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Dated: April 20, 2004.

William P. Nichols,

MPA, Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-9495 Filed 4-26-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Development of Influenza Surveillance Networks

Announcement Type: New.

Funding Opportunity Number: 04106.

Catalog of Federal Domestic

Assistance Number: 93.283.

Key Dates:

Letter of Intent Deadline: May 27, 2004.

Application Deadline: June 28, 2004.

Executive Summary: An influenza pandemic has greater potential than any other naturally occurring infectious disease event to cause large and rapid global and domestic increases in deaths and serious illnesses. Preparedness is the key to substantially reducing the health, social, and economic impacts of an influenza pandemic and other public health emergencies. One component of preparedness involves understanding the impact that annual epidemics of influenza has on the population. These data regarding impact are critical to the development of prevention and control measures such as vaccination policies. Vaccination efforts are the cornerstone of influenza prevention and will be the primary means of mitigating the impact of an influenza pandemic.

The systematic collection of influenza surveillance data over time is necessary to monitor and track influenza virus and disease activity and is essential to understanding the impact influenza has on a country's population. Improving surveillance systems by developing

influenza surveillance networks is critical for the rapid detection of new variants, including those with pandemic potential, to contribute to the global surveillance system. Global collaboration, under the coordination of the World Health Organization (WHO), is a key feature of influenza surveillance. WHO established an international laboratory-based surveillance network for influenza in 1948. The network currently consists of 112 National Influenza Center (NIC) laboratories in 83 countries, and four WHO Collaborating Centers for Reference and Research of Influenza (including one located at the Centers for Disease Control and Prevention). The primary purposes of the WHO network are to detect the emergence and spread of new antigenic variants of influenza, to use this information to update the formulation of influenza vaccine, and to provide as much warning as possible about the next pandemic. This system provides the foundation of worldwide influenza prevention and control.

Monitoring of influenza viruses and providing contributions to the global surveillance system, will assure that data used in annual WHO vaccine recommendations are relevant to each country that participates. Increased participation in the global surveillance system for influenza viruses will enhance each country's ability to monitor severe respiratory illness, to develop vaccine policy and to help build global and regional strategies for the prevention and control of influenza. Monitoring influenza disease activity is important to facilitate resource planning, communication, intervention, and investigation.

This announcement seeks to support foreign governments through their Ministries of Health or other responsible Ministries for human health in the development or improvement of epidemiologic and virologic influenza surveillance networks. These networks will focus on the systematic collection of virological and epidemiological information for influenza. This support is meant to enhance, and not to supplant, current influenza surveillance activities and proposals should build upon infrastructure already in place. Preference will be given to countries where resources are currently limited and influenza surveillance is not well established due to lack of resources.

I. Funding Opportunity Description

Authority: This program is authorized under sections 301(a) and 307 of the Public Health Service Act, [42 U.S.C. sections 241(a), and 2421], as amended.

Purpose: The purpose of the program is to provide support and assistance to foreign governments for the development or improvement of influenza surveillance networks. These networks will focus on the systematic collection of virological and epidemiological information for influenza. Countries applying for support must have an active WHO National Influenza Center recognized by WHO. This program addresses the "Healthy People 2010" focus area of Immunization and Infectious diseases.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Infectious Diseases: Protect Americans from infectious diseases.

The objectives of this program are to (1) Establish or enhance an active influenza surveillance network that uses standardized data collection instruments, operational definitions, and laboratory diagnostic tests to enhance surveillance for influenza at three or more sites within the country; (2) use the experience gained to expand the surveillance system to include additional sites; (3) improve local laboratory diagnostic capabilities by supporting and enhancing those local laboratories that participate in influenza surveillance; (4) develop educational and training opportunities for local public health practitioners as part of broader efforts to improve public health infrastructure in the region; and (5) improve communications and data exchange between laboratories and epidemiologists in the global influenza surveillance network by expanding the network and improving the reporting of data from surveillance sites, laboratories, and National Influenza Centers.

Activities: Awardee activities for this program are as follows:

- Develop a nationwide system to collect virologic and epidemiologic data for influenza by establishing 5 or more sites with good geographic distribution throughout the country. Each site will consist of a local laboratory and one or more clinics or hospitals for data collection. Each site should:
 - Conduct virologic and epidemiologic surveillance for influenza by collecting information year round in countries or regions of countries with tropical and subtropical climates; and/or by collecting surveillance information during the period of respiratory illness circulation in countries or regions of countries with temperate climates.
 - Have laboratory capacity for performing influenza virus isolation and typing.

