

Country Name	<b>The Project for Research and Development of Prevention and Diagnosis for Neglected Tropical Disease, especially Kala-Azar</b>
People's Republic of Bangladesh	

**I. Project Outline**

Background	<p>Leishmaniasis, a vector-borne disease transmitted by a hematophagous insect of Phlebotomus (sandflies) is protozoan zoonosis and regarded as one of neglected tropical diseases (NTD) with large distribution in 88 countries in the world. Visceral leishmaniasis (Kala-Azar), the severest type of Leishmaniasis, is highly prevalent especially in the poor in Bangladesh, India and Nepal. Approximately 200 million people have been endangered for infection in those countries. In Bangladesh, it was estimated that 65 million people were compromised for Kala-Azar infection and more than 50,000 had been newly infected in every year. Kala-Azar has been highly lethal and difficult to achieve a complete cure and control of Kala-Azar including diagnosis, treatment and prevention was lagging behind. Under the circumstances, the government of Bangladesh put efforts to reduce the prevalence of Kala-Azar from 25 to 1 per 10,000 populations by the year of 2015.</p>										
Project Objectives	<p>Through development and evaluation of rapid and reliable diagnostic tools, elucidation of mechanisms of Kala-Azar, establishment of vector control methods, preparation of Standard Operating Procedure (SOP) and implementation of dissemination seminars, the project aimed at improving capacity of International Center for Diarrheal Disease Research, Bangladesh (icddr, b) for surveillance of Kala-Azar and Post Kala-Azar Dermal Leishmaniasis (PKDL), development of rapid diagnostic tools and research on vector insect of Sand Fly.</p> <ol style="list-style-type: none"> <li>Expected Overall Goal: Government Programme on Kala-Azar Elimination is strengthened in Bangladesh.</li> <li>Project Purpose: Capacity of icddr, b, for surveillance of Kala Azar (Visceral Leishmaniasis: VL) and Post-Kala Azar Dermal Leishmaniasis (PKDL), development of its rapid diagnostic tools, and research on vector insect of Sand Fly is improved through collaborative research activities with Japanese research institutions.</li> </ol>										
Project Activities	<ol style="list-style-type: none"> <li>Project Site: Dhaka (icddr,b) and Mymensingh (Surya Kanta Kala-Azar Research Center : SKKRC)</li> <li>Main Activities: 1) Development and evaluation of rapid and reliable diagnostic tools for clinical and sub-clinical Kala-Azar cases, 2) Elucidation of mechanisms of Kala-Azar, 3) Establishment of vector control methods, 4) Preparation of Standard Operating Procedure (SOP) and implementation of dissemination seminars, so on.</li> <li>Inputs (to carry out above activities)</li> </ol> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Japanese Side</td> <td style="width: 50%;">Bangladeshi Side</td> </tr> <tr> <td>1) Experts: 57 persons</td> <td>1) Staff allocated: 12 persons</td> </tr> <tr> <td>2) Equipment: Automated Clinical Chemistry Analyzer, Automated Hematology Analyzer, Refrigerated Micro Centrifuge, High-speed Micro Centrifuge, Inverted microscope, Fluorescence microscope, and vehicle</td> <td>2) Facilities and land: Project office in icddr,b, Surya Kanta Hospital, research spaces in SKKRC</td> </tr> <tr> <td>3) Local operation cost</td> <td>3) Local operation cost: Maintenance cost of SKKRC, rehabilitation cost for laboratory in SKKRC, cost for conference space</td> </tr> </table>			Japanese Side	Bangladeshi Side	1) Experts: 57 persons	1) Staff allocated: 12 persons	2) Equipment: Automated Clinical Chemistry Analyzer, Automated Hematology Analyzer, Refrigerated Micro Centrifuge, High-speed Micro Centrifuge, Inverted microscope, Fluorescence microscope, and vehicle	2) Facilities and land: Project office in icddr,b, Surya Kanta Hospital, research spaces in SKKRC	3) Local operation cost	3) Local operation cost: Maintenance cost of SKKRC, rehabilitation cost for laboratory in SKKRC, cost for conference space
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Project Period	(ex-ante) May 2011 – April 2016 (actual) June 2011 – May 2016	Project Cost	(ex-ante) 465 million yen, (actual) 301 million yen								
Implementing Agencies	International Center for Diarrheal Disease Research, Bangladesh (icddr,b), Ministry of Health and Family Welfare (MoHFW)										
Cooperation Agency in Japan	The University of Tokyo, Aichi Medical University										

