



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

December 1, 2020

DEPARTMENT MEMORANDUM

No. 2020 - _____

TO: 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: Conduct of Preparatory Activities for the Implementation of the "Pilot Study to Evaluate the Effectiveness and Safety of the Bedaquiline-Pretomanid-Linezolid (BPaL) treatment regimen in the Philippines"

The National Tuberculosis 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, International Tuberculosis Research Center, Korea, and TB Alliance, will embark on an operational research entitled *"Pilot study to test the effectiveness and safety of the Bedaquiline, Pretomanid, Linezolid (BPaL) treatment regimen in the Philippines"*. The proposed 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. This is an initiative to ensure successful treatment outcome of patients with extensively drug-resistant tuberculosis, treatment-intolerant or non-responsive multidrug-resistant tuberculosis.

The operational research (OR) will enroll 100 patients for 2 years in the following twelve (12) health facilities providing drug-resistant TB (DR-TB) services:

Region	Facility
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 I Medical Center, Dagupan City
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	Xavier University – Community Health Care Center, Cagayan de Oro City
11	Southern Philippines Medical Center, Davao City

These facilities were selected based on the following: 1) has been implementing the programmatic management of drug-resistant TB (PMDT) for one (1) year or more; 2) has a strategic location providing access to other referring 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 >30 patients with DR-TB

enrolled in 2019; and 6) has a designated physician trained in PMDT.

Prior to the implementation of the OR, the following preparatory activities shall be conducted:

1) **needs assessment** of the study sites and its partner TB laboratories (rapid TB diagnostic, TB culture, drug susceptibility testing and line probe assay laboratories) by LCP-NCPR research team and the National TB Reference Laboratory (NTRL) – Research Institute for Tropical Medicine (refer to Annex 1. List of Proposed Study Sites and Its Partner TB Laboratories),

2) **orientation on the study protocol** of key stakeholders including CHD NTP Coordinators and study site staff **on December 10, 2020** by NTP, LCP-NCPR and partners, and


3) following the orientation, **solicitation of a letter of commitment and support** from the heads of the institution/hospital and STC to implement the study **by the CHD, through the NTP Coordinators.**

Relative to this, **identified health facilities providing DR-TB services including its partner TB laboratories are requested to participate in the said preparatory activities and in this landmark study.** Rest assured that the conduct of the study will be supported by the NTP Management Office, LCP-NCPR, and NTP partners.

Further, the study protocol will undergo technical and ethical review and approval prior to the implementation of the OR. Once approved, a Department Memorandum will be issued to signal the start of the study.

For information, compliance, and dissemination to all concerned.

By Authority of the Secretary of Health


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Undersecretary of Health
Public Health Services Team

Annex 1. List of Proposed Study Sites and Its Partner TB Laboratories

Region	Health Facility Providing DR-TB Services	Rapid TB Diagnostic Laboratory (RTDL)	TB Culture Laboratory	DST Laboratory	LPA Laboratory
NCR	Lung Center of the Philippines (LCP)	LCP	LCP	NTRL	NTRL
	Dr. Jose N. Rodriguez Memorial Hospital (DJNRMH)	DJNRMH	LCP	NTRL	NTRL
I	Ilocos Training and Regional Medical Center (ITRMC)	La Union Medical Center (LUMC)	Dagupan Doctors Villaflo Memorial Hospital (DDVMH)	NTRL	NTRL
	Region I Medical Center (RIMC)	Pangasinan Provincial Hospital (PPH)	DDVMH	NTRL	NTRL
III	Jose B. Lingad Memorial General Hospital (JBLMGH)	JBLMGH	Central Luzon CHD TBC Laboratory	NTRL	NTRL
	Batangas Medical Center (BatMC)	BatMC	Philippine Tuberculosis Society Inc. (PTSI -QI)	PTSI-QI	NTRL
V	Sorsogon Medical Mission Group Hospital and Health Services (SMMGGHSC)	Only patients screened in the SMMGGHSC; the rest of the zoned specimens are temporarily routed to Gubat and Pilar RTDLs	SMMGGHSC	NTRL	NTRL
	Western Visayas Medical Center (WVMC)	WVMC	WVMC	WVMC	NTRL
VII	Eversley Child Sanitarium (ECS)	ECS	PTSI-QI	PTSI-QI	NTRL
	Zamboanga City Medical Center (ZCMC)	ZCMC	ZCMC	Davao TB Reference Laboratory (DTRL)	NTRL
IX	Xavier University-Community Health Care Center (XU-CHCC)	XU-CHCC	CDO Polymedic Plaza (CDOPMP)	DTRL	NTRL
	Southern Philippines Medical Center (SPMC)	SPMC	DTRL	DTRL	NTRL