- Collect information on influenza like illnesses and/or severe respiratory disease at each site by building on information that is already available. Possible sources of information are (1) recording influenza-like-illness visits to physicians or primary care clinics or hospitals based on a standard case definition. (2) Monitoring hospital admissions for severe respiratory illness and pneumonia based on a case definition. Patient information such as age, patient history and other relevant information should be collected.

- Collect a subset of at least 10 (and preferably up to 25) specimens from the patient populations under surveillance with febrile, acute upper respiratory illness. These specimens should be collected weekly during the period of surveillance (based on climate) using a standard case definition (preferably WHO) and should be submitted to the local laboratory for the site.

- During unusual outbreaks of influenza, such as outbreaks with unusual epidemiologic characteristics, or those related to infections by avian or other animal influenza viruses, collect epidemiologic information to characterize the outbreak and collect additional samples for viral isolation and submittal to the site laboratory. Report the outbreak to the National Influenza Center.

- Prepare and provide regular weekly reports on the epidemiologic information that has been collected (influenza-like-illness and/or severe respiratory illness) to the local laboratory and to the National Influenza Center.

- The laboratory will perform viral isolation for influenza viruses either in tissue culture or in eggs. Type positive isolates for influenza A and B, and if possible, subtype influenza viruses.

- Store original clinical materials at – 70 until the beginning of the next influenza season.

- Submit viral isolates to the National Influenza Center within the country on at least a monthly basis for more complete analysis.

- The WHO National Influenza Center (NIC) within a country can be one of the surveillance sites and as such conduct all the activities listed above. If there are two or more NICs within a country each NIC could participate as a site, however NICs within a single country should work together and place emphasis on the addition of new surveillance sites. In addition, the NIC(s) should act as the focal point and authority within their country on influenza surveillance and be the main point of communication with WHO and WHO Collaborating Centers for the

submittal of virus isolates and information into the global surveillance system. Each National Influenza Center (NIC) also will be responsible for the following activities:

- Performing preliminary antigenic and, if possible genetic, characterization on the virus isolates submitted from the laboratories in the surveillance sites (including those isolates grown at the NIC).

- Send representative virus isolates to one of the four WHO Collaborating Centers for Influenza, including any low reacting viruses, as tested using the WHO reagent kit, each month during the period of surveillance and more frequently, if possible.

- If any viruses are unsubtypeable as tested using the WHO kit, alert WHO and send the virus isolate to one of the four WHO Collaborating Centers for Influenza immediately.

- During the period of surveillance, provide weekly influenza surveillance information to WHO through FluNet.

- Provide an annual national summary on influenza activity, virological information and other relevant information on influenza to WHO and the WHO Collaborating Center in Atlanta, GA.

- Provide technical expertise and training to support the surveillance sites and laboratories in the national network.

- Foreign Governments applying for funding through this cooperative agreement should play a substantial role in the development and support of the influenza surveillance network.

- Facilitate the sharing of influenza surveillance information with the WHO Global Influenza Surveillance network by facilitating the regular exchange of information and viruses with one of the four WHO Collaborating Centers.

- Provide continued support for influenza activities within the country and develop a plan for increased participation in the global influenza surveillance network over a five-year period.

- Consider developing a task force or working group for influenza to determine ways to improve national influenza surveillance, develop prevention and control measures such as vaccine policy and work on pandemic preparedness.

- Facilitate communication between the veterinary and the human side of influenza surveillance. Develop systems for the sharing of information.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

- Provide technical assistance on techniques and reagents for the identification of influenza viruses. Annually provide the WHO reagent kit, which is produced and distributed by the WHO Collaborating Center for Influenza in Atlanta, GA.

- Provide epidemiological and laboratory training.

- Provide technical consultation on the development of country networks.

- Provide confirmation of antigenic analysis and more detailed characterization information on the influenza virus isolates submitted to CDC with written reports back to the National Influenza Center.

- Provide technical advice on the conduct of epidemiologic outbreak investigations.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$1,000,000.

Approximate Number of Awards: 5–10.

Approximate Average Award: \$ 50,000 to 250,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: \$250,000.

Anticipated Award Date: August 1, 2004.

Budget Period Length: 12 months.

Project Period Length: 5 years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible applicants

Applications may be submitted by foreign governments, Ministries of Health, or other government offices responsible for disease surveillance in humans. Only one application per country will be accepted.