**II. Result of the Evaluation**

< Special Perspectives Considered in the Ex-Post Evaluation >

[Verification of Continuation of the Project Effect]

- The Indicator 2 for the Project Purpose, the number of research papers published in peer-reviewed journal, was not verified at the time of ex-post evaluation. Although the Indicator 2 was achieved by the five research paper published in the international journals during the project period, the research outputs by the SATREPS project have been utilized for the government programme for elimination of Kala-Azar and Kala-Azar. Therefore, it is considered that the indicator is not essential to verify the continuation status of the project effects.

[Verification of the Expected Overall Goal]

- Although no Overall Goal was set in the project design, the Super Goal of “Government Programme on Kala-Azar Elimination is strengthened in Bangladesh” was set. Since the Super Goal can be as a part of efforts for “utilization of the research outcomes”, it was verified as “Expected Overall Goal”.

**1 Relevance**

<Consistency with the Development Policy of Bangladesh's at the Time of Ex-Ante Evaluation >

The Project was consistent with Bangladesh's policy of the “Communicable Disease Control (CDC) Program” (2008) under the Health Nutrition and Population Sector Program (HNPS) (2003-2010) with the six priority issues including eradication of Kala Azar.

<Consistency with the Development Needs of Bangladesh's at the Time of Ex-Ante Evaluation>

The Project was consistent with Bangladesh's development needs for establishing a rapid diagnosis tool to enable early treatment based on early diagnosis of Kala Azar which had prevailed in rural areas with poverty.

<Consistency with Japan's ODA Policy at the Time of Ex-Ante Evaluation>

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

The Project was consistent with Japan's ODA Policy for Bangladesh, the "Country Assistance Program for Bangladesh" (2006) prioritizing social development and human security.

<Evaluation Result>

In light of the above, the relevance of the project is high.

## 2 Effectiveness/Impact

<Status of Achievement of the Project Purpose at the time of Project Completion>

The Project purpose was partially achieved at the time of project completion. Although a diagnostic tool, "Urine Antibody detection Kit for Visceral Leishmaniasis" was developed and feasibility of a vector control method, utilization of *Olyset® Plus* (a long-lasting insecticidal net), was studied, discussions on the application of those research outputs to the "National Guidelines and Training Module for Kala-Azar Elimination in Bangladesh" was not commenced at the time of terminal evaluation due to the restricted field activities by the deteriorated security situation in Bangladesh (Indicator 1). Five research articles authored by the project members were published in international academic journals during the project period (Indicator 2).

<Continuation Status of Project Effects at the time of Ex-post Evaluation>

The project effects have continued since project completion. The key research outputs by the SATREPS project have been utilized by the Kala-Azar Elimination Program of the government of Bangladesh. For example, rapid diagnostic tests that were evaluated in the SATREPS project is used for diagnosis and management of Kala-azar. SKKRC, which was opened in December, 2012 and equipped by the SATREPS project, became a referral center for diagnosis and treatment of Kala-Azar.

Also, based on the research outputs of the SATREPS project, icddr,b started new research projects. New projects on treatment of Kala-Azar and development of PKDL have been taken up and funded by PATH, an international non-profit organization in the health sector. In addition, projects on the understanding the immune response due to Kala-Azar has been selected and funded by the Drugs for Neglected Diseases initiative (DNDi)<sup>2</sup>, which is an international non-profit research and development organization working to deliver new treatments for neglected diseases.

The research equipment installed by the SATREPS project have been continuously utilized at the SKKRC laboratory.

