LIFT-TB Philippines
Leveraging Innovation for Faster Treatment of Tuberculosis
Introducing the BPaL Regimen under Operational Research

In collaboration with the National Tuberculosis Control Program (NTP) – Department of Health (DOH)

Tropical Disease Foundation, Inc.

Schedule of baseline, routine and post-treatment monitoring evaluations for the BPaL operational research

	Baseline	2 weeks	Monthly	End of treatment	6- and 12-months after treatment
Clinical evaluation					
Clinical assessment*[1]	X	X	X	X	X
Psychosocial assessment*[2]	X	X	X	X	X
Performance status[3]	X				
Weight / BMI	X	X	X	X	X
Peripheral neuropathy screen[4]	X	X	X	X	X
Visual acuity and colour discrimination screen	X	X	X	X	X
Chest X-Ray	X		X, if no response to treatment	X	X
ECG	X	X	X	X	X, if indicated
Assessment and follow-up of AEs	X (X)	X (X)	X (X)	X (X)	X (X)
Treatment outcome assessment				X	X
Bacteriological evaluations					
GeneXpert	X				
Sputum smear	X		X	X	X
Sputum culture[5]	X (X)		X (X)	X (X)	X (X)
Sputum drug susceptibility testing[6]	X (X)		X, if culture-positive[7]		
Other sample smear	X		X, if no response to treatment		
Other sample culture	X (X)		X, if no response to treatment		
Other sample drug susceptibility testing	X		X, if culture-positive[7]		
Laboratory evaluation					
Full blood count	X	X	X	X	X, if indicated
Liver function tests (AST, ALT, bilirubin)	X	X	X	X	X, if indicated
Thyroid stimulating hormone (TSH)	X	X, if indicated	X, if indicated		
Serum electrolytes (Na, K, Ca, Mg)	X	X, if indicated	X	X	X, if indicated
Serum amylase		X, if indicated	X, if indicated		

Schedule of baseline, routine and post-treatment monitoring evaluations for the BPaL operational research

	Baseline	2 weeks	Monthly	End of treatment	6- and 12-months after treatment
Urea, creatinine	X	X, if indicated	X, if indicated		
Baseline Sugar level (fasting or random) [8]	X	X, if indicated	X, if indicated		
HIV / HBV / HCV tests (anti-HBs, anti-HCV)	X				
CD4/Viral load (if HIV +)[9]	X - if indicated				
Pregnancy test[10]	X	X, if indicated	X, if indicated		

* Guidance for physicians, no standardized data collection is required

[1] Vital signs, TB symptom screen, pain, nausea, appetite and nutrition, diarrhoea, candidiasis. Clinical assessment should focus on a) monitoring response to treatment and b) addressing common symptoms associated with TB treatment and long-term antibiotic use, with the goal of supporting adherence.

[2] Food security, housing, mental state, substance use. Psychosocial assessment should offer an opportunity to assess supportive factors for treatment adherence and should be directly linked to relevant interventions wherever possible per country specific questionnaires

[3] Assessed by Karnofsky Performance Status Scale, (Refer to the BPaL Protocol)

[4] Assessed by the Brief Peripheral Neuropathy Screen developed and validated by the National Institutes of Health-funded AIDS Clinical Trials Group (ACTG). (Refer to the BPaL Protocol)

[5]Isolates from all positive cultures collected during every visit, including baseline, and post-treatment will be stored to allow additional investigations, if necessary. *If a patient who is eligible for the BPaL treatment following treatment with another MDR-TB regimen has a negative baseline culture, the last positive culture isolate collected for the previous regimen, should be stored for future testing.*

[6] Xpert MTB/RIF, second-line LPA, culture-based second-line DST; and, if available, Xpert MTB/XDR and pDST for the BPaL component drugs and next generation sequencing. A culture collected prior to start of BPaL treatment should be stored for each enrolled patient for further analysis once pDST methods for Bdq, Pa and Lzd are available, and for comparison of genotype and resistance conferring mutations in case of possible relapse.

[7] Repeat DST if culture is still positive at month 4, end of treatment or post-treatment follow-up.

[8] If abnormal at baseline, diabetes mellitus should first be ruled out. If patient is found to have diabetes mellitus, he should be treated and followed up accordingly.

[9] Perform a viral load test if it has not been done within the last 6 months of the study enrollment date. And perform a CD4 count if it has not been done within the last 3 months of the study enrollment date.

[10] Only for women of reproductive age