III.2. Cost Sharing or Matching

Cost sharing or matching is not required for this program. However, the support provided through this cooperative agreement is meant to enhance, and not supplant, current influenza surveillance activities.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

If your application is incomplete or non-responsive to the requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

This program is not designed or intended to support research, therefore no research will be supported under this cooperative agreement. Any applications proposing research will be considered non-responsive.

In order to apply and be eligible for this funding, your Country must have at least one National Influenza Center (NIC) of record at WHO. Documentation of WHO National Influenza Center status by the Ministry of Health and WHO will be sufficient to establish eligibility. Participation as a NIC is a requirement because to meet the goal of this announcement a significant number of the recipient activities require information and work to be conducted, reported and submitted through the WHO Surveillance network.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity use application form PHS 5161. Application forms and instructions are available on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at: 770-488-2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Letter of Intent (LOI): An LOI is requested. Your LOI must be written in the following format:

- Maximum number of pages: 4
- Font size: 12-point un-reduced
- Single spaced

- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in plain language, avoid jargon

Your LOI must contain the following information:

- Name of the government entity that is applying

Documentation of National Influenza Center status

- Name and contact information for point of contact

Application: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25
- If your narrative exceeds the page limit, only the first pages, which are within the page limit, will be reviewed.
- Font size: 12 point un-reduced
- single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should address activities to be conducted over the entire project period, and must include the following items in the order listed:

- Plan
- Documentation of Results
- Capacity
- Proposed Program Plan
- Goals
- Objectives
- Operational Plan
- Evaluation Plan
- Collaborations
- Budget and justification (not included in page limit) With staffing breakdown and justification, provide a line item budget and a narrative with justification for all requested costs, and separate line-item budgets for each research area. Be to include, if any, in-kind support or other contributions that will be provided by your country as part of the total project, but for which you are not requesting funding. Budgets should be consistent with the purpose, objectives and research activities and include:
 - Line-item breakdown and justification for all personnel, *i.e.*, name, position title, annual salary, percentage of time and effort, and amount requested.
 - For each contract: (1) Name of proposed contractor; (2) breakdown and justification for estimated costs; (3) description and scope of activities to be performed by contractor; (4) period of performance; (5) method of contractor selection (*e.g.*, sole-source of competitive solicitation); and (6) methods of accountability.

Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- Curriculum Vitae
- Resumes
- Organizational Charts
- Letters of Support may be included.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1-866-705-5711.

For more information, see the CDC Web site at: <http://www.cdc.gov/od/pgo/funding/pubcomm.htm>.

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

LOI Deadline Date: May 27, 2004.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: June 28, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. eastern time on the deadline date. If you send your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the

application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770-488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Executive Order 12372 does not apply to this program.

IV.5. Funding restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

Use of Funds

- Funds may be spent for reasonable program purposes, including personnel, travel, supplies, and services. Equipment may be purchased if deemed necessary to accomplish program objectives, however, prior approval by CDC officials must be requested in writing.

- The costs that are generally allowable in grants to domestic organizations are allowable to foreign institutions and international organizations, with the following exception: With the exception of the American University, Beirut and the World Health Organization, Indirect Costs will not be paid (either directly or through sub-award) to organizations located outside the territorial limits of the United States or to international organizations regardless of their location.

- The applicant may contract with other organizations under this program; however the applicant must perform a substantial portion of the activities (including program management and operations, and delivery of prevention services for which funds are required.)

- All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will not compensate foreign grantees for currency exchange fluctuations through the issuance of supplemental awards.

- You must obtain annual audit of these CDC funds (program-specific audit) by a U.S.—based audit firm with international branches and current licensure/authority in-country, and in accordance with International Accounting Standards or equivalent standard(s) approved in writing by CDC.

- A fiscal Recipient Capability Assessment may be required, prior to or post award, in order to review the applicant's business management and fiscal capabilities regarding the handling of U.S. Federal funds.

- Awards will not allow reimbursement of pre-award costs.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: <http://www.cdc.gov/od/pgo/funding/budgetguide.htm>.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: Ken Fortune, National Center for Infectious Diseases, Center for Disease Control and Prevention, Mailstop C-19, 1600 Clifton Road, NE., Atlanta, GA 30333, FAX: 404-639-4195, E-mail: kef2@cdc.gov.

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management-PA# 04106, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

- Objectives and Technical Approach (50 points total)

- Does the applicant describe specific objectives of the proposed program that are consistent with the purpose and goals of this announcement and which are measurable and time-phased? (10 points)

- Does the applicant identify appropriate sites with adequate

geographic distribution for network? (10 points)

- Does the applicant present a detailed operational plan for initiating and conducting the program, which clearly and appropriately addresses all recipient activities that are feasible?

