

Implementing Structure for the Pilot Study to Test the Effectiveness and Safety of the Bedaquiline-Pretomanid-Linezolid (BPaL) Treatment Regimen in the Philippines

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Importance of Organizing

- Relatively long duration of the study (6-9 months treatment + 12 months post-treatment follow-up)
- Many offices and stakeholders are involved
- Input - intensive
- Protection of patient rights

Dr. Mariquita Mantala, former TASC Advisor to NTP, Training on 9-MTR OR Protocol, 2015



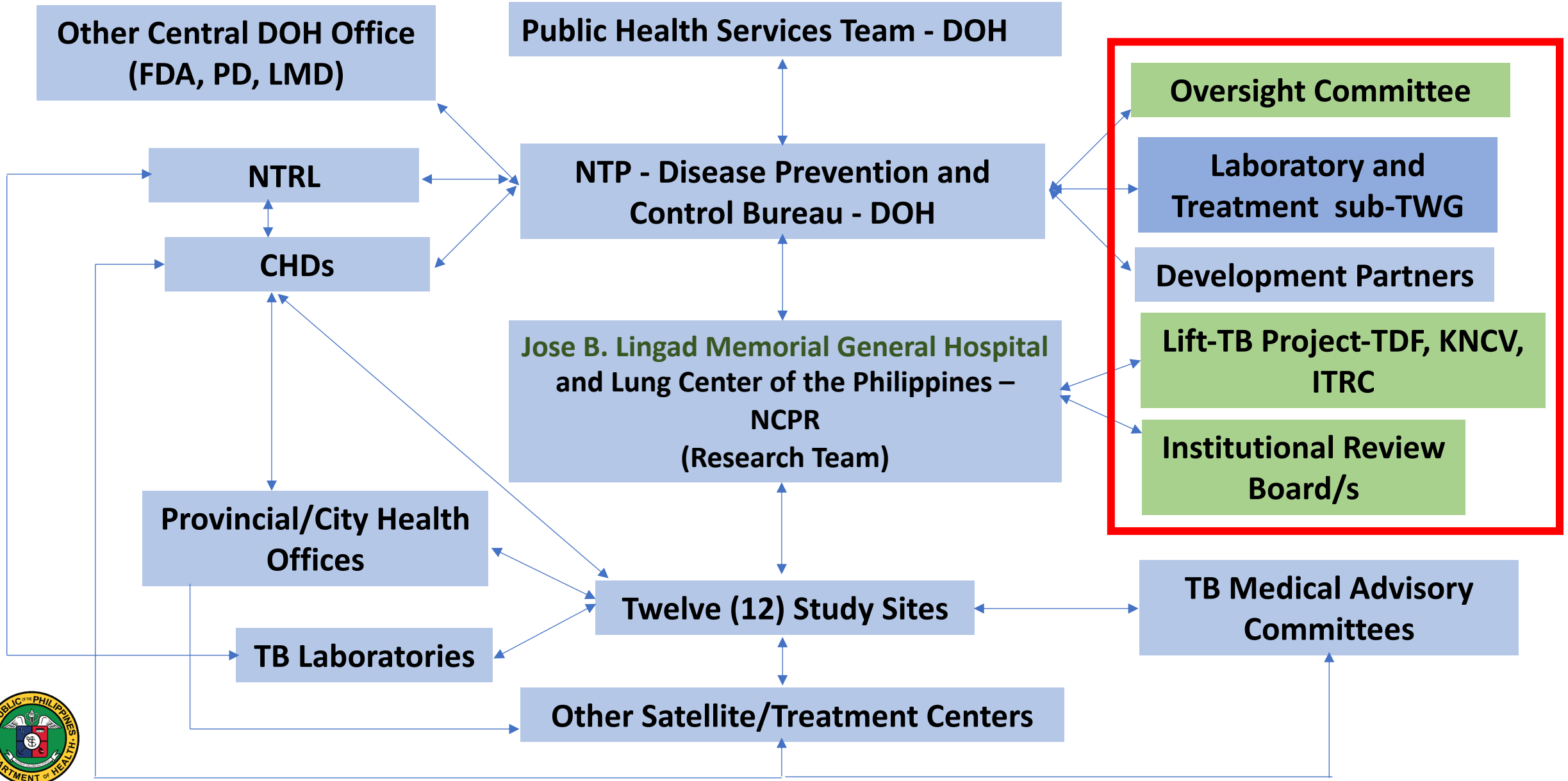
Principles

- Common goals and objectives
- Adherence to protocol
- Unity of command/flow
- Clarity of responsibilities
- Complementation/harmonization/integration
- Accountability