<Status of Achievement for Expected Overall Goal at the time of Ex-post Evaluation>

The Expected Overall Goal, efforts for the utilization of the research outcomes, has been achieved. Namely, the government programme on Kala-Azar elimination has been strengthened. As mentioned above, the key research outputs by the SATREPS project have been utilized by the Kala-Azar Elimination Program of the government of Bangladesh and the Kala-Azar has been almost eliminated in the country. Also, SKKRC has been functioning as reference laboratory for diagnosis of Kala-Azar. The research output of the SATREPS project contributed to enhancement of elimination of Kala-Azar in Bangladesh. In addition, for treatment of Kala-Azar, the Amphotericin B injection has been introduced in the Kala-azar control program. Also, under the Kala-Azar control program of the Directorate General of Health Service (DGHS) of the MoHFW, regular vector control activities, including the vector control methods, have been ongoing in the Kala-Azar endemic areas. In particular, the vector control method by Olyset Plus (sold by Sumitomo Chemical) verified by the SATREPS project has been disseminated in Bangladesh.

On the other hand, "Urine Antibody Detection Kit for Visceral Leishmaniasis", which was established based on the basic technologies of ELISA (Enzyme-Linked ImmunoSorbent Assay), has not officially been approved by MoHFW in order to use for rapid diagnosis on Kala-Azar in Bangladesh. However, the kit was used a lot to detect infected person of Kala-Azar in Bangladesh. The fact indicates that the kit will contribute to the elimination of Kala-Azar in the country.

<Other Impacts at the time of Ex-Post Evaluation>

There are some positive impacts of the project confirmed at the time of the ex-post evaluation. The research capacity of the researchers involved in the project activities has been improved. Several researchers at icddr,b were developed through the SATREPS project. They have still been continuing Kala-azar research and supporting the Kala-Azar Elimination Program. For example, one of researchers, who has participated in the SATREPS project and is now a senior scientist at icddr,b, published several research paper on Kala-Azar in a peer reviewed journal. No negative impact by the SATREPS project was confirmed at the time of ex-post evaluation.

<Evaluation Result>

Therefore, both the effectiveness and impact of the project is high.

### Achievement of Project Purpose

Aim	Indicators	Results	Source
(Project Purpose) Capacity of icddr, b, for surveillance of Kala Azar (Visceral Leishmaniasis: VL) and Post-Kala Azar Dermal Leishmaniasis (PKDL), development of its rapid diagnostic tools, and research on vector insect of Sand Fly is improved through collaborative research activities with Japanese research institutions.	Indicator 1: The diagnostic tools and the vector control method developed by the Project are discussed at the Technical Working Group of Kala-Azar for adoption in "The National Guideline and Training Module for Kala-Azar Elimination in Bangladesh".	Achievement Status: Not achieved (Achieved) (Project Completion) ● Discussion over the application of research outcomes to the Guidelines was not commenced at the time of Terminal Evaluation due to the restricted field activities by the deteriorated security situation in Bangladesh. ● However, a diagnostic tool, "Urine Antibody detection Kit for Visceral Leishmaniasis" was developed and feasibility of a vector control method, utilization of <i>Olyset® Plus</i> was studied by the SATREPS project. (Ex-Post Evaluation) ● After the completion of the project, rapid diagnostic tests that has been evaluated in the SATREPS project is now used for diagnosis and management of Kala-azar in Bangladesh, based on the above	Terminal Evaluation Report Information provided by icddr,b

<sup>2</sup> DNDi was established in 2003 by Doctors Without Borders (Médecins Sans Frontières: MSF), Oswaldo Cruz Foundation (FIOCRUZ) from Brazil, Indian Council for Medical Research (ICMR), Kenya Medical Research Institute (KEMRI), Ministry of Health of Malaysia, and Pasteur Institute of France.

		-mentioned discussion.	
	Indicator 2: More than two research papers in each research topic are published in peer-reviewed journals with its impact factor more than 1.0.	Achievement Status: Achieved (Not verified.) (Project Completion) ● The following five research articles authored by the project members were published in international academic journals during the project period. ➤ Leishmania DNA in a visceral Leishmaniasis endemic area of Bangladesh. ➤ Evaluation of new akute kidney injury biomarkers in a mixed intensive care ➤ Mild elevation of urinary biomarkers in prerenal acute kidney injury. ➤ Application of RFLP-PCR-Based Identification for Sand Fly Surveillance in an Area Endemic for Kala-Azar in Mymensingh, Bangladesh Elevation of serum B-cell activating factor levels during visceral(Ex-Post Evaluation) ● N.A.	Terminal Evaluation Report

### 3 Efficiency

The project cost and the project period were within the plan (the ratio against the plan: 65% and 100%, respectively). The project outputs were produced as planned.  
Therefore, the efficiency of the project is high.

