensive, long-term strategy that includes, besides basic research and non-clinical research, the process of conducting a human trial in the developing countries. Note, however, differing from the research and development of drugs in and for the industrialized nations, for research and development of drugs for diseases rampant mostly in developing countries, there is a low commercial incentive for pharmaceutical makers to pursue such research and development. As per market mechanism, therefore it is not usually practiced as symbolically expressed as “neglected tropical diseases”. Because of this, based on awareness of and response to the difficulty of both the private pharmaceutical companies and an isolated effort of a SATREPS project in dealing with a smooth transition to the productization from the basic medical research result, it is thus desirable that there be continued progress in basic research and nonclinical research, from a comprehensive viewpoint and teaming with personnel responsible for health policy in the nations concerned, and that there be a strategical study of measures for utilization of research outcome or use of such study findings over the medium and long-term after completion of a SATREPS project.

#### Necessity for parallel support for regulatory/legislative aspects of product development in the field of medical and health-related research

In countries where SATREPS projects were implemented, need exists for technical assistance in connection with the governments’ regulatory approval process of study and approval of medical products for domestic use and dissemination in those countries. Further, more generally, in developing countries aspiring to reach the semi-developed country status and where SATREPS projects have functioned to develop human resources in the field of research, in close collaboration with the counterpart personnel of the regulatory body, it is necessary to give attention to and examine the status of drug regulation, policy and law concerning intellectual property, ethical concerns for clinical tests in research and development, as well as the administrative organization and functioning of the matter.

#### Method of evaluation of a SATREPS project lacking a specified overall goal

When the project does not assign an overall goal, that is, there has not been an agreement with the counterpart regarding an overall goal of the project, information and data corresponding to a

super goal of research and development, and results based on the degree of accomplishment of project purpose at the time of terminal evaluation can be adopted as the “expected impact.” However, while the related information should be described in the verification of impact on a trial basis, as long as consideration is given to the outlook for actual utilization of results after project completion, it is not to be directly judged in the evaluation. On the other hand, it is necessary to examine whether there are any collateral impacts and the contents, including those that were not anticipated before the start of the project, those thereby should be appraised as overall effectiveness and impact. Furthermore, the continuation of research activities related to the “expected impact” should be judged in the evaluation for sustainability.

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