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Implementing Arrangement



NTP - Disease Prevention and Control Bureau, DOH

- Provide guidance on the conduct of the study
- Decide on policy and technical issues with the Laboratory and Treatment Sub-TWG
- Lead the over-all planning, monitoring and evaluation of the study
- Convene the Laboratory and Treatment sub-TWG quarterly
- Coordinate with the Oversight Committee
- Ensure adequacy of human, financial and logistical resources to support the study
- Ensure that the study findings are disseminated, published and recommendations are acted upon



JBLMGH and LCP – Research Team (1)

- Finalize the protocol and implementation plan
- Develop field manual
- Secure approval of Institutional Review Boards (IRBs)
- Ensure readiness and participation of the study site
- Responsible for the capability-building of the research team and study site staff
- Monitors adequacy of human, logistical and financial resources of the study
- Conduct the study according to protocol



JBLMGH and LCP – Research Team (2)

- Responsible for data management
- Report progress of the study at least quarterly to NTP and PMDT sub-TWG and on the required frequency by IRB/s
- Act as secretariat with NTP MO to the Oversight Committee
- Draft the study report and seek comments from Partners
- Finalize report and disseminate findings
- Publish the study in coordination with NTP and partners
- Store the study documents for at least five years



National TB Reference Laboratory - RITM

- Participate in the development of the protocol and implementation plan
- Manage the participation of the TB laboratory network
- Ensure the uninterrupted provision of quality laboratory services such as smear microscopy, Xpert MTB/Rif, culture, DST and LPA including maintenance of laboratory equipment, biobanking and sequencing of samples in coordination with ITRC
- Ensure adequacy of laboratory supplies
- Strengthen the referral system between the laboratory network and participating sites
- Submit necessary laboratory reports to JBLMGH and LCP thru NTP
- Participate in the study planning, monitoring and evaluation



Other DOH offices

- FDA: Support implementation of active TB-drug safety monitoring and management (aDSM)
- Pharmaceutical Division: Lead the implementation of aDSM
- Logistics Management Division: Ensure distribution of logistics



Centers for Health Development

- Ensure that all logistical support coming from NTP will be distributed to the implementing sites
- Secure commitment to implement the study from the sites
- Participate in the planning, monitoring and evaluation activities
- Attend study dissemination fora



Provincial/City Health Offices

- Participate in the planning, monitoring and evaluation activities
- Attend study dissemination fora



Study Sites

- Participate in the planning and evaluation of the study
- Implement the study according to protocol
- Maintain necessary records and submit reports on time
- Allow monitors access to data
- Coordinate with necessary offices to ensure the adequacy of funding, technical and logistical support
- Attend study dissemination fora



Oversight Committee

- Approves the technical/progress reports submitted by the research team
- Conducts joint-monitoring with the Laboratory and Treatment sub-TWG and research team, and provides recommendations based on findings and evaluation by the monitoring team
- Recommends final technical report for approval by the Secretary of Health
- Provides recommendations to the Secretary of Health based on the research findings



Oversight Committee

Chair: Undersecretary of the Public Health Services Team

Co-chair: Director of Disease Prevention and Control Bureau

Members:

1. Division Chief, Infectious Disease Prevention and Control Division, DOH
2. Representative, WHO Western Pacific Region
3. Chairman of the Board, PhilCAT
4. USAID Project Management Specialist for Public Health – Infectious Diseases
5. Country Member, Philippine Country Coordinating Committee

Technical Secretariat:

- NTP Manager
- PMDT Specialist, NTPMO
- Account Officer for PMDT, NTPMO
- Research Coordinator, LCP

Laboratory and Treatment sub-TWG

- Chaired by the NTP Manager, and composed of representatives from STAR, LCP, NTRL, development Partners (WHO, USAID, TBIHSS, TBP, ACCESS TB) and key affected population
- Provide technical advice during the different phases of the study
- Participate in the planning, monitoring and evaluation of the study
- Make recommendations to NTP on various policy, technical and operational issues of the study
- Review and provide comments to the draft study report



Partners

- Partners will provide technical assistance in all phases of the study as part of the Laboratory and Treatment sub-TWG
- **GF's ACCESS TB Project – PBSP:** provide funding support to the study, ensure procurement of necessary logistics such as the second line anti-TB drugs (BDQ and LZD), provide human resources for the study



LIFT-TB Project

- **TB Alliance:** project lead of LIFT-TB, scientific support, and procurement of Pretomanid
- **International Tuberculosis Research Center (ITRC), Korea:** project coordination in the Philippines
- **KNCV:** technical support for clinical management, training, and protocol development
- **Tropical Disease Foundation:** local partner organization for project coordination in the Philippines



Thank you!



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