### 4 Sustainability

#### <Policy Aspects>

As mentioned above, the Kala-Azar Elimination Program has been implemented by the government of Bangladesh and the key research outputs of the SATREPS project have been utilized for the Kala-Azar control activities.

#### <Institutional/Organizational Aspects>

The structure of the project members in icddr,b had been changed after eight months of launching the project, which affected the project's implementation progress at the time; however it did not significantly impact the project outputs. Otherwise, there have not been significant changes in the institutional and organizational setting for continuing the research activities on Kala-Azar and implementing the Kala-Azar control activities. In addition, after the project completion, the government of Bangladesh and icddr,b established an institutional arrangement for the utilization of the research outcomes of the SATREPS project under the Kala-Azar Elimination Program. Also, as mentioned above, SKKRC became a referral center for diagnosis and treatment of Kala-Azar.

For the operation and maintenance of the research equipment and facilities, SKKRC has been responsible.

#### <Technical Aspects>

The researchers of icddr,b have enhanced their research capacities through the research activities under the SATREPS project. They continue their research on Kala-azar by using other fundings including PATH, DNDi and the government of Bangladesh. The researchers have been sustaining their skills and knowledge to properly operate and maintain the research facilities/equipment installed by the SATREPS project. The staff of SKKRC has been sustaining their skills and knowledge to properly conduct diagnosis of Kala-Azar by using the multiplex real-time PCR based gene detection.

#### <Financial Aspects>

The research organizations/institutions, including SKKRC, have continuously secured financial resources for the research projects and also they have sufficient budgets for the operation and maintenance of the research facilities/equipment installed by the SATREPS Project. While icddr,b has a possibility to fail to secure a budget constantly because of dependency on the external funds, however, icddr,b has continued their research on Kala-azar by obtaining from external funds as mentioned above. The government authorities and the related institutions continuously secured financial resources for using the research outcomes, such as implementation of policy/program based on/using the research outputs by the SATREPS project.

#### <Evaluation Result>

In the light above, although there is a slight concern from the financial aspect, the sustainability of the effects through the Project is high

### 5 Summary of the Evaluation

The project achieved the Project Purpose for enhancement of research capacity of icddr,b. to develop rapid diagnostic tools and the vector control method. The key research outputs have been utilized for the Kala-Azar Elimination Program of the government of Bangladesh and have been contributing to elimination of the disease.

Considering all of the above points, this project is evaluated to be highly satisfactory.

## III. Recommendations & Lessons Learnt

### Recommendations for Implementing Agency:

[For MOHFW]

- MoHFW should continue to specify the activities and budget of the SKKRC in the Health Sector Programme, maintain the laboratory equipment and internal quality control system provided under this SATREPS project. In addition, to make the best use of the SKKRC's facility capabilities, MoHFW should discuss not only the reference laboratory for the diagnosis of kala-azar, but also its potential application in other infectious disease research with a consideration of the further usage of trained personnel.

Lessons learned for JICA:

- Although icddr,b was the main implementing agency for the project, activities were also carried out in collaboration with the SKKRC, as the implementing facility, as government agency. Regarding the results of the project, the research aspect of the project is mainly led by icddr,b, which is using the research capacity strengthened by the project to obtain external funding and develop its research. In addition, the project's activities to promote the elimination of Kala-Azar have been incorporated into the Health Sector Programme of MoHFW at SKKRC and are continuing. The project activities, contents, and post-project prospects should be considered based on a thorough understanding of the strengths, weaknesses, and possible limitations of the implementing organizations and institutions. In particular, when the implementing organization is not government institution, whose management is externally funded, the financial aspects of the institution can easily affect or restrict the implementation system and budget assurance. It is recommended to hold consultations among the parties concerned to discuss establishing a structure, budget, and resource mobilization during project formation and/or implementation.



Equipment at SKKRC



Scientific Seminar organized by the SATREPS project