BPaL Project Monitoring

BPaL Training of Trainors
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Project Monitoring

Objectives:

- To ensure that people's rights are protected and that the conduct of the OR is in compliance with the approved protocol.
- To identify constraints in the
  - ❖ identification of presumptive MDR-TB
  - ❖ sputum examinations
  - ❖ diagnosis by drug susceptibility pattern,
  - ❖ identification of eligible patients for the BPaL regimen
  - ❖ timely enrolment
  - ❖ pre-treatment assessment
  - ❖ initiation of treatment
  - ❖ identification and management of AEs

Project Monitoring

Objectives:

- ❖ monitoring of examinations during treatment
- ❖ storage status of culture isolates
- ❖ supervised treatment services in the community
- ❖ contacting of patients late for their planned appointments
- ❖ and assessment of outcome of treatment.

Information can be collected via routine field and/or remote supervision and monitoring activities, and the use of the Quality Improvement Checklist (developed by KNCV under the Challenge TB Project).

- To verify that the reported data are complete, timely and accurate.

Study Monitoring

Study Monitoring

- Newly enrolled patients are reviewed weekly by a clinical team remotely with supervision from the Research Specialist, Research Coordinator and Principal Investigator
- Progress of patients on treatment is reviewed on a quarterly basis by the PMDT sub-TWG, NTP and study partners.
- The Research Specialist will conduct monthly on-site or remote monitoring on the:
  - ❖ site's adherence to the process of getting informed consent
  - ❖ to study procedures and protocol
  - ❖ and to data collection and storage guidelines.

Study Monitoring

- The Principal Investigator will meet monthly with the Research Specialist, the study coordinator, and the database manager to monitor on:
  - ❖ overall study progress,
  - ❖ identify issues
  - ❖ deploy strategies to overcome issues

- Data on study enrollment and AEs will be monitored monthly and interim outcomes will be monitored quarterly.

Study Monitoring

- On-site or online monitoring visits will be carried out on a quarterly basis by selecting the study sites
  - ❖ with unusually low or high enrollment,
  - ❖ high SAE and AESI
  - ❖ LTFU
  - ❖ death rates
  - ❖ low culture conversion rates
  - ❖ by randomly selecting sites if there are no issues with study enrolment
  - ❖ study interim outcomes.
- The visits will be led by the NTP Management Office with support from the study Principal Investigator.

Study Monitoring

- The members from the Oversight Committee, PMDT sub-TWG, ITRC, and TDF will also be invited to participate in the on-site or online monitoring visits.
- A quarterly treatment outcomes analysis report will also be presented to the PMDT sub-TWG and Oversight Committee who will review and provide recommendations to address:
  - ❖ any administrative
  - ❖ logistical
  - ❖ or technical issues related to patient care and study implementation in coordination with local government units
  - ❖ the DOH procurement and supply departments and other relevant partners.

Study Monitoring

- The Principal Investigator will be responsible for
  - ❖ identifying
  - ❖ mitigating
  - ❖ reporting
  - ❖ documenting any protocol violations.

Such information should be submitted to NTP as well as to TDF/ ITRC.

- Data will be aggregated across countries and analyzed on a quarterly basis and will be shared with national health authorities, stakeholders, and the larger scientific community with the aim to influence and improve MDR-TB treatment within the country and globally.

Monitoring and Evaluation

Monitoring and Evaluation

- The Research Team shall consolidate the OR data on a monthly basis using the prescribed indicators for monitoring and evaluation defined in the study protocol.
- The Research Team will perform overall project monitoring of research implementation jointly with ITRC in partnership with TDF, and other stakeholders.
- ITRC and TDF may monitor the progress of implementation independently with permission from the Research Team.

