



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

May 18, 2021

DEPARTMENT MEMORANDUM

No. 2021- 0246

FOR: DIRECTORS OF THE DEPARTMENT OF HEALTH CENTERS FOR HEALTH DEVELOPMENT – ILOCOS, CENTRAL LUZON, METRO MANILA, CALABARZON, BICOL, WESTERN VISAYAS, CENTRAL VISAYAS, ZAMBOANGA PENINSULA, NORTHERN MINDANAO, AND DAVAO

SUBJECT: Implementation of “Pilot Study to Evaluate the Effectiveness and Safety of the Bedaquiline-Pretomanid-Linezolid (BPaL) Treatment Regimen in the Philippines”

The National Tuberculosis and Control Program (NTP) of the Department of Health (DOH), in collaboration with the Lung Center of the Philippines – National Center for Pulmonary Research (LCP-NCPR), KNCV Tuberculosis Foundation (KNCV), International Tuberculosis Research Center, Korea (ITRC), Tropical Disease Foundation (TDF), and TB Alliance will conduct an operational research entitled “*Pilot Study to Evaluate the Effectiveness and Safety of the Bedaquiline-Pretomanid-Linezolid (BPaL) Treatment Regimen in the Philippines*”. The study primarily aims to estimate the effectiveness of the BPaL regimen by assessing the end of treatment outcome among patients treated with the regimen, and to estimate the safety of the BPaL regimen by determining the rates of serious adverse events; an initiative to ensure successful treatment outcome of patients with extensively drug-resistant tuberculosis, treatment-intolerant or non-responsive multi-drug resistant tuberculosis.

The operational research shall be implemented in the following 12 treatment facilities providing drug-resistant TB (DR-TB) services:

Region	DR-TB Treatment Facility and Location
NCR	Lung Center of the Philippines, Quezon City
	Dr. Jose N. Rodriguez Memorial Hospital, Caloocan City
1	Ilocos Training and Regional Medical Center, La Union
	Region 1 Medical Center, Dagupan City, Pangasinan
3	Jose B. Lingad Memorial General Hospital, Pampanga
4	Batangas Medical Center, Batangas
5	Sorsogon Medical Mission Group Hospital and Health Services Cooperative, Sorsogon
6	Western Visayas Medical Center, Iloilo City
7	Eversley Childs Sanitarium and General Hospital, Mandaue City
9	Zamboanga City Medical Center, Zamboanga City
10	Northern Mindanao Medical Center, Cagayan de Oro City
11	Southern Philippines Medical Center, Davao City

The study, through the treatment facilities, will enroll 100 patients for two (2) years from May 2021 until December 2022. The treatment facilities were selected based on the following: 1) has been implementing the programmatic management of drug-resistant TB (PMDT) for at least one (1) year; 2) has a strategic location providing access to the other facilities; 3) with access to private and public facilities for the identification and management of adverse events and comorbidities; 4) has access to diagnostic and monitoring laboratories; 5) has more than 30 patients with DR-TB enrolled in 2019; and 6) has designated physician trained in PMDT.

Laboratory diagnostics and treatment monitoring shall be supported by the TB laboratory network composing of the study sites' partner laboratories (rapid TB diagnostic, TB culture, drug susceptibility testing and line probe assay) led by the National TB Reference Laboratory (NTRL) – Research Institute for Tropical Medicine (RITM).

The Single Joint Research Ethics Board (SJREB) of DOH has given the initial approval for the research protocol last April 1, 2021. Also, Institutional Review Boards in the different study sites have granted approval to the same protocol.

Training of the study sites and partner laboratories will be on May 19-21, 2021 and enrollment of patients to the study shall commence right after the training.

Relative to the implementation, all identified facilities both treatment and laboratory are enjoined to wholly participate in the study and research. For matters relative to the conduct of study in your facility, please contact Dr. Irene Flores, principal investigator, through the LCP-NCPR Research Unit at email address researchunit.lcpncpr@gmail.com

For information, compliance, dissemination to all concerned.

By Authority of the Secretary of Health:


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