



## aDSM FACTSHEET

The Challenge TB (CTB) project assists countries in implementing programmatic and sustainable active tuberculosis (TB) drug safety monitoring and management (aDSM).

aDSM involves the systematic clinical and laboratory assessment of patients on treatment with new anti-TB drugs, novel multidrug-resistant TB (MDR-TB), or extensively drug-resistant TB (XDR-TB) regimens, to detect, manage and report suspected or confirmed drug toxicities.

**Myanmar** (Burma) is one country that has greatly advanced in aDSM implementation. It started the core aDSM package (defined below) in July 2017.

### THREE COMPONENTS OF aDSM

**Clinical monitoring:** active and systematic clinical and laboratory assessment during treatment to detect drug toxicity and adverse events (AEs). Proposed monitoring schedules have been developed for use in patients targeted for aDSM. **Clinical management:** all AEs detected should be managed in a timely manner in order to deliver the best possible patient care. **Reporting:** standardized data should be systematically collected and reported for any detected serious AE (SAE). These will be used to characterize the types of SAEs, assess the safety of the treatment, aid in causality assessment and inform future policy on the use of these medicines. SAEs should be reported to the designated national authority and relevant international bodies.

### THREE LEVELS OF MONITORING aDSM

The **Core package** requires monitoring and reporting of all SAEs; the **Intermediate package** includes SAEs as well as AEs of special interest, and the **Advanced package** includes all AEs of clinical significance.

- SAE: an AE which either leads a) to death or a life-threatening experience, b) to hospitalization or prolongation of hospitalization, c) to persistent or significant disability, or d) to a congenital anomaly. An SAE that does not immediately result in one of these outcomes but requires an intervention to prevent it from happening is included.
- AE of clinical significance: an AE that is either a) serious, b) of special interest, c) leads to a discontinuation or change in the treatment, or d) judged as otherwise clinically significant by the clinician.
- AE of special interest: an AE documented to have occurred during clinical trials and for which the monitoring program is specifically sensitized to report regardless of its seriousness, severity or causal relationship to the TB treatment.

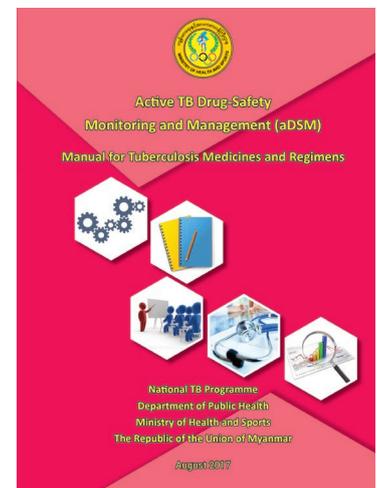
### OPERATIONALIZING THE WHO RECOMMENDED KEY STEPS IN aDSM IMPLEMENTATION IN MYANMAR

Myanmar created the **National Core Committee for aDSM (NCCA)** composed of the National TB Program (NTP), the Food and Drug Authority (FDA), Clinical Professors, TB Specialist Hospital physicians, Medical Superintendents, and partners (FHI360, MSF-H and World Health Organization [WHO]). The NCCA assumes oversight and coordination of aDSM activities at the national level.

#### KEY STEPS IN aDSM IMPLEMENTATION<sup>1</sup>

- (i) Create a national coordinating mechanism for aDSM
- (ii) Develop a plan for aDSM
- (iii) Define management and supervision roles and responsibilities
- (iv) Create standard data collection materials
- (v) Train staff for collection of data
- (vi) Define schedules and routes for data collection and reporting
- (vii) Consolidate aDSM data electronically
- (viii) Develop (or use existing) capacity for signal detection and causality assessment

#### Myanmar aDSM Manual, 2017<sup>2</sup>



<sup>1</sup> Reference: World Health Organization (WHO). Active drug-safety and management (aDSM): framework for implementation. WHO/HTM/TB/2015.28. Geneva: WHO; 2015.  
<sup>2</sup> [https://www.challenge-tb.org/publications/tools/country/aDSM\\_Manual\\_Myanmar.pdf](https://www.challenge-tb.org/publications/tools/country/aDSM_Manual_Myanmar.pdf)

The **aDSM Manual** was developed collaboratively by the NCCA members with CTB support, published in English and translated into Burmese. The manual covers the objectives, scope and purpose of aDSM, the implementation steps for programmatic aDSM in the Myanmar context, and the aDSM components of both clinical monitoring and management, and reporting of AEs.

During a series of workshops, the **roles and responsibilities in aDSM** were discussed among the respective partners and stakeholders. **Standard data collection materials** were drafted for routine use in the specialist hospitals and TB Centers. **Training of staff** on data collection and reporting, clinical monitoring and management and causality assessment was done collaboratively by CTB (KNCV) and the Uppsala Monitoring Centre (UMC), Sweden (a WHO Collaborating Centre for the monitoring of drug related side effects).

**Schedules and routes for data collection and reporting were defined.** AE data were consolidated into a national aDSM electronic database and reported to the WHO Global aDSM database. Simultaneously, collaboration with the UMC led to the membership of the Myanmar FDA in the WHO-Program for International Drug Monitoring. Initial steps for entering data to Vigibase (WHO's global database for adverse drug reactions), maintained by UMC, is ongoing. **Causality assessment** is being conducted by the NCCA quarterly led by the Clinical Professors.

## IMPROVING THE QUALITY OF PATIENT CARE

The regular aDSM meetings enable the NCCA to review the SAE data and improve on the quality of care for patients which is the ultimate goal of aDSM.



aDSM workshop with the NTP and partners



Causality assessment led by Clinical Professors

## Route of SAE reporting: facility to national to global levels