Monitoring and Evaluation

The status of the study will be monitored and evaluated through the following methods:

Methodology	Frequency	Person/s Responsible
1. Online data validation	Weekly	Research Team
2. Online remote monitoring for indicators	Monthly	Research Team, ITRC, KNCV, TDF
3. Review of PMDT reports	Quarterly	Research Team
4. Review of quarterly progress of patients on treatment	Quarterly	Laboratory and Treatment sub-TWG, NTP, Research Team, NTRL, ITRC, KNCV, TDF

Monitoring and Evaluation

Methodology	Frequency	Person/s Responsible
5. Monitoring visit to study sites and laboratory facilities (if feasible)	As Allowable	Joint monitoring team (Research Team, NTP, NTRL, TDF, ITRC, KNCV, members of Laboratory and Treatment sub-TWG, members of Oversight Committee)
6. End of the year evaluation	Dec 2021	Research Team, ITRC, KNCV, TDF
7. End-of-research evaluation	2022	NTP, KNCV, ITRC, TDF, sub-TWG and Oversight Committee

Study Indicators

Study Indicators

- The study will use indicators pertaining to treatment coverage, treatment safety and treatment effectiveness to monitor the progress of the BPaL OR on quarterly basis as well as for analysis. Sending of reports will be every 10th of the Month after the last month of the Quarter.

Cohort Date	Reporting Date
January to March	10Th of April
April to June	10th of July
July to September	10th of October
October to November	10th of January (following year)

- The study will mainstream gender-disaggregated data to analyze the BPaL treatment coverage, effectiveness, and safety

Study Indicators

- **Treatment Coverage**

Treatment Coverage
1. Number and proportion of patients screened for eligibility for enrollment on the BPaL regimen
2. Number and proportion of patients eligible for enrolment on the BPaL regimen from all the screened
3. Number and proportion of patients enrolled on the BPaL regimen from all the eligible

Study Indicators

Treatment Effectiveness

Treatment Effectiveness
1. Number and proportion of enrolled patients with sputum smear conversion after 2 months of treatment with BPaL regimen
2. Number and proportion of enrolled patients with sputum smear conversion after 6 months of treatment with BPaL regimen
3. Number and proportion of enrolled patients with sputum culture conversion after 2 months of treatment with BPaL regimen
4. Number and proportion of enrolled patients with sputum culture conversion after 6 months of treatment with BPaL regimen

Study Indicators

Treatment Effectiveness

Treatment Effectiveness
5. Number and proportion of enrolled patients required the BPaL treatment duration extension from 26 to 39 weeks
6. Number and proportion of enrolled patients with successful treatment outcome ("cure" and "treatment completion") after full course of treatment with the BPaL regimen
7. Number and proportion of enrolled patients with TB recurrence at 6 months after the end of a full course of treatment with the BPaL regimen
8. Number and proportion of enrolled patients with TB recurrence at 12 months after the end of a full course of treatment with the BPaL regimen

Study Indicators

Treatment Safety

Treatment Safety
1. Number and proportion of enrolled patients with SAE(s)
2. Number and proportion of enrolled patients with AESIs (QT-prolongation, hepatotoxicity, myelosuppression, optic neuritis, and peripheral neuropathy)
3. Number and proportion of enrolled patients with permanent dose reduction of Lzd due to AE(s)
4. Number and proportion of enrolled patients with temporary interruption of Lzd due to AE(s)

Study Indicators

Treatment Safety

Treatment Safety
5. Number and proportion of enrolled patients with permanent interruption of Lzd due to AE(s)
6. Number and proportion of enrolled patients with temporary interruption of the BPaL regimen due to AE(s)
7. Number and proportion of enrolled patients with permanent interruption of the BPaL regimen due to AE(s)
8. Number and proportion of enrolled patients who died during the BPaL treatment

Study Indicators

Qualitative Data to be monitored

In addition to the agreed indicators, the Research Team can also monitor qualitative data are as follows:

1. Reasons for non-enrolment of eligible patients (Between indicator 2 and 3 under Treatment coverage)
2. Kinds of SAEs encountered
3. Kinds of AESIs encountered
4. Reasons for dose reduction, interruption (temporary or permanent) of Lzd
5. Reasons for interruption of (temporary or permanent) of BPaL
6. Causes of death
7. Causes of LTFU
8. Causes of non-adherence to protocol, e.g., monthly follow up
9. Reasons for referral to TB MAC

THANK YOU

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