Does the applicant clearly identify specific assigned responsibilities for all key professional personnel? Does the plan clearly describe the applicant's technical approach/methods for developing and conducting the proposed program and evaluation and does it appear feasible and adequate to accomplish the objectives? Does the applicant describe the existence of or plans to establish partnerships? (10 points)

- Does the applicant describe adequate and appropriate collaborations with other health agencies during various phases of the project? (10 points)

- Has the applicant provided a detailed, adequate and feasible plan for evaluating program results? This includes plans for evaluating the improvement of the influenza surveillance network as well as plans for evaluating other aspects of the collaboration (e.g., training). (10 points)

- Capacity (35 points total)

- Does the applicant describe adequate resources and facilities (both technical and administrative) for conducting the project? This includes the capacity to conduct quality laboratory measurements and produce and distribute reports? (20 points)

- Does the applicant provide documentation that professional personnel involved in the project are qualified and have past experience and achievements in research and programs related to the program (as evidenced by curriculum vitae, publications, etc.)? (15 points)

- Background and Need (10 points)

Does the applicant adequately discuss the background for the proposed project and demonstrate a clear understanding of the purpose and objectives of this cooperative agreement program? Does the applicant illustrate and justify the need for the proposed project that is consistent with the purpose and objectives of this program?

- Measures of Effectiveness (5 points)

Does the applicant provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant and the degree to which the measures are objective/quantitative and adequately measure the intended outcome?

- Budget and Justification (not scored): Does the applicant propose a budget that is reasonable, clearly

justifiable, and consistent with the intended use of cooperative agreement funds?

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center for Infectious Diseases. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the "V.1. Criteria" section above.

In addition, the following factors may affect the funding decision: Funding preference will be given to countries where resources are currently limited and influenza surveillance is not well established due to lack of resources and where there have been problems with avian influenza outbreaks posing threats to human health either in their country or surrounding countries. This would include countries in the following geographic region: Asia

V.3. Anticipated Announcement and Award Dates

Anticipated Award Date: August 1, 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92 For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.

The following additional requirements apply to this project:

- AR-9 Paperwork Reduction Act Requirements

- AR-10 Smoke-Free Workplace Requirements
- AR-11 Healthy People 2010
- AR-12 Lobbying Restrictions
- AR-15 Proof of Non-Profit Status
- AR-25 Release and Sharing of Data

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

- a. Current Budget Period Activities Objectives.
- b. Current Budget Period Financial Progress.
- c. New Budget Period Program Proposed Activity Objectives.
- d. Budget.
- e. Additional Requested Information.
- f. Measures of Effectiveness.

2. Financial status report and annual progress report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For program technical assistance, contact: Ann Moen, Project Officer, National Center for Infectious Diseases, Center for Disease Control and Prevention Mailstop G-16, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone: 404-639-4652, E-mail: amoen@cdc.gov.

For financial, grants management, or budget assistance, contact: Steward Nichols, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2788, E-mail: shn8@cdc.gov.

Dated: April 20, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-9494 Filed 4-26-04; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04129]

Improving the Effectiveness of the Diagnosis and Treatment of Tuberculosis and Multi-Drug Resistant Tuberculosis in the Philippines; Notice of Intent to Fund Single Eligibility Award

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2004 funds for a cooperative agreement program to support and ensure the implementation of tuberculosis (TB) control activities that are designed to develop, establish, and coordinate systems and procedures to address the obstacles to achieving control of TB and multi-drug resistant tuberculosis (MDR-TB). The Catalog of Federal Domestic Assistance number for this program is 93.116.

B. Eligible Applicant

Assistance will be provided only to Makati Medical Center (MMC) located in Manila, the Philippines.

The MMC is the only qualified organization that has the technical and administrative capacity to conduct the specific set of activities requested to support CDC TB and MDR-TB prevention and control activities in the Philippines under this cooperative agreement because:

1. The MMC is uniquely positioned, in terms of legal authority, ability, track record, infrastructure and credibility in the Philippines to develop and support TB and MDR-TB control activities in both public and non-governmental organization sites throughout the country.

2. The MMC has already established a framework and mechanisms to develop and implement TB and MDR-TB treatment and control activities in the Philippines, enabling it to immediately become engaged in the activities listed in this announcement.

3. The MMC has demonstrated its ability to coordinate and implement TB treatment and control activities